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Level 2 Application Audit Checklist

Submission ID:	DA-2012-06069-1
Application ID:	DV-2012-DA-15692-1
Registry File No.:	2012/022262

Sponsor Name:	Boston Scientific Pty Ltd
Manufacturer Name:	Boston Scientific Neuromodulation Corporation (United States Of America)[21822]
Notified Body and ID:	
Device Name/UIP:	Precision Spectra Implantable Pulse Generator SC-1132
Classification:	Class AIMD
GMDN Code/Term:	Stimulator, electrical, analgesic, spinal cord[36007]

Application Recommendation and Decision

Recommendation: APPROVE

Assessor:

s.22

Signature:

s.22

Date:

08/02/2013

Delegate's Decision: APPROVE

Comments:

Automated email approval sent to sponsor

Delegate's Name:

s.22

Position Number:

s.22

Signature:

Date:

08/02/2013

Delegates Checklist:

1. Do you have a current delegation under Section 41FI of the Act?	Yes ☒
2. Have you checked that all aspects and/or requirements of Section 41FI have been considered or met in making this decision?	Yes ☒

Guidance for Administrative Officer – Application Summary

<i>Comments / Instructions</i>	
<i>Special Conditions</i>	NIL or...
<i>Special information for notification letter</i>	NIL or...

Instruction: Complete **each** checklist question by clicking on the appropriate checkbox.
If there is a need to add comments, provide them in the 'Application Recommendation' section above.

Part 1 – General Application Details

Information Required	Yes	No	NA
1.1 Is the device a Class IIb long-term implantable orthopaedic medical device? (e.g. total hip replacement system)	☐	☒	☐
1.2 Is the device a Class IIb device disinfectant? (e.g. instrument grade disinfectant)	☐	☒	☐
1.3 Is the manufacturer's Unique Product Identifier (UPI) consistent with the device application? Note: if in doubt the manufacturer's UPI is determined from the name that appears on the labelling, IFU and advertising.	☒	☐	☐
1.4 Are the variant details valid in the device application? If no , please detail deficiencies in the Application Recommendation section to facilitate explanation to the sponsor.	☐	☐	☒
1.5 Is the GMDN term in the device application appropriate for the device? If no , communicate with the sponsor to find a more suitable GMDN code, and have the sponsor amend the device application.	☒	☐	☐
1.6 Were all responses to requests for information provided within the stipulated timeframe?	☒	☐	☐

Part 2 – Applicant's Certification (Section 41FD)

Information Required	Yes	No	NA
General Details, Intended Purpose & Classification			
2.1 Is the product in this application a medical device as defined by section 41BD of the Act?	☒	☐	☐
2.2 Is the intended purpose given in the device application consistent with the manufacturer's intended purpose? Note: the manufacturer's intended purpose is determined from all sources of information that accompany the device, including labelling, IFU and advertising.	☒	☐	☐
2.3 Based on the manufacturer's intended purpose, the details in the application form, and the information provided by the sponsor, has the device been correctly classified in the Australian DoC and the device application? Note: if the device has been incorrectly classified in the device application the application should be rejected, and the sponsor required to submit a new application using the correct classification.	☒	☐	☐

Information Required	Yes	No	NA
2.4 Have all documents that were requested been provided?	☒	☐	☐
2.5 Does the submitted advertising material comply with Australian advertising requirements? Note: if advertising is only aimed at health professionals this item is not applicable.	☐	☐	☒
2.6 Based on the applicant's certification in the device application, does the device contain a substance that is a prohibited import under the Customs Act?	☐	☒	☐
2.7 If yes to Q2.6, does the applicant hold a Customs license?	☐	☐	☒
Essential Principles			
2.8 Is there any evidence of non-compliance with any of the Essential Principles in Schedule 1 of the Regulations? Note: if yes, record details in the Application Recommendation section of this report. This may include non-compliance with the clinical evidence requirements, or inappropriate labelling and IFU.	☐	☒	☐
Australian Declaration of Conformity (DoC)			
2.9 Is the manufacturer's Australian DoC in compliance with the requirements of Schedule 3 of the Regulations, and is it provided as an original or properly notarised copy? Note: the assessor must add a photocopy of the manufacturers Aust. DoC to the registry file.	☒	☐	☐
Appropriate Conformity Assessment Procedure Used			
2.10 Is the Conformity Assessment Procedure appropriate for the class of the device? Note: the chosen conformity assessment procedure shall be specified on the manufacturer's DoC, the CE certificates, and the linked manufacturer's evidence.	☒	☐	☐
2.11 Have the relevant certificates (quality assurance/design exam/type exam) been provided? Note: the assessor must add a photocopy of the QA certificate and Design/Type Exam certificate to the registry file.	☒	☐	☐
2.12 Does the scope of the certificate(s) cover the device(s) in this application? Note: if the submitted certificates have expired, the assessor must check the current version of the manufacturer's evidence to see if it has been updated. If it has, a copy of the updated certificate should be added to the registry file. If not, the sponsor shall be requested for up to date certificates.	☒	☐	☐
2.13 Are the certification bodies designated in the EU for this type of assessment?	☒	☐	☐

Part 3 – Demonstration of the Manufacturer's Compliance with the Essential Principles

Information Required	Yes	No	NA
Labelling & Accompanying Information			
3.1 Has representative labelling and instructions for use (IFU) been provided, and do they demonstrate compliance with Essential Principle 13?	☒	☐	☐
3.2 Has the sponsor demonstrated compliance with Regulation 10.2? Note: The sponsor of a medical device must ensure that the sponsor's name and address are: (a) Provided with the device in such a way that a user of the device can readily identify the sponsor; and (b) located in accordance with clause 13.2 in Schedule 1. (c) It the sponsor's responsibility to ensure they comply with this regulation	☒	☐	☐
Clinical Evidence & Risk Management Report			
3.3 Has a risk management report been submitted and is it applicable to the medical device?	☒	☐	☐
3.4 Has the ODBT Clinical Section reviewed the clinical data together with the risk management report? Note: this questions is not applicable for Class IIb device disinfectants, please see question 3.5 below.	☒	☐	☐
3.5 Does the submitted clinical data meet the requirements of Schedule 1, Part 14 and Schedule 3, Part 8 of the Regulations? If no , the clinical assessor must provide details of specific deficiencies to facilitate explanation to the sponsor, and form part of a statement of reasons if the application is to be rejected on these grounds.	☒	☐	☐
3.6 If the device is a Class IIb device disinfectant, have appropriate efficacy and performance data been submitted? If no , the assessor must provide details of specific deficiencies to facilitate explanation to the sponsor, and form part of a statement of reasons if the application is to be rejected on these grounds.	☐	☐	☒

Neuromodulation

25155 Rye Canyon Loop
Valencia, CA 91355

661.949.4000 Tel

661.949.4843 Fax

www.bostonscientific.com

MANUFACTURER'S DECLARATION OF CONFORMITY

AUSTRALIAN THERAPEUTIC GOODS (MEDICAL DEVICES) REGULATIONS 2002

FULL QUALITY ASSURANCE PROCEDURE

This is a declaration made in accordance with the requirements of Clause 1.8 of Schedule 3 of the Australian Therapeutic Goods (Medical Devices) Regulations 2002 relating to the stated device.

Reference: Precision Spectra™ Implantable Pulse Generator SC-1132

Manufacturer's Name: Boston Scientific Neuromodulation Corporation

Business Address: 25155 Rye Canyon Loop
Valencia CA 91355
USA

Manufacturing Facilities: Boston Scientific Neuromodulation
25155 Rye Canyon Loop
Valencia, CA 91355, USA

Medical Device(s): Precision Spectra™ Implantable Pulse Generator SC-1132

Classification (per TGA): AIMD

GMDN Code and Term:

Code	Term
36007	Stimulator, electrical, analgesic, spinal cord

Scope of Application: Precision Spectra™ Implantable Pulse Generator SC-1132

Each kind of medical device to which the Full Quality Assurance Procedures have been applied complies with the applicable provisions of the essential principles, the classification rules, at each stage, from the design of the device until its final inspection before being supplied.

**Full Quality Management
System Certificates:**

TÜV SÜD Product Services GmbH Annex II.3
Registration Number: (I1 10 06 65561 008)
EC Directive 90/385/EEC Annex 2, Section 3
Full Quality Assurance – Medical Devices

Design Examination Certificate:

TÜV SÜD Product Services GmbH Annex II.4
Registration Number: (I7 12 10 65561 014)
EC Directive 90/385/EEC Annex 2, Section 4
Design Examination – Medical Devices

Precision Spectra™ Implantable Pulse Generator

✓ **Standards Applied:**

Standard	Description
BSI BS EN ISO 13485:2012 (R2008)	Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes
BSI BS EN ISO 14971:2012	Medical Devices – Application of Risk Management to Medical Devices
BSI BS EN ISO 10993-1:2010	Biological Evaluation of Medical Devices, Part 1: Evaluation and Testing
BSI BS EN ISO 10993-7: 2008	Biological Evaluation of Medical Devices, Part 7: Ethylene oxide sterilization residuals
BSI BS EN ISO 11135-1: 2007	Sterilization of health care products — Ethylene oxide — Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
BSI BS EN 45502-1:1998	Active Implantable Medical Devices Part 1: General Requirements for Safety, Marking and Information to be Provided by the Manufacturer
BSI BS EN 60601-1-2: 2007	Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral Standard: Electromagnetic Compatibility - Requirements and Tests
ETSI EN 302 195-1 V1.1.1:2004	Electromagnetic compatibility and Radio spectrum Matters (ERM); Radio equipment in the frequency range 9 kHz to 315 kHz for Ultra Low Power Active Medical Implants (ULP-AMI) and accessories; Part 1: Technical characteristics and test methods: 2004
ETSI EN 302 195-2 V1.1.1:2004	Electromagnetic compatibility and Radio spectrum Matters (ERM); Radio equipment in the frequency range 9 kHz to 315 kHz for Ultra Low Power Active Medical Implants (ULP-AMI) and accessories; Part 2: Harmonized EN covering essential requirements of article 3.2 of the R&TTE Directive: 2004
ETSI EN 301 489-1 V1.8.1:2008	Electromagnetic Compatibility and Radio Spectrum Matters (ERM); Electromagnetic Compatibility (EMC) Standard for Radio Equipment and Services; Part 1: Common Technical Requirements: 2008
ETSI EN 301 489-31 V1.1.1:2005	Electromagnetic compatibility and Radio spectrum Matters (ERM); ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 31: Specific conditions for equipment in the 9 kHz to 315 kHz band for Ultra Low Power Active Medical Implants (ULP-AMI) and related peripheral devices (ULP-AMI-P): 2005
BSI BS EN 1041:2008	Information Supplied by the Manufacturer with Medical Devices
BSI BS EN ISO 15223-1: 2012	Symbols to be Used with Medical Devices, Labeling and Information to be Supplied
BSI BS EN 556-1:2001/AC:2006	Sterilization of Medical Devices - Requirements for Medical Devices to Be Designated "Sterile" - Part 1: Requirements for Terminally Sterilized Medical Devices
BSI BS EN ISO 11607-1	Packaging for terminally sterilized medical devices Part 1: Requirements for materials, sterile barrier systems and packaging systems
BSI BS EN ISO 11607-2	Packaging for terminally sterilized medical devices Part 2: Validation requirements for forming, sealing and assembly processes
BSI BS EN 60601-1-6:2010	General requirements for basic safety and essential performance – Collateral standard: Usability
BSI BS EN 62304: 2006	Medical device software. Software life-cycle processes
AAMI/ANSI/ISO 14708-3:2008 (R2011)	Active implantable medical devices –Part 3: Implantable neurostimulators

Authorized Signatory:

S.22

Vice President, Clinical and Regulatory Affairs

✓ OCT 22, 2012
Date



Product Service

EC-CERTIFICATE

Full Quality Assurance System

(Annex 2, section 3 of the Directive 90/385/EEC on Active Implantable Medical Devices)

No. I1 10 06 65561 008

Manufacturer:

✓ **Boston Scientific Neuromodulation Corporation**

✓ 25155 Rye Canyon Loop
Valencia CA 91355
USA

EC-Representative:

Boston Scientific International, S.A.

55 Avenue des Champs Pierreux
TSA 51101
92729 Nanterre Cedex
FRANCE

Product:

✓ **Implantable Neurostimulator Systems**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective products / product families according to Annex 2, section 3 of the Directive 90/385/EEC on Active Implantable Medical Devices. This quality assurance system conforms to the provisions of this Directive and is subject to periodical surveillance. For marketing of the product an additional Annex 2.4 certificate is mandatory. See also notes overleaf.

Report No.:

71368455

Valid until:

2015-07-22 ✓

H.-H. Junker

Hans-Heiner Junker

Date, 2010-07-23



TÜV SÜD Product Service GmbH is Notified Body according to Council Directive 90/385/EEC concerning Active Implantable Medical Devices with identification no. 0123.

Page 1 of 2



Product Service

EC-Certificate**Full Quality Assurance System**

(Annex 2, section 3 of the Directive 90/385/EEC on
Active Implantable Medical Devices)

No. I1 10 06 65561 008**Facility(ies):**

Boston Scientific Neuromodulation Corporation
25155 Rye Canyon Loop, Valencia CA 91355, USA

Design**Facility(ies):**

Boston Scientific Neuromodulation Corporation
25155 Rye Canyon Loop, Valencia CA 91355, USA

CERTIFICATE ♦ CERTIFICADO ♦ CERTIFICAT
RTIFIKAT ♦ CERTIFICATE ♦ CERTIFICADO ♦ CERTIFICAT
認証証書 ♦ CERTIFICATE ♦ CERTIFICADO ♦ CERTIFICAT



Product Service

EC Certificate

EC Design-Examination Certificate

Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD), Annex 2 (4) ✓
(Other devices than custom made or intended for clinical investigation)

No. 17 12 10 65561 014

Manufacturer:

✓ **Boston Scientific Neuromodulation Corporation**

✓ 25155 Rye Canyon Loop
Valencia CA 91355
USA

EC-Representative:

Boston Scientific International, S.A.

55 Avenue des Champs Pierreux
TSA 51101
92729 Nanterre Cedex
FRANCE

Product:

✓ **Implantable Neurostimulator Systems**

The Certification Body of TÜV SÜD Product Service GmbH declares that a design examination has been carried out on the respective devices in accordance with AIMDD Annex 2 (4). This design of the devices conforms to the requirements of this Directive. For marketing of these devices an additional Annex 2 certificate is mandatory. See also notes overleaf.

Report no.:

713004306

Valid from:

2012-10-04

Valid until:

2017-10-03 ✓

Date, 2012-10-05

Hans-Heiner Junker



TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

Page 1 of 2



Product Service

EC Certificate**EC Design-Examination Certificate**

Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD), Annex 2 (4)
(Other devices than custom made or intended for clinical investigation)

No. 17 12 10 65561 014

Model(s): see attachment

Parameters: ./.

Facility(ies): Boston Scientific Neuromodulation Corporation
25155 Rye Canyon Loop, Valencia CA 91355, USA

Design Facility(ies): Boston Scientific Neuromodulation Corporation
25155 Rye Canyon Loop, Valencia CA 91355, USA



Attachment for Certificate no I7 12 10 65561 014
dated 2012-10-04

Product: Implantable Neurostimulator Systems
(Spinal Cord Stimulator System: Precision Spectra™)

Test Report No.: 713004306

Model:

Model no:

Precision Spectra™ Implantable Pulse Generator	SC-1132 ✓
Precision Spectra™ IPG Port Plug	SC-4401
Precision Spectra™ External Trial Stimulator	SC-5132
Precision Spectra™ Patient Trial Belt	SC-6360-32
Precision Spectra™ Patient Trial Kit	SC-6500-32
Precision Spectra™ Remote Control	SC-5232
Precision Spectra™ Remote Control Kit	SC-5532-1
OR Cable 1x16, 61 cm and Extension	SC-4116
OR Cable 2x8, 61 cm and Extension	SC-4108
Programming Wand	NM-7190
Clinician Programmer	NM-7151-30
Clinician Programmer (Refurbished)	NM-7151-30R

Munich, CRT2, 2012-10-04

Hans-Heiner Junker
Certification Medical Technology

n:\mhslamp\ami\general\certificat\amd\annex2.4_product\boston scientific\2011-2012\attachment\12-014.000.docx
Attachment for Certificate No. I7 12 10 65561 014 incl. supplement 000
Date of current supplement 000: 2012-10-04
Active Medical Implants – Project Handler: Andreas Kopp
Page 1 of 1

Request for Clinical Assessment Level 2 Application Audit

To be completed by MDAS Assessor:

Device:	Precision Spectra Implantable Pulse Generator
Applicant:	Boston Scientific Pty Ltd
Manufacturer:	Boston Scientific Neuromodulation Corporation (United States Of America)[21822]
Work Process ID:	DA-2012-06069-1
File No.:	2012/022262
Date:	06/12/2012

Required Level Of Assessment:	Review of Clinical Evaluation Report suitable for a Level 2 Application Audit (complete Clinical Evidence Checklist in Attachment A)
Manufacturer's Clinical Evaluation Report?	Indicate where located, including preliminary comments.
Notified Body Clinical Evaluation?	Indicate where located, including preliminary comments. Eg referenced in Design / Type Examination Report. Note This will not exist for many lower class devices

To be completed by Clinical Assessor:

Does the submitted clinical data meet the requirements of Schedule 3, Part 8 of the <i>Therapeutic Goods (Medical Devices) Regulations 2002</i>?	YES
---	------------

Comments & Rationale:

The product is a spinal cord stimulation device which provides such stimulation via an implanted electrode array on a commercially available in line or plate style lead placed in the epidural space. Leads are placed subcutaneously and the actual generator is typically placed in an infraclavicular, gluteal or abdominal subcutaneous pocket. A programmer is used externally via remote and the battery can be charged wirelessly via a 'charging belt'. The system comprises the IPG, external trial stimulator, remote, clinician's programmer and an RF 'wand' for communication between the IPG and the CP. These components are described in detail on p4 of the clinical expert report (CER). The commercially available components like the leads and electrodes mentioned are tabulated on p5 of the CER. Presumably they are sold separately such that the appropriate electrode array can be selected according to the discretion of the physician.

Literature review is chosen as the method of trying to demonstrate safety and performance. This is documented satisfactorily and in generally better detail than is typical. Once inclusion and exclusion criteria were applied, only ten articles remained.

A brief discussion and description of Medtronic devices that have the same intended purpose is provided. They are also tabulated on pages 9-10 of the CER. The statement is made that the systems in the literature are also implantable, battery powered (rechargeable or not) and have external RF powered or controlled systems. An in-line type lead and plate type lead are mentioned in the literature. Hence while similar, one has the impression that these devices

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differ in precise characteristics but have generally similar form and function. The contention is made that the physical and biocompatibility characteristics are similar for the devices to which published literature has been retrieved and the Precision Spectra device. The Precision Spectra has been designed to be compatible with all commercially available leads, hence including those of the competitors. It is not even certain that this sponsor actually makes the leads themselves at all from this documentation.

Quite a reasonable effort is made to summarise the available publication data and these are available in tabular and narrative form on pages 12-20 of the CER. Pain was essentially quantified via visual analogue scale or other subjective measures of pain experience. An endpoint also used was a 50% reported reduction in pain. Those studies making use of the VAS all showed a statistically significant improvement in pain severity. i.e. a baseline average of 7.4 on the VAS at baseline compared to 4.15 at 12 months. Obviously a chronic pain experience remains, it has simply been reduced in intensity (or perhaps duration as well). For those studies measuring 50% reduction as a target endpoint, a mean of 51% of patients achieved this. Adverse event profile is typical of what one would expect for a long-term implantable device. This must be weighed against the severity of the pain experienced. Obviously this is a significant and invasive method of treating such chronic pain. Infection and pain associated with the device figure most prominently. In terms of component performance, lead migration is the greatest complication reported at 19%. Device failure and lead breakage are also significant in terms of frequency.

The MAUDE database on these devices generally demonstrate a similar adverse event profile.

ONE study is presented very late as being conducted by Boston Scientific on 65 patients using this actual device for the treatment of chronic pain. This involved the 50% improvement after 2 weeks endpoint, and was actually part of the literature retrieved. The specific % of patients in this instance achieving this outcome measure was 55%.

The clinical expert has, in my view, adequately argued for comparability and safety and performance based upon literature review.

The clinical expert is an MD and a CV has been provided.

What, if any, additional clinical data is required:

Name & Dated Signature of Clinical Assessor:

Name:	s.22	s.22	Date:	7.12.12
Signature:				

ATTACHMENT A

Application Audit Clinical Evidence Checklist

1. Has the manufacturer compiled clinical data for the device in question when used in accordance with the proposed intended purpose?

☐ Yes. Go to 2.

☒ No. Go to 1a.

- 1a. Are there clinical data for a device with which the manufacturer has claimed and demonstrated equivalence? (Consult with MDAS assessor)

☒ Yes. Go to 2.

☐ No. Go to 1b.

- 1b. Has the manufacturer provided an acceptable justification as to why clinical data are not required?

☐ Yes. Go to 2.

☐ No. The legislative requirements for clinical evidence have not been met.

2. Has the manufacturer submitted an acceptable report detailing the clinical evaluation (critical appraisal) of the clinical data?

☒ Yes. Go to 3.

☐ No. The legislative requirements for clinical evidence have not been met.

3. Has the clinical evaluation been performed by a person with expertise appropriate to the clinical application of the device?

☒ Yes. The legislative requirements for clinical evidence have been met.

☐ No. The legislative requirements for clinical evidence have not been met.

Boston Scientific

Boston Scientific Pty Ltd
 ABN 45 071 676 063
 PO Box 332
 Botany NSW 1455
 Australia
 +61 2 8063 8100 Tel
 +61 2 9330 1404 Fax
 www.bostonscientific.com

Administration Officer
 Devices Applications Section
 Office of Devices Authorisation
 Therapeutic Goods Administration
 PO Box 100
 WODEN ACT 2606

05 November 2012

Application Identifier	Sponsor's Reference	Submission ID
DV-2012-DA-15692-1	Precision Spectra IPG	DV-2012-06069-1

The above inclusion applications were submitted in eBS on 12 October 2012.

In response to the Level 2 audit request, we have compiled the dossier based on TGA device guidelines:

1. An original, or correctly notarized, copy of the manufacturer's Australian declaration of conformity
2. Copies of the latest and current third party certification of an assessment of the medical device and/or manufacturer
3. Clear, legible copies of representative information that is to accompany the kind of medical device when supplied in Australia – including labeling, instructions for use and advertising material. Please note – contact details for the Australian Sponsor are included in the Directions for Use supplied with this product
4. Labels and/or product information to comply with Regulation 10.2 of the Therapeutic Goods (Medical Devices) Regulation 2002.
5. A summary of the risk management activities performed by the manufacturer of the device.
6. A summary of clinical evidence used to establish conformity with Australian Essential Principle number 14, including evidence to support the clinical competence of its author

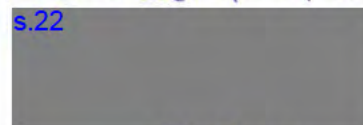
Payment of \$6,170 for the level 2 audit fees has been made online and proof of payment is included in section D of this dossier.

Please contact me directly if you have any questions.

Regards,



1 Vol + 1 CD
 DA-12-06069-CD-VI-CI
 DA-12-06069-VI-CI
 Data stored in H Block
 s.22
 21.11.12



FAX TRANSMISSION REPORT

Document 1

9.

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Please pass this report to the sender.

Fax number: +61293301406

Status:

Completed: Friday, 26 October 2012 at 10:38 AM

Pages sent: 6 of 6

Duration: 63 seconds

Received fax CSID: Boston Scientific

MSN: 267208



Australian Government

Department of Health and Ageing
Therapeutic Goods Administration

25/10/2012

Submission ID: DA-2012-06069-1

Boston Scientific Pty Ltd
PO Box 332
BOTANY NSW 1455

Fax: 02 9330 1406

Attention: **s.22**

Application for Inclusion in the ARTG: DV-2012-DA-15692-1

Applicant's Reference: Precision Spectra IPG

I refer to the above application(s) for inclusion in the Australian Register of Therapeutic Goods (ARTG).

As the Delegate to the Secretary under section 41FH of the *Therapeutic Goods Act 1989* (the Act), I am writing to advise you under section 41FH(2) of the Act I am required to select this application for auditing under section 41FH(1)(a) of the Act.

In particular, Regulation 5.3(1) of the *Therapeutic Goods (Medical Devices) Regulations 2002*, prescribes that the following kinds of medical devices be selected for auditing:

(e) a Class AIMD medical device;

Pursuant to section 41FI(1) of the Act, I will be considering the following matters:

- whether the application is in accordance with Subdivision A; and
- whether matters as to which the applicant has certified under section 41FD are correct.

Under section 41LA(3) of the Act, an application audit fee determined in accordance with the regulations is payable by you. In accordance with Schedule 5 of the Regulations, the total amount payable by you in respect of this audit is \$6170.00

You will receive a separate invoice for this amount.

Pursuant to section 41FH of the Act, you are hereby requested to provide the information detailed below by **22 November 2012**.



Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

25/10/2012
Submission ID: DA-2012-06069-1

Boston Scientific Pty Ltd
PO Box 332
BOTANY NSW 1455

Fax: 02 9330 1406

Attention: [s.22](#)

Application for Inclusion in the ARTG: DV-2012-DA-15692-1

Applicant's Reference: Precision Spectra IPG

I refer to the above application(s) for inclusion in the Australian Register of Therapeutic Goods (ARTG).

As the Delegate to the Secretary under section 41FH of the *Therapeutic Goods Act 1989* (the Act), I am writing to advise you under section 41FH(2) of the Act I am required to select this application for auditing under section 41FH(1)(a) of the Act.

In particular, Regulation 5.3(1) of the *Therapeutic Goods (Medical Devices) Regulations 2002*, prescribes that the following kinds of medical devices be selected for auditing:

(e) a Class AIMD medical device;

Pursuant to section 41FI(1) of the Act, I will be considering the following matters:

- whether the application is in accordance with Subdivision A; and
- whether matters as to which the applicant has certified under section 41FD are correct.

Under section 41LA(3) of the Act, an application audit fee determined in accordance with the regulations is payable by you. In accordance with Schedule 5 of the Regulations, the total amount payable by you in respect of this audit is \$6170.00

You will receive a separate invoice for this amount.

Pursuant to section 41FH of the Act, you are hereby requested to provide the information detailed below by **22 November 2012**.

Please note that pursuant to section 41FK(a) of the Act, your application will lapse if you do not deliver the information requested to the address below. Once the application lapses, you will need to lodge a new application for inclusion.

To enable cross referencing of the information supplied with the original medical device application, please quote the Submission ID when supplying this information.

You are reminded that in submitting a medical device application via TGA eBusiness Services (eBS), you have certified under Subsection 41FD(e)(ii) and (g)(ii) of the Act that you can obtain this information to substantiate compliance with the Essential Principles and demonstrate the application of an appropriate conformity assessment procedure, within 20 working days (Regulation 5.2).

If any aspect of this request requires clarification please first refer to Section 11 of the current version of the Australian Regulatory Guidelines for Medical Devices (ARGMD) on the TGA website <http://www.tga.gov.au/industry/devices-argmd.htm> , or contact the Medical Devices Information Line on 1800 141 144, before submitting your supporting information package.

You are requested under section 41FH(2)(a)(ii) to provide the following information necessary for the auditing of the application:

1. Manufacturer's Australian Declaration of Conformity (DoC)

Please provide an original, or correctly notarised, copy of the manufacturer's Australian Declaration of Conformity, as required under Schedule 3 of the *Therapeutic Goods (Medical Devices) Regulations 2002* (the Regulations).

Notes:

- The declaration of conformity must conform to Australian requirements. A European declaration of conformity is **not** acceptable.
- For further guidance on Declarations of Conformity please refer to Section 6 of the current version of the ARGMD on the TGA website.
<http://www.tga.gov.au/industry/devices-argmd.htm>
- For further guidance on Declarations of Conformity and templates refer to 'Declaration of conformity templates (medical devices)' on the TGA website.
<http://www.tga.gov.au/industry/devices-forms-declaration-conformity.htm>

2. Evidence of Appropriate Conformity Assessment Procedure

Please provide a copy of the latest and current certification of an assessment of the medical device and/or manufacturer, as required by the Conformity Assessment Procedures under Schedule 3 of the Regulations.

Notes:

- Certification includes quality assurance certificates, and design examination or type examination certificates, issued under the European Medical Devices Directives (MDD) from an EU Notified Body, as relevant to the class of the medical device.

- The details in the CE certificates must match the details entered in the TGA eBS medical device application form, and the manufacturer's Australian Declaration of Conformity.
- Where the manufacturer has applied the special conformity assessment procedure for systems or procedure packs under Schedule 3, Part 7.5 of the Regulations, the sponsor must submit copies of the original manufacturer's certification for each high risk (Class III or AIMD) device in the system or procedure pack.
- Certificates issued for an ISO standard (such as ISO13485 or ISO9001), or by the US FDA, are **not** considered to be suitable evidence that the manufacturer has applied an appropriate conformity assessment procedure. If any such certificates are submitted to the TGA, they will not be considered during the application audit process.

3. Information to be Supplied with the Device

Please provide clear, legible copies of representative information that is to accompany the kind of medical device when supplied in Australia, including:

- Labelling;
- Instructions For Use; and
- Advertising material (e.g. brochures, web-pages, published advertisements, etc).

Notes:

- Labelling and instructions for use are not necessarily required for every model or variant, unless there are significant differences in content. However, the copies provided are required to be representative of what will be supplied in Australia.
- Please include a document that lists the links where the device is advertised on the Internet.
- All representative information must be provided in English.

4. Information to be Supplied with the Device (Regulation 10.2)

Please provide labels and / or product information to comply with Regulation 10.2 of the Therapeutic Goods (Medical Devices) Regulations 2002.

The sponsor of a medical device must ensure that the sponsor's name and address are:

- (a) Provided with the device in such a way that a user of the device can readily identify the sponsor; and
- (b) Located in accordance with clause 13.2 in Schedule 1.

Note: It the sponsor's responsibility to ensure you comply with this regulation.

5. Risk Management Report

Please provide a summary of the risk management activities performed by the manufacturer of the device. An example of such a summary is the Risk Management Report required by Clause 8 of ISO14971:2000.

6. Clinical Evaluation Report

Please provide a summary of the clinical evidence used to establish conformity with Australian Essential Principle number 14; and as required by Part 8 of Schedule 3 of the Regulations, including evidence to support the clinical competence of its author (e.g. a short curriculum vitae).

Notes:

- For further guidance on Clinical Evidence requirements please refer to Section 3 of the current version of the ARGMD on the TGA website <http://www.tga.gov.au/industry/devices-argmd.htm>.

Required Form of Information

- The requested information must be provided as a complete stand-alone submission. Cross-referencing to information submitted in support of previous applications that are already included in the ARTG, or still in process, is **not** acceptable.
- A single hard copy of the information is required.
- Submitting the information electronically is not acceptable.
- The information must be supplied in loose-leaf binders. Plastic sleeves or stapled material should be avoided.
- The information must be sectioned for ease of reference, and a table of contents provided which details the content of the binder(s).
- Standard A4 paper must be used for all information (where possible). Text and tables should be prepared using margins that allow the document to be printed on A4 paper. The left hand margin should be sufficiently large that information is not obscured through binding.
- All requested information must be provided in English. Where material is not originally in English a full translation must be submitted, the accuracy of which is the responsibility of the sponsor.
- For devices that have a measuring function, Australian legal units (metric) must be used. Units generally accepted in clinical practice may also be used (e.g. mmHg).
- All text and pictures must be legible, and pictures must be clearly labelled.

Please Note:

- You should be aware that submission of the required information does not necessarily imply acceptance of the application.
- If you have any concerns with this request for information, you are encouraged to direct all enquires via email to the devices email in-tray (devices@tga.gov.au).
- Prior to contacting the TGA please refer to the current version of the ARGMD on the TGA website for further guidance.
<http://www.tga.gov.au/industry/devices-argmd.htm>

One copy of the requested information above is to be forwarded to:

Administration Officer
Devices Applications Section
Office of Devices Authorisation
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

or

Administration Officer
Devices Applications Section
Office of Devices Authorisation
Therapeutic Goods Administration
136 Narrabundah Lane
SYMONSTON ACT 2609

Yours sincerely,

s.22

Delegate of the Secretary of the Department of Health and Ageing



Work Management

Task - AA Assessment Fees

Work Process ID: DA-2012-06069-1

Work Process In Progress

Work Process Manager: aa2c

Status: s.22

Applications: Device Application: Boston Scientific Pty Ltd
DV-2012-DA-15692-1 Class: AIMD FLAGS: R

Task Description

Task Information

Task Information

Work Process Component: Administration

Task Status: Inactive

Planned Start:

06/11/2012

Planned End:

12/11/2012

Actual Start:

25/10/2012

Actual End:

Other tasks' comments:
Management Comment:

Checklist:

☒ Assessment fees set

☒ Fees Invoiced

☐ Fees Paid

Checklist Comments:

Receipt Number:

Outcome:

Task Specifics

Sponsor Id:

Sponsor Name:

Client ID:

23932

Client Name:

Boston Scientific Pty Ltd [Change Client](#)

Billing Address:

PO Box 332 BOTANY NSW 1455

Submission Identifier:

Application Identifier:

DV-2012-DA-15692-1

Product Name:

Precision Spectra IPG

TGAIN:

084611

Invoice Name:

Date Received:

25/10/2012

Payment Details Complete:
(Ready for FSG Processing)

☒ Complete

Invoice Details

Material Code

Material Description

Quantity

Amount

1	ID5038	Application Audit Assessment - Level 2	1	\$6170.00
2				
3				
4				
5				

Fee Total: \$6170.00

FSG Comment

Line 1:
Line 2:
Line 3:

Work Process Summary

Clock Information

Clock Information

View Stop Clocks

Task Clock Status Inactive
Elapsed TGA Days: 7 Remaining TGA Days: 53

Supporting Information

Letter History:

Attached Document History:

No Task Related Documents



Medical Device Application

AIMD Status : Under Review

Application Change history

Application Progress Date

Date received: 12/10/2012

Review Information

Review flag: Class or Type requires review

Auto review required: No

ARTG & Product ID

ARTG ID

Product ID

Application Details

Application identifier: DV-2012-DA-15692-1

Submission identifier: DA-2012-06069-1

Sponsor's own reference: Precision Spectra IPG

Application for: Medical Device - Included

Will you be applying for listing of this product or procedure in the Medicare Benefit Schedule (MBS)? ☐ Yes ☒ No

Will you be applying for listing of this product on the Prosthesis List? ☒ Yes ☐ No

Will you be applying for listing of this product on the Co-dependent or hybrid technology application list? ☐ Yes ☒ No

Cancel ARTG - product:

Sponsor Details

Sponsor name: Boston Scientific Pty Ltd

Contact details: s.22

Contact email:

s.22

Class Details

Class:

✓ AIMD

Intended purpose:

(AS RU 12)

The Precision Spectra™ Implantable Pulse Generator (IPG) system is intended to treat chronic pain by electrically stimulating the spinal cord through multi-channel, multi-electrode capabilities.

Device Product Characteristics

Is the device, or any form of the device, supplied sterile:

✓ Yes

Sterilisation Method:

Is the device intended to be invasive:

✓ Yes

Is the device, or any form of the device, intended for single use:

✓ Yes

Is the device an active device:

✓ Yes

Does the device contain material or ingredients of microbial origin:

No

Does the device contain material or ingredients of recombinant origin:

No

Does the device contain material or ingredients manufactured or formulated using a genetically modified organism:

No

Does the device contain material or ingredients of Human Origin:

No

Does the device contain Human Blood or its components:

Does the device consist of:

✓ Products packaged as a system

Does the device contain material or ingredients of Animal Origin rendered non-viable

Animal Species:

Country of Origin:

Does any component in the procedure, kit or system contain material or ingredients of Animal Origin rendered non-viable:

No

Is the device medicated:

No

Is the device formulated:

Does the product contain a medicine that is supplied separately in the Australian Market:

No

Does the product contain a medical device which incorporates a medicine as an integral part and that has an ancillary action to the device:

No

I declare that this device contains only components that are medical devices which have been individually certified.

No

Manufacturer Details

Manufacturer evidence number:

✓ DV-20051006-MC-010170-1 :Annex II.3- BSC Neuromodulation (TUV), Exp 22-Jul-2015 (Valencia).

Manufacturer name:

✓ Boston Scientific Neuromodulation Corporation (United States Of America)[21822]

Manufacturer address as on evidence: 25155 Rye Canyon Loop Valencia CA 91355 United States Of America S [124770]

GMDNS Code and Description

GMDNS code and description: Stimulator, electrical, analgesic, spinal cord[36007]

Device Category Terms

Device category 1: Electro mechanical medical devices

Device category 2: Anaesthetic and respiratory devices

Device category 3:

Product Details

UPI (Unique product identifier): Precision Spectra Implantable Pulse Generator SC-1132

Total number of devices covered: 1

Functional description: The Precision Spectra Implantable Pulse Generator (IPG) system is intended to treat chronic pain by electrically stimulating the spinal cord through multi-channel, multi-electrode device capabilities. It uses a rechargeable battery which increases IPG longevity. The IPG is controlled by a handheld Remote Control, and can be engaged by a clinician programmer using proprietary programming software. Periodically, the IPG battery requires replenishing with an external RF charging device.

(As per IFR)

Variant List

#	Variant type	Variant range
1.	Nil variant (as 1 device)	N/A

Device system name if applicable:

Standard Conditions

The standard conditions that are imposed under section 41FO of the Therapeutic Goods Act 1989 when kinds of medical devices are included in the Register are as set out in the following paragraphs.

Each sponsor shall retain records of the distribution of all of the sponsor's medical devices included in the Register under Chapter 4. In the case of records relating to a Class AIMD medical device, Class III medical device, or Class IIb medical device that is an implantable medical device, the distribution records shall be retained for a minimum period of 10 years. In the case of records relating to any other device, the distribution records shall be retained for a minimum period of 5 years.

Where a medical device included in the Register, contains a substance which is included in the Fourth Schedule to the Customs (Prohibited Imports) Regulations or the Eighth Schedule to the Customs (Prohibited Exports) Regulations the Sponsor shall, at the time of importation or exportation of the medical device, be in possession of a licence and a permission for importation or exportation of each consignment of the goods as

required by those regulations.

The automatic conditions applicable to the inclusion of all kinds of medical devices in the Register are as specified in section 41FN of the Therapeutic Goods Act 1989.

For a medical device included in the Register under Chapter 4 and imported into Australia, the Sponsor must ensure that information about the Sponsor is provided in such a way as to allow the sponsor to be identified. A sponsor shall ensure that a medical device within their control is stored and transported in accordance with the instructions and information provided by the manufacturer.

It is a condition of inclusion in the ARTG that the sponsor of a medical device that is an AIMD, Class III or implantable Class IIb provides three consecutive annual reports to the Head of the Office of Devices, Blood and Tissues, Therapeutic Goods Administration following inclusion of the device in the ARTG. (as specified in 5.8 of the regulations) Annual reports are due on 1 October each year. Reports should be for the period 1 July to 30 June. The first report following the date of inclusion in the ARTG must be for a period of at least six months but no longer than 18 months. Subsequent reports are to be provided on 1 October for a further 2 years. The annual report must include all complaints received by the manufacturer relating to problems with the use of the device that have been received by them over the year.

The sponsor of a medical device included in the Register under Chapter 4 shall keep an up to date log of information of the kind specified in Regulation 5.8.

Non Standard Conditions

Note: A non standard conditions must not contain semi colons.

To remove, enter item #

Non Standard Indication

Non standard indication:

Declaration

I being a person authorised to make this application hereby certify that

- (a) devices of the kind in question are medical devices; and
- (b) devices of that kind are intended for a specified purpose, as ascertained under The definition of a medical device; and
- (c) the kind of device is correctly classified according to the medical device classifications; and
- (d) devices of that kind comply with the essential principles; and
- (e) I:
 - (i) have available sufficient information to substantiate that compliance with the essential principles; or
 - (ii) have procedures in place, to ensure that such information can be obtained from the manufacturer within the period specified in the regulations; and
- (f) an appropriate conformity assessment procedure has been applied to devices of that kind; and
- (g) I:
 - (i) have available sufficient information to substantiate the application of those conformity assessment procedures; or
 - (ii) have procedures in place, to ensure that such information can be obtained from the manufacturer within the period specified in the regulations; and
- (h) devices of that kind comply with every requirement (if any) relating to advertising applicable under the regulations; and
- (i) devices of that kind do not contain substances that are prohibited imports for the purposes of the Customs Act 1901; and
- (j) the information included in or with the application is complete and correct.

In electronically submitting this application to TGA, I hereby declare that in relation to this medical device the information given in this application and the above statements on this declaration form are current and correct.

PLEASE NOTE:

A false declaration will result in the device entry being removed/cancelled from the ARTG.

Signatory name of the person submitting the application.:

.....

History

Payment notification mail has been sent to PDC on 19/10/2012

Record	Date	
Fee	1150	Date Paid 17/10/2012 12:00:00 AM
		Date Decision

Start Dates	Finish Dates	Working Days
Application Received	12/10/2012	Payment Received 17/10/2012 3
Total Working Days		3



Work Management

Task - Level 2 Pre-assessment

Work Process ID:	DA-2012-06069-1	Work Process Status:	In Progress
Work Process Manager:	aa2c - QA - 2013-02-08	Assigned To:	s.22
Applications:	Device Application: Boston Scientific Pty Ltd DV-2012-DA-15692-1 Class: AIMD FLAGS: R		

Task Description

Send out initial letter - selection for level 2 audit
 Raise invoice using payment subform in this task
 Receive payment
 Generate registry file
 Recieve application data

Task Information

Task Information

Work Process Component:	Administration		
Task Status:	Completed		
Planned Start:	17/10/2012	Planned End:	06/11/2012
Actual Start:	25/10/2012	Actual End:	21/11/2012
Other tasks' comments:			
Management Comment:			
Checklist:	☒ Initial request sent ☒ Generate registry file ☒ Invoice raised ☒ Fees paid ☒ Documentation received		
Checklist Comments:	complete		
D- Registry File Number:	2012/022262		
D- ADETS Sub ID Number:			
D- Number of Volumes:	1		
D- Number of Copies:	1		
Outcome:	complete		

Work Process Summary

POOR QUALITY ORIGINAL DOCUMENT

The following image
represents an accurate depiction
of the original document.



Device Application: Boston Scientific Pty Ltd DV/2012 DA 15602 1 Class: AIMD FLAG: D
Task: Level 2 Pre-assessment - Completed

Stop Clock - Start Date: 25/10/2012 End Date: 28/11/2012 Created By s.22

Task: Level 2 Compulsory Audit Assessment - Active

Task: AA Assessment Fees - Completed

Must be complete before 'Level 2 Compulsory Audit Assessment' can start

Task: Application Audit Clinical Assessment - Active

Task: Level 2 AA Decision - Active

Task: Level 2 AA Notification - Inactive

Letter: AA - Initial Request - Compulsory Level 2 - Draft Created on: 25/10/2012

Letter: AA - Clinical Assessment Request - Draft Created on: 28/11/2012

Clock Information

Clock Information

[View Stop Clocks](#)

Task Clock Status Stopped
Elapsed TGA Days: 53

Remaining TGA Days: 7

Supporting Information

Letter History:

 Letter: AA - Initial Request - Compulsory Level 2 - Draft Created on: 25/10/2012

Attached Document History:

No Task Related Documents

For Official Use Only

Document 1

2012/022262



For Official Use Only



Australian Government
Department of Health
 Therapeutic Goods Administration

TRIM reference: 2015/026929
 (R15/694754)

St Jude Medical Australia Pty Ltd
 17 Orion Road
 LANE COVE NSW 2066

Email: [s.22](#)

Attention:

**Notice under section 41FH of the *Therapeutic Goods Act 1989*
 about selecting application for audit and requiring information to be provided
 (the selection notice)**

Device Application Submission ID:	DV-2015-DA-14695-1, DV-2015-DA-14698-1 DA-2015-06754-1
GMDN¹:	Stimulator, electrical, analgesic, spinal cord [36007] x2
Unique Product Identifier (UPI)	Proclaim 5 Elite IPG, Model 3660 Proclaim 7 Elite IPG, Model 3662

Information is required by no later than close of business 8 October 2015.

I refer to the abovementioned applications for inclusion of the kinds of medical devices Proclaim 5 Elite IPG, Model 3660 and Proclaim 7 Elite IPG, Model 3662 (GMDN: Stimulator, electrical, analgesic, spinal cord [36007]), Class AIMD (the Devices) in the Australian Register of Therapeutic Goods (ARTG).

In accordance with paragraph 41FH(1)(a) of the *Therapeutic Goods Act 1989* (the Act) the Secretary of the Department of Health (the Secretary) must select for auditing any application for a kind of medical device to be included in the ARTG that is an application of the kind prescribed by the regulations.

In accordance with subregulations 5.3(1)(e) and 5.3(2) of the *Therapeutic Goods (Medical Devices) Regulations 2002* (the Regulations), applications for Class AIMD (active implantable medical device) in relation to which conformity assessment certificates² have not been issued, must be selected for audit.

You stated in the application that the Devices are AIMD medical devices.

¹ Information as stated in the application

² *Conformity assessment certificate* means a certificate issued under section 41EE of the *Therapeutic Goods Act 1989* (this means the certificate issued by the TGA)

The evidence of the application of the appropriate conformity assessment procedures to the Devices provided in the applications is EC Certificate issued for the Full Quality Assurance System in accordance with Directive 90/385/EEC, Annex 2 excluding section 4 (s.22) and EC Design-Examination Certificate issued in respect of implantable neuro-stimulators, in accordance with Directive 90/385/EEC, Annex 2 Section 4 (). Both Certificates have been issued by (notified body).

Therefore as a delegate of the Secretary for the purposes of subsection 41FH(1) of the Act, I must select the applications DV-2015-DA-14695-1 and DV-2015-DA-14698-1 for auditing.

In accordance with paragraph 41FH(2)(a)(i), I am obliged to inform you of the selection of the application for audit. I consider that this letter fulfils the requirements of this subsection of the Act.

Also in accordance with section 41LA(3) of the Act, an application audit assessment fee determined in accordance with the Regulations is payable by the applicant in respect of the audit, if the application for inclusion of a kind of medical device in the ARTG is required to be selected for the audit under paragraph 41FH(1)(a).

Therefore the prescribed application audit assessment fees are payable for abovementioned applications. Regulation 9.1 and Schedule 5 of the Regulations specify the fees that are prescribed in relation to medical devices.

I note you have submitted a request for reduction of the audit assessment fee together with these applications. You will be invoiced for the amount of the audit assessment fees approved by the delegate of the Secretary for the purposes of Regulation 9.7.

Note: Any reduction of audit assessment fees remains at the discretion of the delegate of the Secretary for the purposes of regulation 9.7. The amount of any reduced audit assessment fees is not negotiable. The decision to reduce the audit assessment fees is not subject to review under section 60 of the Act³.

The fees are due and payable according to the instructions on the invoice.

The TGA has recently updated the Online Client Portal so that sponsors can now view, print and pay outstanding invoices. For further information on how to use the new portal please visit <http://www.tga.gov.au/tga-business-services-how-use-site>.

Important

If information required by this *selection notice* is not received within 10 working days after the end of the period specified in this notice, the applications DV-2015-DA-14695-1 and DV-2015-DA-14698-1 will lapse (paragraph 41FK(a) of the Act).

The application will also lapse if you failed to pay an application audit assessment fee within 28 days after the date you are notified of the amount of the fee⁴ (i.e. the day when the invoice is issued in relation to this audit) (paragraph 41FK(e) of the Act).

For further information refer to:

- the relevant legislation:
 - *Therapeutic Goods Act 1989* (the Act) (<http://www.comlaw.gov.au/Series/C2004A03952>);
 - *Therapeutic Goods (Medical Devices) Regulations 2002* (the Regulations) (<http://www.comlaw.gov.au/Series/F2002B00237/Compilations>); and

³ Further information on reduction of the audit assessment fees refer: <http://www.tga.gov.au/publication/reduction-assessment-fees-medical-devices> (section 2)

⁴ Section 41LB of the Act (When assessment fee due for payment) and Regulation 9.2 (Application audit assessment fee) of the Regulations

- Australian regulatory guidelines for medical devices (ARGMD) (<https://www.tga.gov.au/publication/australian-regulatory-guidelines-medical-devices-argmd>).

Information provided in and with the application

1. On 18 August 2015, the Therapeutic Goods Administration (TGA) received application DV-2015-DA-14695-1 and DV-2015-DA-14698-1 for inclusion of the Devices in the ARTG. The application fees were paid on 24 August 2015.
2. You provided the following information in and with your application:
 - EC Certificate issued by BSI Product Services for the Full Quality Assurance System in accordance with Directive 90/385/EEC, Annex 2 excluding section 4 [s.22](#) and
 - EC Design-Examination Certificate issued in respect of implantable neuro-stimulators, in accordance with Directive 90/385/EEC Annex 2 Section 4 ()

Under section 41FI of the Act, in auditing the application all or some aspects of one or both of the following matters may be considered:

- whether the application is in accordance with Subdivision A of the Act; and
- whether matters as to which the applicant has certified under section 41FD of the Act are correct.

1. Essential principles

Any medical device supplied in Australia, must comply with relevant provisions of the essential principles (EP). The essential principles set out the requirements relating to the safety and performance of medical devices⁵. Under subsection 41FD(d) and (e) of the Act, you certified that the Devices comply with the essential principles and that you have available, sufficient information to substantiate that compliance of the Devices with the essential principles, or have procedures in place to ensure that this information can be obtained from the manufacturer within the period specified in the Regulations.

Essential principle 14 states that every medical device to be included in the ARTG requires ***clinical evidence***, appropriate for the use and classification of the device, demonstrating that the device complies with the applicable provisions of the essential principles (EP).

In particular, the clinical evaluation procedures must be applied to the Devices, for the purpose of demonstrating that the Devices comply with the applicable provisions of: EP 1 Use of medical devices not to compromise health and safety; EP 3 Medical devices to be suitable for intended purpose; and EP 6 Benefits of medical devices to outweigh any undesirable effects⁶.

Clauses 8.4, 8.5 and 8.6 of Part 8 of Schedule 3 of the Regulations set out requirements for the clinical investigation data, literature review and evaluation of clinical data in relation to a kind of medical device.

Essential principle 13 (Information to be provided with medical devices) specifies the requirements for the information, including the location of the information; and requirements for the instructions for use of the Devices.

Regulation 10.2

The information provided with the Devices should demonstrate compliance of the kind of medical device with Regulation 10.2 (information about the sponsor).

⁵ Section 41CA of the Act prescribes that these requirements are set out in the Regulations. Regulation 2.1 specifies that the essential principles (EP) are set out in Schedule 1 of the Regulations. There are six general principles that apply to all devices; and nine principles about design and construction that apply to devices on a case-by-case basis.

⁶ Regulation 3.11 - Medical devices to which the clinical evaluation procedures must be applied

2. Conformity assessment procedures

Kinds of medical devices can be included in the ARTG if, amongst other things, conformity assessment procedures have been applied to the kinds of devices. You, as a person who applied for inclusion of the Devices in the ARTG certified under section 41FD of the Act as to these matters (paragraph 41FD(f) and (g) of the Act) that an appropriate conformity assessment procedure has been applied to the Devices and that you have available sufficient information or agreement in place with the manufacturer to obtain the information to substantiate the application of the conformity assessment procedures.

Therefore, in order to enable the auditing of the application and consideration of the matters certified under section 41FD of the Act, I require you, under paragraph 41FH(2)(a)(ii) of the Act, to provide information that is relevant to the audit.

INFORMATION TO BE PROVIDED

- Labels for the Devices and/or Pictorial images of the Devices (copies of the manufacturer's product information as supplied with the Devices in Australia);
- Instructions for use for the Devices (manufacturer's instructions for use or product inserts as supplied in Australia);
Note: Labelling and instructions for use are not necessarily required for every device of the kind (variant/model), unless there are significant differences in content. However, the copies provided are required to be representative of what will be supplied in Australia.
- Information provided with the Devices about the sponsor (Regulation 10.2);
- Manufacturer's declaration of conformity made in accordance with Schedule 3 of the *Therapeutic Goods (Medical Devices) Regulations 2002*;
Note: declaration of conformity made in accordance with European Medical Devices Directive is not acceptable. For further information refer the Australian Regulatory Guidelines for Medical Devices (ARGMD) and Declaration of Conformity prototype forms available at:
<http://www.tga.gov.au/industry/devices-forms-declaration-conformity.htm>
- Clinical Evidence that demonstrates compliance of the Devices with the essential principle 14 and Part 8 of Schedule 3 of the Regulations, including:
 - Clinical evidence report*Note:* It is strongly recommended that you provide the data and information in the format set out in Attachment A. Please fill in the Clinical Evidence Report (CER) Checklist provided and include it as the first page for your clinical evidence submission in order to ensure all required information is included in your submission.
 Further guidance on Clinical evidence is available in the ARGMD as published on the TGA website at www.tga.gov.au.
- Evidence of compliance of the Devices with the applicable essential principles set out in Schedule 1 of the Regulations, including:
 - Risk Management Report;*Note:* Summary of the risk management activities performed by the manufacturer of the Device to demonstrate that the manufacturer applied appropriate procedures to address possible risks associated with the use of the Devices.
 An example of the summary of the risk management activities performed by the manufacturer of the device is the Risk Management Report as required by Clause 8 of ISO14971:2000.
- Any manufacturer's promotional and advertising material relevant to the Devices.

IMPORTANT

Please ensure that in your response you provide all information that has been required. The first response received by the TGA will be considered to be the complete and final response for this submission.

Note: All text must be in English, pictures must be clearly labelled, and text and pictures must be legible.

Timeframe for submitting this information

Under Regulation 5.2 the period for obtaining information from the manufacturer that demonstrates that the matters certified under section 41FD were correct in relation to the compliance with the essential principles and application of conformity assessment procedures appropriate to the kind of medical device, is 20 working days.

Therefore, consistently with the above, I request that you provide your response to the address specified below by no later than close of business 8 October 2015.

Note: Subsection 41FH(2)(a)(ii) of the Act does not limit section 41JA of the Act (further information may be required in relation to this audit)⁷.

It means that if assessment of the information you provided indicates that further clarification is required, further information would be requested at a later stage under section 41JA of the Act.

Lapsing or rejection of the application

If no information is received in response to the selection notice within 10 working days after the end of the period specified in this notice, the application will lapse (section 41FK(a) of the Act).

Failure to provide sufficient response may also result in the Delegate making a decision not to include the Device in the ARTG (refer section 41FI(3) of the Act).

Note: Please ensure that all required information is provided in your response. The first response received by the TGA will be considered to be the complete and final response for this submission. You should be aware however, that submission of the required information does not necessarily imply acceptance of the application.

If the application lapses or is rejected, you may submit another application at a later date, once all the information is available. Application fees and assessment fees will not be refunded once an application is lapsed or rejected.

Withdraw

You may withdraw your application at any time prior to a decision being made whether or not to include the devices in the ARTG. You should note, however, that the fee paid for the application is not refundable (<http://www.tga.gov.au/about/fees-refunds.htm>). If you wish to withdraw your application, you should advise the TGA of this request in writing, via e-mail: **devices@tga.gov.au**.

How to present the submission

The requested information must be provided as a complete stand-alone submission. Cross-referencing to information submitted in support of previous applications that are already included in the ARTG, or still in process, may not be acceptable and considered or reviewed.

All requested information must be provided in English. Where material is not originally in English a full translation must be submitted, the accuracy of which is the responsibility of the sponsor. All text and pictures must be legible, and pictures must be clearly labelled.

If your submission is less than 15 pages, you may clearly state the application ID and the applicant name in the subject line and email your submission to: devices@tga.gov.au.

⁷ Subsection 41FH(4) of the Act

If your submission is longer than 15 pages, it should be sent to:

Devices Application and Verification Section
Medical Devices Branch
Therapeutic Goods Administration
Department of Health
PO Box 100
WODEN ACT 2606

The information should be provided in either of the following formats:

- a) An electronic copy (in the form of a CD or DVD containing all of the relevant material)
– **[Preferred Method]**

Note: Responses that contain 15 pages or more of the data/information must **not** be sent to the TGA as email attachments. The submitted electronic information must be complete and clearly tabulated and titled.

OR:

- b) A single hard copy of the information (two-sided print is acceptable).
- Standard A4 paper must be used for all information (where possible). The margin should be sufficiently large that information is not obscured through binding.
 - The information must be supplied in loose-leaf binders. Plastic sleeves or stapled material should be avoided.
 - The information must be sectioned for ease of reference, and a table of contents provided which details the content of the binder(s).

The decision to select an application for audit under section 41FH(1) of the Act is not an 'initial decision' within the meaning of section 60 of the Act. This means that this decision is not subject to internal review under section 60 of the Act.

Yours sincerely,

s.22

Delegate of the Secretary for the purposes of section 41FH of the Act
Medical Devices Branch
4 September 2015

Attachment A**Clinical Evidence required to substantiate compliance of the kind of device with the essential principles, including requirements set out under Schedule 1 and Part 8 of Schedule 3 of the Therapeutic Goods (Medical Devices) Regulations 2002**

All medical devices supplied in Australia must comply with relevant legislative provisions. One of these is compliance with the essential principles. These are set out in Schedule 1 of the *Therapeutic Goods (Medical Devices) Regulations 2002* (the Regulations).

Clinical Evidence

Essential principle 14 of Schedule 1 of the Regulations states that each medical device requires appropriate clinical evidence.

Regulation 3.11 - stipulates that in addition to the conformity assessment procedures that are applied to a medical device, clinical evaluation procedures must also be applied to the device, for the purpose of demonstrating that the device complies with the applicable provisions of the essential principles, in particular:

- Principle 1 - Use of medical device not to compromise health and safety;
- Principle 3 - Medical devices to be suitable for intended purpose;
- Principle 6 - Benefits of the medical devices to outweigh undesirable effects.

Part 8 of Schedule 3 of the Regulations provides requirements for the clinical data that the manufacturer of a kind of medical device must obtain and evaluate in relation to the kind of device.

What you need to do

In order to demonstrate compliance with the abovementioned requirements, you need to provide the clinical data in the format specified below.

Refer the last two pages of this Attachment for further information about the requirements for clinical evidence.

Fill in the Clinical Evidence Report (CER) Checklist and provide it as the first page for your clinical evidence submission.

CLINICAL EVIDENCE REPORT (CER) CHECKLIST

[To be completed by the sponsor. It is a requirement that you check that all aspects of the CER are complete and correct prior to submission the clinical evidence to the TGA]

1. Specify the avenue(s) the manufacturer has selected to meet the requirements of Clause 14 (Clinical Evidence) of Schedule 2 and Part 8 (Clinical Evaluation Procedures) of Schedule 3 of the *Therapeutic Goods (Medical Devices) Regulations 2002*?

☐ Full Study Report(s) for the device or comparator(s)*

* Bear in mind a comparator MUST be clinically justified in the expert report.

☐ Literature review*

* A fully documented search strategy MUST be included in the expert report (i.e. databases searched, search terms used, inclusion and exclusion criteria to a level of detail that can be reproduced).

☐ Clinical Justification*

* Note that this avenue is only valid in some instances, i.e. a change of no clinical impact to a current device might be one instance.

If there are none of the above avenues used, the submission is incomplete and would not have adequate clinical data.

2. Has the manufacturer provided a clinical expert C.V. with the CER or sufficient documentation so that a judgement can be made about the “expert’s” status?

☐ Yes

If not, the submission is incomplete and may result in a delay in processing.

3. Does the nominated clinical expert have relevant clinical qualifications and experience with the use of the device under assessment in a clinical setting?

☐ Yes – the clinical expert has relevant qualifications and experience*

* A clinical expert should be clinically qualified and be able to comment upon the use of the device for its intended purpose. For example, an engineering degree is inadequate.

If not, the submission is incomplete.

4. Has the manufacturer submitted post market data within the CER for this device or its comparators (if relevant)?

☐ Yes

☐ No – If available, consider adding this information as it provides some extra data about real-world use of the device(s).

5. Does the submission have adequate indexing and pagination such that the totality of clinical evidence documentation can be readily identified and assessed? Please note that there should typically only be ONE CER encompassing the clinical evidence available for the device(s).

☐ Yes

☐ No*

*If not, difficulty with evaluation and requests for additional information may occur, delaying the finalisation of the submission.

Sponsor name:	
Title:	
Signature:	
Date:	

FURTHER INFORMATION

The Clinical Expert Report

- All clinical submissions MUST contain a Clinical Expert Report. This report MUST contain a summary presentation of all relevant clinical evidence for the device(s) under assessment, including clinical trial reports, published literature, post-market data and any clinical justification arguments. The author MUST provide a critique of those data and describe WHY those data support safety and performance for the specific device(s) when used as intended.
- All clinical data should typically be encompassed by ONE Clinical Expert Report. Multiple Clinical Expert Report documents would be a rarity and typically not an acceptable format for submission.
- The Clinical Expert Report MUST be authored by a 'competent clinical expert'; in other words, an individual with clinical qualifications relevant to the device and its use, who also has experience in the use of the device in a clinical setting.
- The appropriateness of the clinical expert will clearly vary depending upon the nature of the device and the intended purpose(s).
- Full curriculum vitae for such an expert or other documentation to enable verification of their suitability is also a necessary component of the clinical evidence submission.

The Clinical Data

Clinical data can take many forms depending upon the device, its development programme, and whether it is a new or novel device, or simply another iteration of a previous model. Data may be provided in one of several forms, and can include full clinical trial reports, published and unpublished literature, clinical justifications and post-market data. The following describes these data types more fully:

Clinical Study Reports

- Full clinical study reports for the device(s) under assessment used in the indications claimed.

Clinical Study Reports for a Similar Device

- Full study reports similar device(s), with a reasoned clinical argument why the safety and performance of that device may be taken to support the device under assessment [paying particular note to the intended purpose(s)]. Full study reports refers to complete study reports will all related documentation, not publications or journal articles. It is acknowledged that full study reports may only be summarised in the CER.

Documented Literature Search

- A documented literature search with a review of the publications retrieved. Such a review would discuss and critique the use of these devices in the publications, and why they support safety and performance for the device(s) under assessment. Particular attention should be paid to the intended purposes for the device(s) under assessment and those of the devices revealed by the literature search.

The following shall be taken into account:

- The documented search strategy should include information such as the databases searched, search terms used and any inclusion and exclusion criteria applied, in sufficient detail to enable the search to be reproduced if desired. This is necessary to enable an assessment of whether or not the review adequately searched current available published literature about the device(s) under assessment.
- A critical discussion of the literature revealed by the search strategy must be undertaken with particular emphasis on how the publications demonstrate safety and performance of the device under assessment for the indications claimed (i.e. in terms of similarity, predicates, the actual device, etc.).
- If there are no actual clinical data for the specific device, depending upon the nature of it and the reasons for submission, it may be possible to provide a full clinical justification for why clinical evidence is not required.

- Typically, a justification may reference the clinical safety and performance data of a 'predicate' or similar marketed device and critically examine each change or difference in terms of materials, design, clinical use, and their likely impact on safety and performance.
- A justification may also take the form of a minor change to a currently approved device, where the change is considered too minor to have any clinical impact, and this is justified by the clinical expert.
- If it can be established via justification that changes do not pose any clinical impact on safety and performance, a clinical justification can, in some circumstances, suffice for clinical evidence.
- Post-market data can be a valuable addition to the clinical evidence in a submission. These data should typically at least provide world-wide distribution numbers of the relevant device(s) since launch, as well as complaints and adverse events reported to the manufacturer. Complaint and adverse event rates should be given, and where the clinical expert deems it relevant, MDRs and other adverse event and complaint data should be discussed and critiqued to enable an understanding of the safety profile of the relevant device(s) in a 'real-world' setting.

Format

The documentation must be presented in a particular format. The following principles apply:

- Submissions must be appropriately paginated and indexed so that the totality of information can be seen, as well as each part of it easily identified.
- If the sponsor chooses to provide the submission electronically, this must be provided on a CD, separate from all other submitted information.
- The form of the electronic submission MUST enable easy referencing and provide a clear indication of the extent of the clinical documentation submitted. i.e. a cover letter with a clear list and location of all clinical documents, or an index as part of a PDF as two examples.



Australian Government

Department of Health

Therapeutic Goods Administration

Application Audit - Level 2 Clinical Assessment – 1st Round

TRIM Reference: Rxx/xxxxx

To be completed by DAVS Assessor:

Device UPI	Proclaim 5 Elite IPG, Model 3660, Proclaim 7 Elite IPG, Model 3662
Sponsor:	St Jude Medical Australia Pty Ltd
Manufacturer:	St Jude Medical (United States Of America)
Application ID:	DV-2015-DA-14695-1, DV-2015-DA-14698-1
Submission ID:	DA-2015-06754-1
DAVS Assessor:	S.22
TRIM File No.:	2015/026929 DATA R15/728632
Date submitted to TGA:	18/08/2015
Date Referred to Clinical Section:	23/09/2015
Clinical Round:	1

Required Level Of Assessment:	Review of Clinical Evaluation Report suitable for a Level 2 Application Audit (complete Clinical Evidence Checklist in Attachment A)
Manufacturer's Clinical Evaluation Report?	Include TRIM record number where it is located, including preliminary comments and clarification where required.
Notified Body Clinical Evaluation?	If available, provide TRIM record reference number and comments where clarification is required. Eg referenced in Design / Type Examination Report. <i>Note:</i> This will not exist for many lower class devices.

To be completed by Clinical Assessor:

Does the submitted clinical data meet the requirements of essential principle 14 of Schedule 1 and Part 8 of Schedule 3 of the Therapeutic Goods (Medical Devices) Regulations 2002?	NO
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Comments & Rationale:

Device

The Proclaim 5 Elite IPG, Model 3660 is manufactured by St Jude Medical (United States of America).

Device Description

The Proclaim 5 Elite IPG Model 3660 and Proclaim 7 Elite IPG Model 3662 are implantable pulse generators that are designed to be connected to one or more lead extensions with up to 16 electrodes total. According to the submission, the devices are powered by a hermetically sealed battery within a titanium case and use microelectronic circuitry to generate constant-current electrical stimulation.

The Proclaim IPGs can deliver stimulation with a single program or with multiple programs. Each program can provide stimulation to a single anatomical area or to multiple areas. The IPG communicates wirelessly with system programmers and controllers.

The Proclaim IPG is available in two sizes. The Proclaim 5 Elite IPG Model 3660 is the smaller size, and the Proclaim 7 Elite IPG Model 3662 is the larger size. These two sizes accommodate for different power requirements.

The IPG is a part of the Proclaim SCS system. The system is comprised of the following components:

- a lead(s) that delivers electrical stimulation pulses to the patient's tissue;
- an external trial system that allows temporary evaluation of therapy efficacy;
- an IPG that generates the therapeutic electrical waveforms;
- a clinician programmer that allows the physician to prescribe the parameters of therapy; and
- a patient controller that allows the patient to control the delivery of therapy.

While the Proclaim IPG sits within a SCS system, the Clinician Programmer App, Patient Controller App, external trial system and leads will not be assessed as part of this Clinical Assessment Report. This is because the Clinician Programmer App and Patient Controller App have been assessed in a separate TGA Application Audit Clinical Assessment Report (located at TRIM R15/738307), and the leads have been deemed as outside the scope the CER included in the submission, and, according to the CER, are already approved products (page 11, CER).

The Proclaim IPG 3660 and 3662 are new hardware platforms whose clinical functionality are predicated on CE marked, commercially available St Jude Medical neurostimulation systems, namely the Eon C IPG Model 3688 and the Genesis IPG 3608 (page 13, CER).

Proposed therapeutic indication(s)

Under the 'Intended Use' heading of the IFU document (*Proclaim IPG Clinician's Manual*), it is stated that:

This neurostimulation system is designed to deliver low-intensity electrical impulses to nerve structures. The system is intended to be used with leads and associated extensions that are compatible with the system (page 4, IFU).

This matches the proposed therapeutic indications in the eBS Device Application Form, which is stated as:

This neurostimulation system is designed to deliver low-intensity electrical impulses to nerve structures. The system is intended to be used with leads and associated extensions that are compatible with the system. (eBS Device Application Form).

The 'Indications for Use' heading in the IFU document states,

This neurostimulation system is indicated as an aid in the management of chronic, intractable pain of the trunk and/or limbs, including unilateral or bilateral pain associated with the following: failed back surgery syndrome and intractable low back and leg pain (page 4, IFU).

In addition, the *IFU Angina & PVD Insert* includes the following statement:

This spinal cord stimulation system is indicated as an aid in the management of chronic, intractable pain of the trunk and limbs, including unilateral or bilateral pain associated with angina pectoris and peripheral vascular disease (page 1, Angina & PVD Insert).

Contraindications

The Proclaim neurostimulation system is contraindicated for patients who are unable to operate the system or who have failed to receive effective pain relief during trial stimulation (page 25, Section 3.4, *CER*).

Status in other countries

Australia

The Manufacturer's Declaration of Conformity has been provided in the submission. It is dated 14 September 2015 and is signed by [s.22](#). Both devices have been classified as AIMDs with GMDN Code 36007 ('stimulator, electrical, analgesic, spinal cord').

Other similar St Jude Medical devices currently listed on the ARTG include: the St Jude Medical Eon C IPG Model 3688 (ARTG 158502, 15/01/2009), the St Jude Genesis Pulse Generator 8-Channel, Model 3608 (ARTG 131543, 21/09/2006) and the St Jude Medical Prodigy IPG 3799 (ARTG 230721, 18/11/2014).

Other similar devices from different manufacturers currently listed on the ARTG include: the Boston Scientific Precision IPG (ARTG 129091, 27/06/2006), the Medtronic Prime Advanced 37702 IPG (ARTG 141860, 9/07/2007) and the Medtronic RestoreULTRA model 37712 (ARTG 154866, 28/08/2008).

Europe

Both the Proclaim 5 Elite IPG and the Proclaim 7 Elite IPG obtained the CE mark [s.47](#).

United States of America

The St Jude Medical Proclaim Neurostimulation System obtained premarket approval from the United States Food and Drug Administration (FDA) on 2 November 2015 ([s.47](#)). The Proclaim 5 Elite and the Proclaim 7 Elite have been in commercial distribution in the United States since [s.47](#).

Canada

The Proclaim Implantable Pulse Generators were issued a licence in Canada (Device Class 4) on 26 April 2016 ([s.47](#)).

Overview of the clinical data

The *CER* provided in the submission pertains to the whole Proclaim Spinal Cord Stimulation (SCS) system, which includes both the small (model 3660) and the large (model 3662) sizes of the Proclaim Elite IPG (the subject devices of this application), the St Jude Medical Clinician Programmer App and the St Jude Medical Patient Controller App. As discussed above, the TGA assessor notes that the Clinician Programmer App and Patient Controller App have been assessed in a separate TGA Application Audit Clinical Assessment Report (located at TRIM R15/738307).

No clinical studies are presented in the submission on the subject Proclaim 5 Elite IPG device or the Proclaim 7 Elite IPG device. The *CER* states that this is because 'the Proclaim

neurostimulation system has equivalent SCS functionality to the predicate SJM neurostimulation systems and neurostimulation systems that are currently CE marked and reported in the literature' (page 30, Section 6.4, *CER*).

The *CER* draws on three key components in its presentation of the risks and benefits of the Proclaim Elite IPGs:

- 1) claims of substantial equivalence with predicate SJM IPG devices
- 2) a review of published literature on spinal cord stimulation devices in general; and
- 3) post-market data from predicate devices to the Proclaim IPGs.

In addition, non-clinical Design Verification and Validation testing has also been presented at Section 6.1 of the *CER*:

Design verification and design validation confirmed that all acceptance criteria were met. Thus, this testing demonstrates the safety and performance of the Proclaim neurostimulation system design. The detailed reports are provided in the respective summary of technical documentation. Therefore, the preponderance of test results demonstrates that the Proclaim neurostimulation system meets safety and performance requirements for its intended use (page 28, CER).

While the Design Verification and Validation testing provides some reassurance about the performance of the subject Proclaim IPG devices in the non-clinical setting, the TGA assessor does not consider this testing to act in lieu of clinical data.

The TGA assessor will consider these three components in the same order below.

Assessment of clinical data

Substantial Equivalence

The *CER* claims substantial equivalence between the Proclaim IPG and its predicates, the Eon C IPG (3688) and the Genesis IPG (3608): 'because the basic SCS functionality was unaltered ...the Proclaim neurostimulation system SCS functionality is equivalent to the predicate SJM neurostimulation system' (page 13, *CER*).

Table 1 on page 14 of the *CER* provides a comparison of the functionality of the Proclaim IPG with its predicates. This table suggests that the only features of clinical significance which have been added to the device that are novel from the predicates are Bluetooth wireless communication and the option for longer pulse width.

The Bluetooth functionality allows the device to communicate wirelessly with external instruments such as the Clinician Programmer and the Patient Controller. The submission states that this communication link is encrypted to protect confidential patient information (page 13, *CER*). The risks associated with the addition of wireless capability are discussed in more detail in the TGA Application Audit Clinical Assessment Report for the Clinician Programmer and the Patient Controller (located at TRIM R15/738307).

s.47

s.47

The 'Executive Summary' section of the *CER* states that, 'the incremental design changes proposed for the Proclaim SCS system do not impact safety or performance. Based on the review of the risks associated with the Proclaim IPG, CP and PC, SJM concludes the benefits outweigh the risks' (page 2, *CER*).

Based on the information available to the TGA assessor at this time, from the documentation provided, the assertion made in the submission that the Proclaim 5 Elite IPG Model 3660 and the Proclaim 7 Elite IPG Model 3662 are substantially equivalent to the predicate Eon C IPG Model 3688 and the Genesis IPG Model 3608 is reasonable. However, post-market data will be of particular importance s.47

Review of published literature

A literature review of studies pertaining to the use of spinal cord stimulation devices in general is provided in the submission.

The *Literature Review* was conducted using the Embase database. The stated aim was to 'identify clinical evidence with SCS systems equivalent to the Proclaim/Proclaim SCS system used in the treatment of chronic pain, angina and peripheral vascular disease' (page 6, *Literature Review*). The stated methods, search strategy, inclusion criteria and exclusion criteria of the literature review are adequately described and appropriate in coverage.

s.47

S.47

While the *Literature Review* is useful in providing broad context around the safety and performance of spinal cord stimulation systems in general, the TGA assessor does not consider clinical data which may be derived from non-predicate spinal cord stimulation devices as evidence of the safety of the subject Proclaim Elite IPG devices. If the applicant wishes to use clinical data from the predicate Eon C IPG Model 3688 and/or the Genesis IPG Model 3608 in lieu of clinical data for the subject devices, the literature review must clearly indicate which clinical studies pertain to the Eon and/or Genesis IPG devices.

S.47

Post-market data

S.47

S.47

Comment on Instructions For Use (IFU) and labelling

The Instructions for Use (IFU) documents provided in this submission include:

- a Clinicians Manual; and
- an Angina and PVD IFU Insert; and
- an e-IFU Insert card.

The *Clinicians Manual* clearly outlines that the Proclaim IPG is intended for single use only, and that the device has been sterilised using ethylene oxide gas before shipment and are supplied in sterile packaging to permit direct introduction into the sterile field (page 3, under the 'Sterilization and Storage' heading).

The manual also indicates that a trained operator is required for use of the device, 'implanting physicians should be experienced in the diagnosis and treatment of chronic pain syndromes and have undergone surgical and device implantation training' (page 3, *Clinicians Manual*).

The indications for use are described on page 2 of the manual:

this neurostimulation system is indicated as an aid in the management of chronic, intractable pain of the trunk and/or limbs, including unilateral or bilateral pain associated with the following: failed back surgery syndrome and intractable low back and leg pain.

The manual also specifically outlines the need for careful patient selection:

It is extremely important to select patients appropriately for neurostimulation. Thorough psychiatric screening should be performed. Patients should not be dependent on drugs and should be able to operate the neurostimulation system (page 3, Clinicians Manual).

The contraindications are detailed on page 2 of the manual, citing patients who are unable to operate the system or who have failed to receive effective pain relief during trial stimulation. The manual also cautions against the use of the device in patients who 'are poor surgical risks of patients with multiple illnesses or active general infections'.

MRI safety information is clearly presented under the 'Warnings' heading, which states that patients with an implanted neurostimulation system should not be subjected to MRI because the electromagnetic field generated by an MRI may damage the device electronics and induce voltage through the lead that could jolt or shock the patient (page 2, *Clinicians Manual*).

However, the device labels provided in the submission do not include the MR Unsafe icon. This should be rectified.

The manual also cautions against the use of diathermy or electrosurgery devices in patients implanted with Proclaim IPGs (page 2, *Clinicians Manual*).

The manual also includes important warnings pertaining to patients with implanted cardiac devices:

Physicians need to be aware of the risk and possible interaction between a neurostimulation system and an implanted cardiac system, such as a pacemaker or defibrillator. Electrical pulses from a neurostimulation system may interact with the sensing operation of an implanted cardiac system, causing the cardiac system to respond inappropriately. To minimize or prevent the implanted cardiac system from sensing the output of the neurostimulation system, (1) maximize the distance between the implanted systems; (2) verify that the neurostimulation system is not interfering with the functions of the implanted cardiac system; and (3) avoid programming either device in a unipolar mode (using the device's can as an anode) or using neurostimulation system settings that interfere with the function of the implantable cardiac system (page 2, Clinicians Manual).

The *Angina & PVD IFU* and *e-IFU Insert card* appear to be addendums to the original *IFU* document. The *Angina & PVD IFU Insert* outlines the indications for use of the device. Under the 'adverse effects' heading, the IFU simply states: 'for information about adverse effects related to this product, refer to the clinician's manual for the applicable device'. The *e-IFU Insert card* is a simple statement which reads, 'product manuals are available online. Adobe Reader 6.0 or later is required to view PDF files. You can order a paper copy of the product manual free of charge. It will be delivered to you within seven days. Follow instructions for use on this website'. It also provides the website address: 'manuals.sjm.com'.

Comment on Risk Management Report

The *CER* states at Section 7, 'Risk Assessment', 'throughout the product lifecycle for the Proclaim SCS system, a full risk assessment of potential risks related to design, process and application will be performed' (page 30, *CER*).

The *Risk Management Report* provided in the submission appears to relate to the Orion Neuro Hibrid IPG, rather than the subject Proclaim Elite IPG devices.

As per Essential Principle 9.2, 'Minimisation of risks associated with use of medical devices', the submission must provide documentation that demonstrates the risks associated with the use of the subject Proclaim 5 Elite IPG Model 3660 and the Proclaim 7 Elite IPG Model 3662 devices, and how these risks have been mitigated as far as possible. This should include relevant risk management standard operating procedures, hazard analyses and FMECA documents. A Risk Assessment Report specific to the subject devices must be provided so that the TGA assessor can be confident that the risk management process is based on clinical evidence.

s.47

Comment on Expert Report

Both *CERs* have been signed by the clinical expert, s.22.

s.22 [REDACTED] has a Bachelors degree, Masters degree, PhD in Electrical and Computer Engineering, and MD from the s.22 [REDACTED]. He is a qualified cardiothoracic surgeon, and has current registration with the American Board of Thoracic Surgery. He has been a senior medical director at St Jude Medical [REDACTED].

[REDACTED] has an extensive number of publications in the field of cardiac surgery and was a practicing cardiothoracic surgeon in Southern California from [REDACTED]. He has sufficient skills and knowledge to act as a suitably qualified medical expert for the purposes of this application.

Conclusion(s)

Based on the information available to the TGA assessor at this time, from the documentation provided, the assertion made in the submission that the Proclaim 5 Elite IPG Model 3660 and the Proclaim 7 Elite IPG Model 3662 are substantially equivalent to the predicate Eon C IPG Model 3688 and the Genesis IPG Model 3608 is reasonable.

s.47 [REDACTED]

Non-clinical Design Verification and Validation testing has also been presented at Section 6.1 of the *CER*, in which all acceptance criteria were met. While the Design Verification and Validation testing provides some reassurance about the performance of the subject Proclaim IPG devices in the non-clinical setting, the TGA assessor does not consider this testing to act in lieu of clinical data.

While the *Literature Review* is useful in providing broad context around the safety and performance of spinal cord stimulation systems in general, the TGA assessor does not consider clinical data which may be derived from non-predicate spinal cord stimulation devices as evidence of the safety of the subject Proclaim Elite IPG devices. If the applicant wishes to use clinical data from the predicate Eon C IPG Model 3688 and/or the Genesis IPG Model 3608 in lieu of clinical data for the subject devices, the literature review must clearly indicate which clinical studies pertain to the Eon and/or Genesis IPG devices.

s.47 [REDACTED]

S.47

While MRI safety information has been clearly presented under the 'Warnings' heading of the *Clinician's Manual*, which states that patients with an implanted neurostimulation system should not be subjected to MRI (page 2, *Clinicians Manual*), the device labels provided in the submission do not include the MR Unsafe icon. This should be rectified by the applicant.

The *Risk Management Report* provided in the submission appears to relate to the Orion Neuro Hibrid IPG, rather than the subject Proclaim Elite IPG devices. As per Essential Principle 9.2, 'Minimisation of risks associated with use of medical devices', the submission must provide documentation that demonstrates the risks associated with the use of the subject Proclaim Elite IPG devices, and how these risks have been mitigated as far as possible.

A Risk Assessment Report specific to the subject devices must be provided so that the TGA assessor can be confident that the risk management process is based on clinical evidence. S.47

On balance, the applicant has not provided sufficient clinical evidence to demonstrate performance and safety of the device.

Is additional clinical data required?	YES
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Specific Questions to be asked:

To address the deficiencies noted above, the applicant will need to provide the following:

- S.47

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- [s.47](#) 
- inclusion of the MR unsafe icon on all device labelling; and
- a Risk Management Report specific to the Proclaim 5 Elite IPG Model 3660 and the Proclaim 7 Elite IPG Model 3662, including any relevant risk management standard operating procedures, any hazard analysis documents, FMECA documents. These documents should name and classify specific risks, detail how those risks have been mitigated, and how the risk management process is informed by clinical evidence.

Name & Dated Signature of Clinical Assessor:

Name:	s.22 	Date:	21/06/2016
Signature:			

s.47

ATTACHMENT A

Application Audit Clinical Evidence Checklist

1. Has the manufacturer compiled clinical data for the device in question when used in accordance with the proposed intended purpose?
 - ☐ Yes. Go to 2.
 - ☐ No. Go to 1a.
- 1a. Are there clinical data for a device with which the manufacturer has claimed and demonstrated equivalence? (Consult with MDAS assessor)
 - ☐ Yes. Go to 2.
 - ☐ No. Go to 1b.
- 1b. Has the manufacturer provided an acceptable justification as to why clinical data are not required?
 - ☐ Yes. Go to 2.
 - ☐ No. The legislative requirements for clinical evidence have not been met.
2. Has the manufacturer submitted an acceptable report detailing the clinical evaluation (critical appraisal) of the clinical data?
 - ☐ Yes. Go to 3.
 - ☐ No. The legislative requirements for clinical evidence have not been met.
3. Has the clinical evaluation been performed by a person with expertise appropriate to the clinical application of the device?
 - ☐ Yes. The legislative requirements for clinical evidence have been met.
 - ☐ No. The legislative requirements for clinical evidence have not been met.



Australian Government
Department of Health
 Therapeutic Goods Administration

TRIM Reference: 2015/026929
 2015/026930
 (R16/475726)

St Jude Medical Australia Pty Ltd
 17 Orion Road
 LANE COVE NSW 2066

Email: [s.22](#)

Attention:

**Notice under section 41JA of the *Therapeutic Goods Act 1989*
 requiring information/documents to be provided**

Application ID:	DV-2015-DA-14695-1 DV-2015-DA-14698-1
Submission ID:	DA-2015-06754-1
GMDN¹:	Stimulator, electrical, analgesic, spinal cord[36007]
Unique Product Identifier (UPI):	Proclaim 5 Elite IPG, Model 3660 Proclaim 7 Elite IPG, Model 3662

Information is requested by no later than close of Business 27 July 2016.

As a delegate of the Secretary of the Department of Health (the Secretary) for the purposes of section 41JA of the Therapeutic Goods Act 1989 (the Act), I have made a decision to request information in relation to the abovementioned applications for the inclusion of the kinds of medical devices: Proclaim 5 Elite IPG, Model 3660 and Proclaim 7 Elite IPG, Model 3662 (GMDN: Stimulator, electrical, analgesic, spinal cord [36007]), Class AIMD (the Devices) in the Australian Register of Therapeutic Goods (ARTG).

I have made this decision because following evaluation of the information provided to the Therapeutic Goods Administration (TGA) in relation to these applications, I am not satisfied as to all aspects considered in the application(s)' audit.

In particular, I am not satisfied:

- That all matters in relation to which certifications have been made under section 41FD are correct, including the certification made under:
 - Paragraph 41FD(d) of the Act, that the Devices comply with the essential principles;
 - Paragraph 41FD(e) of the Act, that you, as the applicant, for the inclusion of the Devices in the ARTG, have available sufficient information to substantiate that compliance with the essential principles or have procedures in place, including a written agreement with the manufacturer of the Devices setting out matters required

¹ Information as stated in the application

- by the regulation to ensure such information can be obtained from the manufacturer within the period specified in the Regulations; and
- Paragraph 41FD(j) of the Act, that the information included in or with the applications is complete and correct.

Therefore, additional information is required prior to a decision being made whether to include the Device in the ARTG.

Important

If you fail to comply with this notice and information relating to the Devices is not received by the TGA within a further 10 working days from the day specified in this notice (see the day specified above), the applications DV-2015-DA-14695-1 and DV-2015-DA-14698-1 will lapse (subsection 41FK(c) of the Act).

For further information refer to:

- the relevant legislation:
 - *Therapeutic Goods Act 1989* (<http://www.legislation.gov.au/Series/C2004A03952>);
 - *Therapeutic Goods (Medical Device) Regulations 2002* (<http://www.legislation.gov.au/Series/F2002B00237/Compilations>); and
- Australian regulatory guidelines for medical devices (ARGMD) (<https://www.tga.gov.au/publication/australian-regulatory-guidelines-medical-devices-argmd>)

Background:

On 24 August 2015, TGA received the applications for inclusion of the Devices in ARTG, and on 4 September 2015, the TGA notified you that your applications were selected for audit.

On 15 September 2015, you provided the following information:

- Table of Contents;
- SJMA cover letter dated 15 September 2015;
- Risk Management Report;
- Australian Proclaim IPGs DoC;
- General Derails;
- Labelling;
- Instructions for Use; and
- Clinical Evaluation Report

The information provided, has been assessed and I have come to the view that further information is required in order for me to conclude whether the certifications made under section 41FD of the Act are correct.

1. Essential principles

Kinds of medical devices can be included in the ARTG, if amongst other things the device complies with relevant provisions of the essential principles (EP)².

Under subsections 41FD(d) and (e) of the Act, you as the applicant for inclusion of the Devices in the ARTG, certified that it complies with essential principles, and that you have available sufficient information to substantiate the compliance of the Devices with the essential principles or have procedures in place to ensure that this information can be obtained from the manufacturer within the period specified in the Regulations.

² The essential principles set out the requirements relating to the safety and performance of medical devices. Section 41CA of the Act prescribes that these requirements are set out in the Regulations. Regulation 2.1 specifies that the essential principles are set out in Schedule 1 of the Regulations. There are six general principles and nine principles about design and construction (some principles may apply to devices on a case-by-case basis).

EP 13- Information that must be provided with the device

EP 13 specifies requirements for the information that must be provided with the kind of the device, location of this information, and requirements for the instructions for use of the device.

On 15 September 2015, you provided copies of the product information for the Device. Assessment of this information has raised concerns that while MRI safety information has been clearly presented under the 'Warnings' heading of the Clinician's Manual, which states that patients with an implanted neurostimulation system should not be subjected to MRI (page 2, Clinicians Manual), the device labels provided in the submission do not include the MR Unsafe icon. (compliance with the EP 13.3 Item 5).

Therefore, further clarification is required to substantiate compliance with the EP 13.

Essential principle 14-Clinical evidence

Essential principle 14 states that every medical device to be included in the ARTG requires clinical evidence, appropriate for the use and classification of the device, demonstrating that the device complies with the applicable provisions of the essential principles (EP).

In particular, the clinical evaluation procedures must be applied to the kind of device, for the purpose of demonstrating that the kind of device complies with the applicable provisions of: EP 1 (Use of medical devices not to compromise health and safety); EP 3 (Medical devices to be suitable for intended purpose); and EP 6 (Benefits of medical devices to outweigh any undesirable effects)³.

Clauses 8.4, 8.5 and 8.6 of Part 8 of Schedule 3 of the Regulations set out requirements for the clinical investigation data, literature review and evaluation of clinical data in relation to a kind of medical device.

The Devices are Proclaim 5 Elite IPG, Model 3660 and Proclaim 7 Elite IPG, Model 3662 (subject devices). On 15 September 2015, you provided the first submission of the clinical evidence. The submission was provided in the form of the Clinical Evaluation Report (CER). The assessment of this information however, indicated that it did not demonstrate compliance of the Devices with the requirements of the essential principles. Specifically, the assessment has raised issues, including those identified below.

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While the Literature Review is useful in providing broad context around the safety and performance of spinal cord stimulation systems in general, the clinical data derived from non-predicate spinal cord stimulation devices cannot be considered as evidence of the safety of the Devices. The clinical data related to the predicate Eon C IPG Model 3688 and/or the Genesis IPG Model 3608 has been noted however the literature review does not clearly indicate which clinical studies pertain to the Eon and/or Genesis IPG devices.

³ Regulation 3.11 – Medical devices to which the clinical evaluation procedures must be applied

s.47

The Risk Management Report provided in the submission appears to relate to the Orion Neuro Hibrid IPG, rather than the subject Proclaim Elite IPG devices. As per Essential Principle 9.2, 'Minimisation of risks associated with use of medical devices', the submission must provide documentation that demonstrates the risks associated with the use of the subject Proclaim Elite IPG devices, and how these risks have been mitigated as far as possible. A Risk Assessment Report specific to the subject devices is required. s47G

A detailed (de-identified) copy of the clinical assessment of your submission is provided in Attachment A for your information.

Based on the above, I have come to the view that the clinical evidence provided to the TGA is not sufficient to demonstrate compliance of the Devices (Proclaim 5 Elite IPG, Model 3660 and Proclaim 7 Elite IPG, Model 3662) with the essential principle 14 for the purposes of demonstrating that the Devices comply with the essential principle 1 (identification of benefits and risks associated with the use of the Devices), and essential principle 6 (acceptability of any side effects associated with the use of the Devices); and/or conformance with part 8 of Schedule 3 of the Regulations.

Therefore, you need to provide further information to substantiate compliance of the Devices with the essential principles.

INFORMATION TO BE PROVIDED

You are requested therefore, to provide information listed below within the prescribed timeframe:

- Evidence that demonstrates compliance of the Device with the essential principle 13, 14 and Part 8 of Schedule 3 of the Regulations, including the following:

- s.47

- Inclusion of the MR unsafe icon on all device labelling; and
- A Risk Management Report specific to the Proclaim 5 Elite IPG Model 3660 and the Proclaim 7 Elite IPG Model 3662, including any relevant risk management standard operating procedures, any hazard analysis documents, FMECA documents. These documents should name and classify specific risks, detail how those risks have been mitigated, and how the risk management process is informed by clinical evidence.

IMPORTANT

Please ensure that all information that has been required is provided. The first response received by the TGA will be considered to be the complete and final response for this submission.

Please do not provide the same information that has already been submitted and evaluated in the previous submissions. It is advisable to be precise in sending the data specifically addressing the concerns identified in this Notice.

Failure to provide sufficient response may result in the Delegate making a decision not to include the device in the ARTG.

If you require further information please refer Section 3 of the Australian Regulatory Guidelines for Medical Devices (ARGMD)

([http:// www.tga.gov.au/sites/default/files/devices-argmd-01.pdf](http://www.tga.gov.au/sites/default/files/devices-argmd-01.pdf))

All text must be in English, pictures must be clearly labelled, and text and picture must be legible.

These documents should clearly articulate the manufacturer's intended purpose for the Device, and demonstrate compliance with the regulatory requirements, including compliance with the essential principles.

Timeframe for submitting this information

Regulation 5.2 prescribes that for the purpose of obtaining information that demonstrates that the matters certified under section 41FD were correct in relation to the compliance with the essential principles and application of conformity assessment procedures appropriate to the kind of medical device, the period of obtaining information is 20 working days.

Consistently with these requirements, I request that you provide your response to the address specified below by no later than 27 July 2016.

Lapsing or Rejection of the Application

If no reply is received in response to the Notice within a further 10 working days from the day specified in this notice, the application will lapse (section 41FK(c) of the Act).

Failure to provide sufficient response may also result in the Delegate making a decision not to include the device in the ARTG (refer section 41FI(3) of the Act).

You will also have a right of review of any decision not to include the Devices in the ARTG, however, lapsing of the applications is not 'an initial decision' within the meaning of section 60 of the Act.

If the application lapses or is rejected, you may submit another application at a later date, once all the information is available. Application fees and assessment fees will not be refunded once an application is lapsed or rejected.

Withdraw

You may withdraw your application at any time prior to a decision being made whether or not to include the devices in the ARTG. You should note, however, that the fee paid for the

application is not refundable (<http://www.tga.gov.au/about/fees-refunds.htm>). If you wish to withdraw your application, you should advise the TGA of this request in writing, via e-mail: devices@tga.gov.au

How to present the submission

The requested information must be provided as a complete stand-alone submission. Cross-referencing to information submitted in support of previous applications that are already included in the ARTG, or still in process, may not be acceptable and may not be considered or reviewed.

All requested information must be provided in English. Where material is not originally in English a full translation must be submitted, the accuracy of which is the responsibility of the sponsor.

All text and pictures must be legible, and pictures must be clearly labelled. If your submission is less than 15 pages, you may clearly state the Application ID and the applicant name in the subject line and email the information to: devices@tga.gov.au.

If your submission is longer than 15 pages, it should be sent to:

Devices Applications & Verification Section
Medical Devices Branch
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

The information should be provided in either of the following formats:

- a) An electronic copy (in the form of a CD or DVD containing all of the relevant material)
 - **[Preferred Method]**

Note: Responses that contain 15 pages or more of the data/information must **not** be sent to the TGA as email attachments. The submitted electronic information must be complete and clearly tabulated and titled.

OR:

- b) A single hard copy of the information (two-sided print is acceptable).
 - Standard A4 paper must be used for all information (where possible). The margin should be sufficiently large that information is not obscured through binding.
 - The information must be supplied in loose-leaf binders. Plastic sleeves or stapled material should be avoided.
 - The information must be sectioned for ease of reference, and a table of contents provided which details the content of the binder(s).

Review of the decision

Should you wish to seek a review of my decision to require you to provide information/documents about the Device, your rights of review are outlined in Attachment C to this letter.

Yours sincerely,

s.22

(Signed electronically)

Delegate of the Secretary for the purposes of section 41JA of the Act
Medical Devices Branch
27 June 2016

Attachment A**Audit Assessment**
Clinical Evaluation – 1st Round

Does the submitted clinical data meet the requirements of Essential principle 14 of Schedule 1 and Part 8 of Schedule 3 of the <i>Therapeutic Goods (Medical Devices) Regulations 2002</i>?	NO
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Comments & Rationale:**Device**

The Proclaim 5 Elite IPG, Model 3660 is manufactured by St Jude Medical (United States of America).

Device Description

The Proclaim 5 Elite IPG Model 3660 and Proclaim 7 Elite IPG Model 3662 are implantable pulse generators that are designed to be connected to one or more lead extensions with up to 16 electrodes total. According to the submission, the devices are powered by a hermetically sealed battery within a titanium case and use microelectronic circuitry to generate constant-current electrical stimulation.

The Proclaim IPGs can deliver stimulation with a single program or with multiple programs. Each program can provide stimulation to a single anatomical area or to multiple areas. The IPG communicates wirelessly with system programmers and controllers.

The Proclaim IPG is available in two sizes. The Proclaim 5 Elite IPG Model 3660 is the smaller size, and the Proclaim 7 Elite IPG Model 3662 is the larger size. These two sizes accommodate for different power requirements.

The IPG is a part of the Proclaim SCS system. The system is comprised of the following components:

- a lead(s) that delivers electrical stimulation pulses to the patient's tissue;
- an external trial system that allows temporary evaluation of therapy efficacy;
- an IPG that generates the therapeutic electrical waveforms;
- a clinician programmer that allows the physician to prescribe the parameters of therapy; and
- a patient controller that allows the patient to control the delivery of therapy.

While the Proclaim IPG sits within a SCS system, the Clinician Programmer App, Patient Controller App, external trial system and leads will not be assessed as part of this Clinical Assessment Report. This is because the Clinician Programmer App and Patient Controller App have been assessed in a separate TGA Application Audit Clinical Assessment Report (located at TRIM R15/738307), and the leads have been deemed as outside the scope the CER included in the submission, and, according to the CER, are already approved products (page 11, CER).

The Proclaim IPG 3660 and 3662 are new hardware platforms whose clinical functionality are predicated on CE marked, commercially available St Jude Medical neurostimulation systems, namely the Eon C IPG Model 3688 and the Genesis IPG 3608 (page 13, CER).

Proposed therapeutic indication(s)

Under the 'Intended Use' heading of the IFU document (*Proclaim IPG Clinician's Manual*), it is stated that:

This neurostimulation system is designed to deliver low-intensity electrical impulses to nerve structures. The system is intended to be used with leads and associated extensions that are compatible with the system (page 4, IFU).

This matches the proposed therapeutic indications in the eBS Device Application Form, which is stated as:

This neurostimulation system is designed to deliver low-intensity electrical impulses to nerve structures. The system is intended to be used with leads and associated extensions that are compatible with the system. (eBS Device Application Form).

The 'Indications for Use' heading in the IFU document states,

This neurostimulation system is indicated as an aid in the management of chronic, intractable pain of the trunk and/or limbs, including unilateral or bilateral pain associated with the following: failed back surgery syndrome and intractable low back and leg pain (page 4, IFU).

In addition, the IFU Angina & PVD Insert includes the following statement:

This spinal cord stimulation system is indicated as an aid in the management of chronic, intractable pain of the trunk and limbs, including unilateral or bilateral pain associated with angina pectoris and peripheral vascular disease (page 1, Angina & PVD Insert).

Contraindications

The Proclaim neurostimulation system is contraindicated for patients who are unable to operate the system or who have failed to receive effective pain relief during trial stimulation (page 25, Section 3.4, CER).

Status in other countries

Australia

The Manufacturer's Declaration of Conformity has been provided in the submission. It is dated 14 September 2015 and is signed by [S.22](#) St Jude Medical. Both devices have been classified as AIMDs with GMDN Code 36007 ('stimulator, electrical, analgesic, spinal cord').

Other similar St Jude Medical devices currently listed on the ARTG include: the St Jude Medical Eon C IPG Model 3688 (ARTG 158502, 15/01/2009), the St Jude Genesis Pulse Generator 8-Channel, Model 3608 (ARTG 131543, 21/09/2006) and the St Jude Medical Prodigy IPG 3799 (ARTG 230721, 18/11/2014).

Other similar devices from different manufacturers currently listed on the ARTG include: the Boston Scientific Precision IPG (ARTG 129091, 27/06/2006), the Medtronic Prime Advanced 37702 IPG (ARTG 141860, 9/07/2007) and the Medtronic RestoreULTRA model 37712 (ARTG 154866, 28/08/2008).

Europe

Both the Proclaim 5 Elite IPG and the Proclaim 7 Elite IPG obtained the CE mark [S.47](#)

United States of America

The St Jude Medical Proclaim Neurostimulation System obtained premarket approval from the United States Food and Drug Administration (FDA) on 2 November 2015 (S.47 [REDACTED]). The Proclaim 5 Elite and the Proclaim 7 Elite have been in commercial distribution in the United States [REDACTED].

Canada

The Proclaim Implantable Pulse Generators were issued a licence in Canada (Device Class 4) on 26 April 2016 ([REDACTED]).

Overview of the clinical data

The CER provided in the submission pertains to the whole Proclaim Spinal Cord Stimulation (SCS) system, which includes both the small (model 3660) and the large (model 3662) sizes of the Proclaim Elite IPG (the subject devices of this application), the St Jude Medical Clinician Programmer App and the St Jude Medical Patient Controller App. As discussed above, the TGA assessor notes that the Clinician Programmer App and Patient Controller App have been assessed in a separate TGA Application Audit Clinical Assessment Report (located at TRIM R15/738307).

No clinical studies are presented in the submission on the subject Proclaim 5 Elite IPG device or the Proclaim 7 Elite IPG device. The CER states that this is because 'the Proclaim neurostimulation system has equivalent SCS functionality to the predicate SJM neurostimulation systems and neurostimulation systems that are currently CE marked and reported in the literature' (page 30, Section 6.4, CER).

The CER draws on three key components in its presentation of the risks and benefits of the Proclaim Elite IPGs:

- 1) claims of substantial equivalence with predicate SJM IPG devices
- 2) a review of published literature on spinal cord stimulation devices in general; and
- 3) post-market data from predicate devices to the Proclaim IPGs.

In addition, non-clinical Design Verification and Validation testing has also been presented at Section 6.1 of the CER:

Design verification and design validation confirmed that all acceptance criteria were met. Thus, this testing demonstrates the safety and performance of the Proclaim neurostimulation system design. The detailed reports are provided in the respective summary of technical documentation. Therefore, the preponderance of test results demonstrates that the Proclaim neurostimulation system meets safety and performance requirements for its intended use (page 28, CER).

While the Design Verification and Validation testing provides some reassurance about the performance of the subject Proclaim IPG devices in the non-clinical setting, the TGA assessor does not consider this testing to act in lieu of clinical data.

The TGA assessor will consider these three components in the same order below.

Assessment of clinical data

Substantial Equivalence

The CER claims substantial equivalence between the Proclaim IPG and its predicates, the Eon C IPG (3688) and the Genesis IPG (3608): 'because the basic SCS functionality was unaltered ...the Proclaim neurostimulation system SCS functionality is equivalent to the predicate SJM neurostimulation system' (page 13, CER).

Table 1 on page 14 of the *CER* provides a comparison of the functionality of the Proclaim IPG with its predicates. This table suggests that the only features of clinical significance which have been added to the device that are novel from the predicates are Bluetooth wireless communication and the option for longer pulse width.

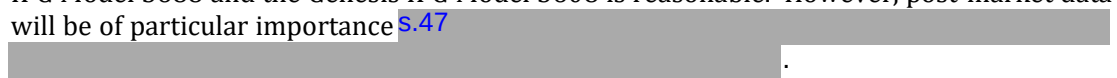
The Bluetooth functionality allows the device to communicate wirelessly with external instruments such as the Clinician Programmer and the Patient Controller. The submission states that this communication link is encrypted to protect confidential patient information (page 13, *CER*). The risks associated with the addition of wireless capability are discussed in more detail in the TGA Application Audit Clinical Assessment Report for the Clinician Programmer and the Patient Controller (located at TRIM R15/738307).

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The 'Executive Summary' section of the *CER* states that, 'the incremental design changes proposed for the Proclaim SCS system do not impact safety or performance. Based on the review of the risks associated with the Proclaim IPG, CP and PC, SJM concludes the benefits outweigh the risks' (page 2, *CER*).

Based on the information available to the TGA assessor at this time, from the documentation provided, the assertion made in the submission that the Proclaim 5 Elite IPG Model 3660 and the Proclaim 7 Elite IPG Model 3662 are substantially equivalent to the predicate Eon C IPG Model 3688 and the Genesis IPG Model 3608 is reasonable. However, post-market data will be of particular importance s.47



Review of published literature

A literature review of studies pertaining to the use of spinal cord stimulation devices in general is provided in the submission.

The *Literature Review* was conducted using the Embase database. The stated aim was to 'identify clinical evidence with SCS systems equivalent to the Proclaim/Proclaim SCS system used in the treatment of chronic pain, angina and peripheral vascular disease' (page 6, *Literature Review*). The stated methods, search strategy, inclusion criteria and exclusion criteria of the literature review are adequately described and appropriate in coverage.

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While the *Literature Review* is useful in providing broad context around the safety and performance of spinal cord stimulation systems in general, the TGA assessor does not consider clinical data which may be derived from non-predicate spinal cord stimulation devices as evidence of the safety of the subject Proclaim Elite IPG devices. If the applicant wishes to use clinical data from the predicate Eon C IPG Model 3688 and/or the Genesis IPG Model 3608 in lieu of clinical data for the subject devices, the literature review must clearly indicate which clinical studies pertain to the Eon and/or Genesis IPG devices.

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Post-market data

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Comment on Instructions For Use (IFU) and labelling

The Instructions for Use (IFU) documents provided in this submission include:

- a Clinicians Manual; and
- an Angina and PVD IFU Insert; and
- an e-IFU Insert card.

The *Clinicians Manual* clearly outlines that the Proclaim IPG is intended for single use only, and that the device has been sterilised using ethylene oxide gas before shipment and are supplied in sterile packaging to permit direct introduction into the sterile field (page 3, under the 'Sterilization and Storage' heading).

The manual also indicates that a trained operator is required for use of the device, 'implanting physicians should be experienced in the diagnosis and treatment of chronic pain syndromes and have undergone surgical and device implantation training' (page 3, *Clinicians Manual*).

The indications for use are described on page 2 of the manual:

this neurostimulation system is indicated as an aid in the management of chronic, intractable pain of the trunk and/or limbs, including unilateral or bilateral pain associated with the following: failed back surgery syndrome and intractable low back and leg pain.

The manual also specifically outlines the need for careful patient selection:

It is extremely important to select patients appropriately for neurostimulation. Thorough psychiatric screening should be performed. Patients should not be dependent on drugs and should be able to operate the neurostimulation system (page 3, Clinicians Manual).

The contraindications are detailed on page 2 of the manual, citing patients who are unable to operate the system of who have failed to receive effective pain relief during trial stimulation. The manual also cautions against the use of the device in patients who 'are poor surgical risks of patients with multiple illnesses or active general infections'.

MRI safety information is clearly presented under the 'Warnings' heading, which states that patients with an implanted neurostimulation system should not be subjected to MRI because the electromagnetic field generated by an MRI may damage the device electronics and induce voltage through the lead that could jolt or shock the patient (page 2, *Clinicians Manual*). However, the device labels provided in the submission do not include the MR Unsafe icon. This should be rectified.

The manual also cautions against the use of diathermy or electrosurgery devices in patients implanted with Proclaim IPGs (page 2, *Clinicians Manual*).

The manual also includes important warnings pertaining to patients with implanted cardiac devices:

Physicians need to be aware of the risk and possible interaction between a neurostimulation system and an implanted cardiac system, such as a pacemaker or defibrillator. Electrical pulses from a neurostimulation system may interact with the sensing operation of an implanted cardiac system, causing the cardiac system to respond inappropriately. To minimize or prevent the implanted cardiac system from sensing the output of the neurostimulation system, (1) maximize the distance between the implanted systems; (2) verify that the neurostimulation system is not interfering with the functions of the implanted cardiac system; and (3) avoid programming either device in a unipolar mode (using the device's can as an anode) or using neurostimulation system settings that interfere with the function of the implantable cardiac system (page 2, Clinicians Manual).

The *Angina & PVD IFU* and *e-IFU Insert card* appear to be addendums to the original *IFU* document. The *Angina & PVD IFU* Insert outlines the indications for use of the device. Under the 'adverse effects' heading, the IFU simply states: 'for information about adverse effects related to this product, refer to the clinician's manual for the applicable device'. The *e-IFU Insert card* is a simple statement which reads, 'product manuals are available online. Adobe Reader 6.0 or later is required to view PDF files. You can order a paper copy of the product manual free of charge. It will be delivered to you within seven days. Follow instructions for use on this website'. It also provides the website address: 'manuals.sjm.com'.

Comment on Risk Management Report

The *CER* states at Section 7, 'Risk Assessment', 'throughout the product lifecycle for the Proclaim SCS system, a full risk assessment of potential risks related to design, process and application will be performed' (page 30, *CER*).

The *Risk Management Report* provided in the submission appears to relate to the Orion Neuro Hibrid IPG, rather than the subject Proclaim Elite IPG devices.

As per Essential Principle 9.2, 'Minimisation of risks associated with use of medical devices', the submission must provide documentation that demonstrates the risks associated with the use of the subject Proclaim 5 Elite IPG Model 3660 and the Proclaim 7 Elite IPG Model 3662 devices, and how these risks have been mitigated as far as possible. This should include relevant risk management standard operating procedures, hazard analyses and FMECA documents. A Risk Assessment Report specific to the subject devices must be

provided so that the TGA assessor can be confident that the risk management process is based on clinical evidence.

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Comment on Expert Report

Both *CERs* have been signed by the clinical expert, s.22 .

has a Bachelors degree, Masters degree, PhD in Electrical and Computer Engineering, and MD from . He is a qualified cardiothoracic surgeon, and has current registration with the American Board of Thoracic Surgery. He has been a senior medical director at St Jude Medical since .

has an extensive number of publications in the field of cardiac surgery and was a practicing cardiothoracic surgeon in Southern California from . He has sufficient skills and knowledge to act as a suitably qualified medical expert for the purposes of this application.

Conclusion(s)

Based on the information available to the TGA assessor at this time, from the documentation provided, the assertion made in the submission that the Proclaim 5 Elite IPG Model 3660 and the Proclaim 7 Elite IPG Model 3662 are substantially equivalent to the predicate Eon C IPG Model 3688 and the Genesis IPG Model 3608 is reasonable.

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Non-clinical Design Verification and Validation testing has also been presented at Section 6.1 of the *CER*, in which all acceptance criteria were met. While the Design Verification and Validation testing provides some reassurance about the performance of the subject Proclaim IPG devices in the non-clinical setting, the TGA assessor does not consider this testing to act in lieu of clinical data.

While the *Literature Review* is useful in providing broad context around the safety and performance of spinal cord stimulation systems in general, the TGA assessor does not consider clinical data which may be derived from non-predicate spinal cord stimulation devices as evidence of the safety of the subject Proclaim Elite IPG devices. If the applicant wishes to use clinical data from the predicate Eon C IPG Model 3688 and/or the Genesis IPG Model 3608 in lieu of clinical data for the subject devices, the literature review must clearly indicate which clinical studies pertain to the Eon and/or Genesis IPG devices.

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While MRI safety information has been clearly presented under the 'Warnings' heading of the *Clinician's Manual*, which states that patients with an implanted neurostimulation system should not be subjected to MRI (page 2, *Clinicians Manual*), the device labels provided in the submission do not include the MR Unsafe icon. This should be rectified by the applicant.

The *Risk Management Report* provided in the submission appears to relate to the Orion Neuro Hibrid IPG, rather than the subject Proclaim Elite IPG devices. As per Essential Principle 9.2, 'Minimisation of risks associated with use of medical devices', the submission must provide documentation that demonstrates the risks associated with the use of the subject Proclaim Elite IPG devices, and how these risks have been mitigated as far as possible.

A Risk Assessment Report specific to the subject devices must be provided so that the TGA assessor can be confident that the risk management process is based on clinical evidence.

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On balance, the applicant has not provided sufficient clinical evidence to demonstrate performance and safety of the device.

Is additional clinical data required?	YES
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Specific Questions to be asked:

To address the deficiencies noted above, the applicant will need to provide the following:

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- inclusion of the MR unsafe icon on all device labelling; and
- a Risk Management Report specific to the Proclaim 5 Elite IPG Model 3660 and the Proclaim 7 Elite IPG Model 3662, including any relevant risk management standard operating procedures, any hazard analysis documents, FMECA documents. These documents should name and classify specific risks, detail how those risks have been mitigated, and how the risk management process is informed by clinical evidence.

Name & Dated Signature of Clinical Assessor:

Name:		Date:	
Signature:			

Attachment B**Clinical Evidence required to substantiate compliance of the kind of device with the essential principles, including requirements set out under Schedule 1 and Part 8 of Schedule 3 of the Therapeutic Goods (Medical Devices) Regulations 2002**

All medical devices supplied in Australia must comply with relevant legislative provisions. One of these is compliance with the essential principles. These are set out in Schedule 1 of the *Therapeutic Goods (Medical Devices) Regulations 2002* (the Regulations).

Clinical Evidence

Essential principle 14 of Schedule 1 of the Regulations states that each medical device requires appropriate clinical evidence.

Regulation 3.11 - stipulates that in addition to the conformity assessment procedures that are applied to a medical device, clinical evaluation procedures must also be applied to the device, for the purpose of demonstrating that the device complies with the applicable provisions of the essential principles, in particular:

- Principle 1 - Use of medical device not to compromise health and safety;
- Principle 3 - Medical devices to be suitable for intended purpose;
- Principle 6 - Benefits of the medical devices to outweigh undesirable effects.

Part 8 of Schedule 3 of the Regulations provides requirements for the clinical data that the manufacturer of a kind of medical device must obtain and evaluate in relation to the kind of device.

What you need to do

In order to demonstrate compliance with the abovementioned requirements, you need to provide the clinical data in the format specified below.

Refer the last two pages of this Attachment for further information about the requirements for clinical evidence.

Fill in the Clinical Evaluation Report (CER) Checklist and provide it as the first page for your clinical evidence submission.

CLINICAL EVALUATION REPORT (CER) CHECKLIST

[To be completed by the sponsor. It is a requirement that you check that all aspects of the CER are complete and correct prior to submission the clinical evidence to the TGA]

1. Specify the avenue(s) the manufacturer has selected to meet the requirements of Clause 14 (Clinical Evidence) of Schedule 1 and Part 8 (Clinical Evaluation Procedures) of Schedule 3 of the *Therapeutic Goods (Medical Devices) Regulations 2002*?

☐ Full Study Report(s) for the device or comparator(s)*

* Bear in mind a comparator MUST be clinically justified in the expert report.

☐ Literature review*

* A fully documented search strategy MUST be included in the expert report (i.e. databases searched, search terms used, inclusion and exclusion criteria to a level of detail that can be reproduced).

☐ Clinical Justification*

* Note that this avenue is only valid in some instances, i.e. a change of no clinical impact to a current device might be one instance.

If there are none of the above avenues used, the submission is incomplete and would not have adequate clinical data.

2. Has the manufacturer provided a clinical expert C.V. with the CER or sufficient documentation so that a judgement can be made about the “expert’s” status?

☐ Yes

If not, the submission is incomplete and may result in a delay in processing.

3. Does the nominated clinical expert have relevant clinical qualifications and experience with the use of the device under assessment in a clinical setting?

☐ Yes – the clinical expert has relevant qualifications and experience*

* A clinical expert should be clinically qualified and be able to comment upon the use of the device for its intended purpose. For example, an engineering degree is inadequate.

If not, the submission is incomplete.

4. Has the manufacturer submitted post market data within the CER for this device or its comparators (if relevant)?

☐ Yes

☐ No – If available, consider adding this information as it provides some extra data about real-world use of the device(s).

5. Does the submission have adequate indexing and pagination such that the totality of clinical evidence documentation can be readily identified and assessed? Please note that there should typically only be ONE CER encompassing the clinical evidence available for the device(s).

☐ Yes

☐ No*

*If not, difficulty with evaluation and requests for additional information may occur, delaying the finalisation of the submission.

Sponsor name:	
Title:	
Signature:	
Date:	

FURTHER INFORMATION

The Clinical Evaluation Report

- All clinical submissions **MUST** contain a Clinical Evaluation Report. This report **MUST** contain a summary presentation of all relevant clinical evidence for the device(s) under assessment, including clinical trial reports, published literature, post-market data and any clinical justification arguments. The author **MUST** provide a critique of those data and describe **WHY** those data support safety and performance for the specific device(s) when used as intended.
- All clinical data should typically be encompassed by **ONE** Clinical Evaluation Report. Multiple Clinical Evaluation Report documents would be a rarity and typically not an acceptable format for submission.
- The Clinical Evaluation Report **MUST** be authorised by a ‘competent clinical expert’; in other words, an individual with clinical qualifications relevant to the device and its use, who also has experience in the use of the device in a clinical setting.
- The appropriateness of the clinical expert will clearly vary depending upon the nature of the device and the intended purpose(s).
- Full curriculum vitae for such an expert or other documentation to enable verification of their suitability is also a necessary component of the clinical evidence submission.

The Clinical Data

Clinical data can take many forms depending upon the device, its development programme, and whether it is a new or novel device, or simply another iteration of a previous model. Data may be provided in one of several forms, and can include full clinical trial reports, published and unpublished literature, clinical justifications and post-market data. The following describes these data types more fully:

Clinical Study Reports

- Full clinical study reports for the device(s) under assessment used in the indications claimed.

Clinical Study Reports for a Similar Device

- Full study reports similar device(s), with a reasoned clinical argument why the safety and performance of that device may be taken to support the device under assessment [paying particular note to the intended purpose(s)]. Full study reports refers to complete study reports will all related documentation, not publications or journal articles. It is acknowledged that full study reports may only be summarised in the CER.

Documented Literature Search

- A documented literature search with a review of the publications retrieved. Such a review would discuss and critique the use of these devices in the publications, and why they support safety and performance for the device(s) under assessment. Particular attention should be paid to the intended purposes for the device(s) under assessment and those of the devices revealed by the literature search.

The following shall be taken into account:

- The documented search strategy should include information such as the databases searched, search terms used and any inclusion and exclusion criteria applied, in sufficient detail to enable the search to be reproduced if desired. This is necessary to enable an assessment of whether or not the review adequately searched current available published literature about the device(s) under assessment.
- A critical discussion of the literature revealed by the search strategy must be undertaken with particular emphasis on how the publications demonstrate safety and performance of the device under assessment for the indications claimed (i.e. in terms of similarity, predicates, the actual device, etc.).
- If there are no actual clinical data for the specific device, depending upon the nature of it and the reasons for submission, it may be possible to provide a full clinical justification for why clinical evidence is not required.

- Typically, a justification may reference the clinical safety and performance data of a 'predicate' or similar marketed device and critically examine each change or difference in terms of materials, design, clinical use, and their likely impact on safety and performance.
- A justification may also take the form of a minor change to a currently approved device, where the change is considered too minor to have any clinical impact, and this is justified by the clinical expert.
- If it can be established via justification that changes do not pose any clinical impact on safety and performance, a clinical justification can, in some circumstances, suffice for clinical evidence.
- Post-market data can be a valuable addition to the clinical evidence in a submission. These data should typically at least provide world-wide distribution numbers of the relevant device(s) since launch, as well as complaints and adverse events reported to the manufacturer. Complaint and adverse event rates should be given, and where the clinical expert deems it relevant, MDRs and other adverse event and complaint data should be discussed and critiqued to enable an understanding of the safety profile of the relevant device(s) in a 'real-world' setting.

Format

The documentation must be presented in a particular format. The following principles apply:

- Submissions must be appropriately paginated and indexed so that the totality of information can be seen, as well as each part of it easily identified.
- If the sponsor chooses to provide the submission electronically, this must be provided on a CD, separate from all other submitted information.
- The form of the electronic submission MUST enable easy referencing and provide a clear indication of the extent of the clinical documentation submitted. i.e. a cover letter with a clear list and location of all clinical documents, or an index as part of a PDF as two examples.

Attachment C**Request for reconsideration of an initial decision**

This decision is a reviewable initial decision under section 60 of the Act. Under section 60, a person whose interests are affected by a 'reviewable' initial decision, can seek reconsideration of the initial decision.

As this document constitutes written notice of the making of an initial decision being given by the Secretary, a request for reconsideration of this initial decision must be given to the Minister within 90 days and be accompanied by any information that you wish to have considered. A request for reconsideration given to the Minister outside the statutory 90 day reconsideration period cannot be accepted.

The Minister may either personally undertake a request for reconsideration of an initial decision or delegate to an officer of the Department with the appropriate delegation.

Under section 60(3A) of the Act, the Minister (or the Minister's delegate) is not able to consider any information provided after the notification is made of a request for reconsideration of an initial decision unless the information is provided in response to a request from the Minister (or the Minister's delegate), or it is information that indicates that the quality, safety or efficacy of the relevant therapeutic goods is unacceptable.

Guidelines for requesting reconsideration of an initial decision

A request for reconsideration should be made in writing, signed and dated by the person requesting reconsideration, should be titled "**Request for Reconsideration Under Section 60 of the Therapeutic Goods Act 1989**" and should include the following:

- a copy of the initial decision notification letter (or other evidence of notification);
- identify, and describe with as much specificity as possible, which component(s) of the initial decision should be reconsidered and set out the reasons why reconsideration is requested;
- any information/documentation in support of the request, clearly labelled to correspond with (any or each of) the reasons why reconsideration is requested; and
- an email address nominated for the purposes of receiving correspondence in relation to the request for reconsideration.

All requests for reconsideration should be given to the Minister by email:

Email: **'minister.ley@health.gov.au'** and **'decision.review@tga.gov.au'**

Where a request for reconsideration includes dossiers (or similar bulk material) that cannot easily be attached to the request given by email, the supporting documentation and original (signed) request for reconsideration can then be sent by express post or registered mail to:

Mail: **Minister for Health**
Suite M1 41
c/- Parliament House
CANBERRA ACT 2600

Subject to the *Administrative Appeals Tribunal Act 1975* (AAT Act), if you are dissatisfied with the decision upon reconsideration by the Minister (or the Minister's delegate), you can apply to the Administrative Appeals Tribunal (AAT) for a review of that decision upon reconsideration.

NOTE: This initial decision remains in effect unless and until it is revoked or revoked and substituted by the Minister (or the Minister's delegate) as a result of a request for reconsideration under section 60 of the Act OR is set aside, varied or remitted by the AAT or is otherwise overturned or stayed.



Australian Government

Department of Health

Therapeutic Goods Administration

Application Audit - Level 2 Clinical Assessment – 2nd Round

TRIM Reference: 2015/026929

To be completed by DAVS Assessor:

Device UPI	Proclaim 5 Elite IPG, Model 3660, Proclaim 7 Elite IPG, Model 3662
Sponsor:	St Jude Medical Australia Pty Ltd
Manufacturer:	St Jude Medical (United States Of America)
Application ID:	DV-2015-DA-14695-1, DV-2015-DA-14698-1
Submission ID:	DA-2015-06754-1
DAVS Assessor:	S.22
TRIM File No.:	2015/026929 DATA R15/728632 1 st round clinical assessment report: R15/746510 Sponsors response (data): <u>R16/529842</u>
Date submitted to TGA:	18/08/2015
Date Referred to Clinical Section:	13/07/2016
Clinical Round:	2

Required Level Of Assessment:	Review of Clinical Evaluation Report suitable for a Level 2 Application Audit (complete Clinical Evidence Checklist in Attachment A)
Manufacturer's Clinical Evaluation Report?	Include TRIM record number where it is located, including preliminary comments and clarification where required.
Notified Body Clinical Evaluation?	If available, provide TRIM record reference number and comments where clarification is required. Eg referenced in Design / Type Examination Report. <i>Note:</i> This will not exist for many lower class devices.

To be completed by Clinical Assessor:

Does the submitted clinical data meet the requirements of essential principle 14 of Schedule 1 and Part 8 of Schedule 3 of the Therapeutic Goods (Medical Devices) Regulations 2002?	NO
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The last round of clinical assessment concluded as follows:

Based on the information available to the TGA assessor at this time, from the documentation provided, the assertion made in the submission that the Proclaim 5 Elite IPG Model 3660 and the

Proclaim 7 Elite IPG Model 3662 are substantially equivalent to the predicate Eon C IPG Model 3688 and the Genesis IPG Model 3608 is reasonable.

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Non-clinical Design Verification and Validation testing has also been presented at Section 6.1 of the CER, in which all acceptance criteria were met. While the Design Verification and Validation testing provides some reassurance about the performance of the subject Proclaim IPG devices in the non-clinical setting, the TGA assessor does not consider this testing to act in lieu of clinical data.

While the Literature Review is useful in providing broad context around the safety and performance of spinal cord stimulation systems in general, the TGA assessor does not consider clinical data which may be derived from non-predicate spinal cord stimulation devices as evidence of the safety of the subject Proclaim Elite IPG devices. If the applicant wishes to use clinical data from the predicate Eon C IPG Model 3688 and/or the Genesis IPG Model 3608 in lieu of clinical data for the subject devices, the literature review must clearly indicate which clinical studies pertain to the Eon and/or Genesis IPG devices.

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In light of the fact that both the Proclaim 5 Elite IPG Model 3660 and the Proclaim 7 Elite Model 3662 devices obtained the [REDACTED], post-market surveillance data for the subject devices, if available, would assist the TGA assessor in the evaluation of their safety.

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While MRI safety information has been clearly presented under the 'Warnings' heading of the Clinician's Manual, which states that patients with an implanted neurostimulation system should not be subjected to MRI (page 2, Clinicians Manual), the device labels provided in the submission do not include the MR Unsafe icon. This should be rectified by the applicant.

The Risk Management Report provided in the submission appears to relate to the Orion Neuro Hibrid IPG, rather than the subject Proclaim Elite IPG devices. As per Essential Principle 9.2, 'Minimisation of risks associated with use of medical devices', the submission must provide documentation that demonstrates the risks associated with the use of the subject Proclaim Elite IPG devices, and how these risks have been mitigated as far as possible.

A Risk Assessment Report specific to the subject devices must be provided so that the TGA assessor can be confident that the risk management process is based on clinical evidence.

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On balance, the applicant has not provided sufficient clinical evidence to demonstrate performance and safety of the device.

The applicant is requested to provide the following information.

TGA Question 1

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TGA Question 2

Clinical expert's analysis to determine the most common complications found in the Literature Review of undesirable changes in stimulation, lead migration and uncomfortable stimulation could be in any way related to the increased pulse width in tonic stimulation mode;

Applicant response

The applicant states that the s.22, has directly examined the existent literature on this topic s.47

Assessor comments

The response is acceptable provided s.22 can be demonstrated to be suitably qualified to be the clinical expert for this application. A CV will be requested from the applicant.

TGA Question 3

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Applicant response

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Assessor comments

The response is acceptable.

TGA Question 4

Inclusion of the MR unsafe icon on all device labelling;

Applicant response

It is stated that the current Proclaim IFU (Clinician's Manual) includes the following warning in regard to use in the MR environment:

Patients with an implanted neurostimulation system should not be subjected to MRI because the electromagnetic field generated by an MRI may damage the device electronics and induce voltage through the lead that could jolt or shock the patient.

The applicant states that the IFU will be updated to include the MR unsafe symbol and descriptive text in the symbol table as per ASTM F2503-13, although no date is given. However, the applicant expressed the opinion that since the *TGA Position on the Requirements for MRI Labelling* is currently under consultation, a reasonable transition period should be allowed for new labelling requirements to allow manufacturers to update product labelling in an orderly manner while still allowing the product to be supplied in the interim.

The clinical assessor was informed by the coordinating assessor that the applicant has indicated a timeframe of approximately 6 months to include the MR-unsafe icon onto the labelling and within the IFU.

Assessor comments

The response is acceptable.

TGA Question 5

A Risk Management Report specific to the Proclaim 5 Elite IPG Model 3660 and the Proclaim 7 Elite IPG Model 3662, including any relevant risk management standard operating procedures, any hazard analysis documents, FMECA documents. These documents should name and classify specific risks, detail how those risks have been mitigated, and how the risk management process is informed by clinical evidence.

Applicant response

The applicant provided the following risk management documents.

Risk Management Process Procedure

This competently presented document describes the risk management process as a standard operating procedure for medical devices produced by various stated facilities of the manufacturer, covering the entire product lifecycle. The document covers management responsibilities, definition of terms, associated documents (including ISO 14971, IEC 60601-1 and IEC 62304), personnel requirements, risk management file contents, risk management process flow chart, risk management process steps (including risk planning, risk analysis and risk control, completeness of risk control, overall risk acceptability, and overall risk/benefit evaluation), and production / post-production information.

Risk Management Report

This document covers the subject IPGs and several accessories including tunnelling tool, torque wrench, port plug, and pocket sizer, summarising the risk management activities conducted per the above SOP.

Hazards are rated as Acceptable, Acceptable* (risks reduced to ALARP after mitigation measures including design changes, additional protective measures in the device or in the manufacturing process, and/or providing additional information for safety), and Unacceptable. There were no unacceptable hazards identified for the subject devices. The risk analysis results are summarised as follows.

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No risk-benefit analyses were performed as there were no unacceptable risks noted.

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Assessor comments

The submitted risk management documents are acceptable and demonstrate adequate risk mitigation measures and acceptable residual risks for the safety and performance of the subject devices, provided the Software FMECA risk table and Software FMECA list of mitigations as described above are submitted and found satisfactory.

The clinical assessor defers to the delegate with regard to the acceptability of use of an electronic IFU for this device system [REDACTED].

Is additional clinical data required?	YES
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Specific Questions to be asked:

- Provide direct post-market surveillance data for the subject devices, including the complaint data analysis mentioned in the hazard analysis report (68-4167 Rev. G; page 4 under "Complaint Data Review") S.47 [REDACTED]
- Provide a CV for S.22 [REDACTED] to demonstrate suitability as clinical expert for this application.

S.47 [REDACTED]

Name & Dated Signature of Clinical Assessor:

Name:	S.22 [REDACTED]	Date:	26 Jul 2016
Signature:	Signed electronically		

ATTACHMENT A

Application Audit Clinical Evidence Checklist

1. Has the manufacturer compiled clinical data for the device in question when used in accordance with the proposed intended purpose?
 - ☐ Yes. Go to 2.
 - ☒ No. Go to 1a.
- 1a. Are there clinical data for a device with which the manufacturer has claimed and demonstrated equivalence? (Consult with MDAS assessor)
 - ☒ Yes. Go to 2.
 - ☐ No. Go to 1b.
- 1b. Has the manufacturer provided an acceptable justification as to why clinical data are not required?
 - ☐ Yes. Go to 2.
 - ☐ No. The legislative requirements for clinical evidence have not been met.
2. Has the manufacturer submitted an acceptable report detailing the clinical evaluation (critical appraisal) of the clinical data?
 - ☒ Yes. Go to 3.
 - ☐ No. The legislative requirements for clinical evidence have not been met.
3. Has the clinical evaluation been performed by a person with expertise appropriate to the clinical application of the device?
 - ☐ Yes. The legislative requirements for clinical evidence have been met.
 - ☒ No. The legislative requirements for clinical evidence have not been met.



Australian Government
Department of Health
 Therapeutic Goods Administration

TRIM Reference: 2015/026929
 (R16/568104)

St Jude Medical Australia Pty Ltd
 17 Orion Road
 LANE COVE NSW 2066

Email: s.22

Attention: s.22

**Notice under section 41JA of the *Therapeutic Goods Act 1989*
 requiring information/documents to be provided**

Application ID:	DV-2015-DA-14695-1, DV-2015-DA-14698-1
Submission ID:	DA-2015-06754-1
GMDN¹:	Stimulator, electrical, analgesic, spinal cord[36007]
Unique Product Identifier (UPI):	Proclaim 5 Elite IPG, Model 3660, Proclaim 7 Elite IPG, Model 3662

Information is requested by no later than close of Business 24 August 2016.

As a delegate of the Secretary of the Department of Health (the Secretary) for the purposes of section 41JA of the *Therapeutic Goods Act 1989* (the Act), I have made a decision to request information in relation to the abovementioned applications for the inclusion of the kinds of medical devices: Proclaim 5 Elite IPG, Model 3660 and Proclaim 7 Elite IPG, Model 3662 (GMDN: Stimulator, electrical, analgesic, spinal cord[36007]), Class AIMD (the Devices) in the Australian Register of Therapeutic Goods (ARTG).

I have made this decision because following evaluation of the information provided to the Therapeutic Goods Administration (TGA) in relation to these applications, I am not satisfied as to all aspects considered in the applications' audit.

In particular, I am not satisfied:

- That all matters in relation to which certifications have been made under section 41FD are correct, including the certification made under:
 - Paragraph 41FD(d) of the Act, that the Devices comply with the essential principles;
 - Paragraph 41FD(e) of the Act, that you, as the applicant, for the inclusion of the Devices in the ARTG, have available sufficient information to substantiate that compliance with the essential principles or have procedures in place, including a written agreement with the manufacturer of the Devices setting out matters required by the regulation to ensure such information can be obtained from the manufacturer within the period specified in the Regulations; and

¹ Information as stated in the application

- Paragraph 41FD(j) of the Act, that the information included in or with the applications is complete and correct.

Therefore, additional information is required prior to a decision being made whether to include the Devices in the ARTG.

Important

If you fail to comply with this notice and information relating to the Devices is not received by the TGA within a further 10 working days from the day specified in this notice (see the day specified above), the applications DV-2015-DA-14695-1 and DV-2015-DA-14698-1 will lapse (subsection 41FK(c) of the Act).

For further information refer to:

- the relevant legislation:
 - *Therapeutic Goods Act 1989* (<http://www.legislation.gov.au/Series/C2004A03952>);
 - *Therapeutic Goods (Medical Device) Regulations 2002* (<http://www.legislation.gov.au/Series/F2002B00237/Compilations>); and
- Australian regulatory guidelines for medical devices (ARGMD) (<https://www.tga.gov.au/publication/australian-regulatory-guidelines-medical-devices-argmd>)

Background:

On 24 August 2015, TGA received the applications for inclusion of the Devices in ARTG, and on 4 September 2015, the TGA notified you that your applications were selected for audit.

On 17 September 2015, you provided the following information:

- Table of Contents;
- SJMA cover letter dated 15 September 2015;
- Risk Management Report;
- Australian Proclaim IPGs DoC;
- General Derails;
- Labelling;
- Instructions for Use; and
- Clinical Evaluation Report

On 27 June 2016, you were requested to provide further information under section 41JA.

On 13 July 2016, you provided the following information:

- Cover letter dated 12 July 2016;
- Table of attachments;

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On 13 July 2016, you also notified the TGA that 'the manufacturer has indicated a timeframe of approximately 6 months to include the MR symbol onto the labelling and within the IFU'.

The information provided, has been assessed and I have come to the view that further information is required in order for me to conclude whether the certifications made under section 41FD of the Act are correct.

1. Essential principles

Kinds of medical devices can be included in the ARTG, if amongst other things the device complies with relevant provisions of the essential principles (EP)².

Under subsections 41FD(d) and (e) of the Act, you as the applicant for inclusion of the Devices in the ARTG, certified that it complies with essential principles, and that you have available sufficient information to substantiate the compliance of the Devices with the essential principles or have procedures in place to ensure that this information can be obtained from the manufacturer within the period specified in the Regulations.

Essential principle 14-Clinical evidence

Essential principle 14 states that every medical device to be included in the ARTG requires clinical evidence, appropriate for the use and classification of the device, demonstrating that the device complies with the applicable provisions of the essential principles (EP).

In particular, the clinical evaluation procedures must be applied to the kind of device, for the purpose of demonstrating that the kind of device complies with the applicable provisions of: EP 1 (Use of medical devices not to compromise health and safety); EP 3 (Medical devices to be suitable for intended purpose); and EP 6 (Benefits of medical devices to outweigh any undesirable effects)³.

Clauses 8.4, 8.5 and 8.6 of Part 8 of Schedule 3 of the Regulations set out requirements for the clinical investigation data, literature review and evaluation of clinical data in relation to a kind of medical device.

The Devices are Proclaim 5 Elite IPG, Model 3660 and Proclaim 7 Elite IPG, Model 3662. On 17 September 2015, you provided the first submission of the clinical evidence. The submission was provided in the form of the Clinical Evaluation Report (CER). On 13 July 2016, you provided the second submission of the clinical evidence to address the deficiencies identified. The assessment of this information however, indicated that it did not demonstrate compliance of the Devices with the requirements of the essential principles. Specifically, the assessment has raised a number of issues, including those identified below.

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CV for s.22 to demonstrate suitability as clinical expert for this application has not been provided. Therefore a copy of the most up-to-date CV of s.22 must be provided.

² The essential principles set out the requirements relating to the safety and performance of medical devices. Section 41CA of the Act prescribes that these requirements are set out in the Regulations. Regulation 2.1 specifies that the essential principles are set out in Schedule 1 of the Regulations. There are six general principles and nine principles about design and construction (some principles may apply to devices on a case-by-case basis).

³ Regulation 3.11 – Medical devices to which the clinical evaluation procedures must be applied

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A detailed (de-identified) copy of the clinical assessment of your submission is provided in Attachment A for your information.

Based on the above, I have come to the view that the clinical evidence provided to the TGA is not sufficient to demonstrate compliance of the Devices (DV-2015-DA-14695-1 and DV-2015-DA-14698-1) with the essential principle 14 and/or conformance with part 8 of Schedule 3 of the Regulations.

Therefore, you need to provide further information to substantiate compliance of the Devices with the essential principles.

INFORMATION TO BE PROVIDED

You are requested therefore, to provide information listed below within the prescribed timeframe:

- Clinical Evidence presented in the form of a Clinical Evaluation Report (CER) that demonstrates compliance of the Device with the essential principle 14 and Part 8 of Schedule 3 of the Regulations, including/summarising the following:
 - s.47
 - CV for s.22 to demonstrate suitability as clinical expert for this application;
 -

IMPORTANT

Please ensure that all information that has been required is provided. The first response received by the TGA will be considered to be the complete and final response for this submission.

Please do not provide the same information that has already been submitted and evaluated in the previous submissions. It is advisable to be precise in sending the data specifically addressing the concerns identified in this Notice.

Failure to provide sufficient response may result in the Delegate making a decision not to include the device in the ARTG.

If you require further information please refer Section 3 of the Australian Regulatory Guidelines for Medical Devices (ARGMD)

([http:// www.tga.gov.au/sites/default/files/devices-argmd-01.pdf](http://www.tga.gov.au/sites/default/files/devices-argmd-01.pdf))

All text must be in English, pictures must be clearly labelled, and text and picture must be legible.

These documents should clearly articulate the manufacturer's intended purpose for the Device, and demonstrate compliance with the regulatory requirements, including compliance with the essential principles.

Timeframe for submitting this information

Regulation 5.2 prescribes that for the purpose of obtaining information that demonstrates that the matters certified under section 41FD were correct in relation to the compliance with the essential principles and application of conformity assessment procedures appropriate to the kind of medical device, the period of obtaining information is 20 working days.

Consistently with these requirements, I request that you provide your response to the address specified below by no later than 24 August 2016.

Lapsing or Rejection of the Application

If no reply is received in response to the Notice within a further 10 working days from the day specified in this notice, the application will lapse (section 41FK(c) of the Act).

Failure to provide sufficient response may also result in the Delegate making a decision not to include the device in the ARTG (refer section 41FI(3) of the Act).

You will also have a right of review of any decision not to include the Devices in the ARTG, however, lapsing of the applications is not 'an initial decision' within the meaning of section 60 of the Act.

If the application lapses or is rejected, you may submit another application at a later date, once all the information is available. Application fees and assessment fees will not be refunded once an application is lapsed or rejected.

Withdraw

You may withdraw your application at any time prior to a decision being made whether or not to include the devices in the ARTG. You should note, however, that the fee paid for the application is not refundable (<http://www.tga.gov.au/about/fees-refunds.htm>). If you wish to withdraw your application, you should advise the TGA of this request in writing, via e-mail: devices@tga.gov.au

How to present the submission

The requested information must be provided as a complete stand-alone submission. Cross-referencing to information submitted in support of previous applications that are already included in the ARTG, or still in process, may not be acceptable and may not be considered or reviewed.

All requested information must be provided in English. Where material is not originally in English a full translation must be submitted, the accuracy of which is the responsibility of the sponsor.

All text and pictures must be legible, and pictures must be clearly labelled.

If your submission is less than 15 pages, you may clearly state the Application ID and the applicant name in the subject line and email the information to: devices@tga.gov.au.

If your submission is longer than 15 pages, it should be sent to:

Devices Applications & Verification Section
Medical Devices Branch
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

The information should be provided in either of the following formats:

- a) An electronic copy (in the form of a CD or DVD containing all of the relevant material)
 - **[Preferred Method]**

Note: Responses that contain 15 pages or more of the data/information must **not** be sent to the TGA as email attachments. The submitted electronic information must be complete and clearly tabulated and titled.

OR:

- b) A single hard copy of the information (two-sided print is acceptable).
 - Standard A4 paper must be used for all information (where possible). The margin should be sufficiently large that information is not obscured through binding.

- The information must be supplied in loose-leaf binders. Plastic sleeves or stapled material should be avoided.
- The information must be sectioned for ease of reference, and a table of contents provided which details the content of the binder(s).

Review of the decision

Should you wish to seek a review of my decision to require you to provide information/documents about the Device, your rights of review are outlined in Attachment C to this letter.

Yours sincerely,

 (Signed electronically)

Delegate of the Secretary for the purposes of section 41JA of the Act
Medical Devices Branch
28 July 2016

Attachment A**Audit Assessment
Clinical Evaluation – 1st Round**

Does the submitted clinical data meet the requirements of Essential principle 14 of Schedule 1 and Part 8 of Schedule 3 of the <i>Therapeutic Goods (Medical Devices) Regulations 2002</i>?	NO
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The last round of clinical assessment concluded as follows:

Based on the information available to the TGA assessor at this time, from the documentation provided, the assertion made in the submission that the Proclaim 5 Elite IPG Model 3660 and the Proclaim 7 Elite IPG Model 3662 are substantially equivalent to the predicate Eon C IPG Model 3688 and the Genesis IPG Model 3608 is reasonable.

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Non-clinical Design Verification and Validation testing has also been presented at Section 6.1 of the CER, in which all acceptance criteria were met. While the Design Verification and Validation testing provides some reassurance about the performance of the subject Proclaim IPG devices in the non-clinical setting, the TGA assessor does not consider this testing to act in lieu of clinical data.

While the Literature Review is useful in providing broad context around the safety and performance of spinal cord stimulation systems in general, the TGA assessor does not consider clinical data which may be derived from non-predicate spinal cord stimulation devices as evidence of the safety of the subject Proclaim Elite IPG devices. If the applicant wishes to use clinical data from the predicate Eon C IPG Model 3688 and/or the Genesis IPG Model 3608 in lieu of clinical data for the subject devices, the literature review must clearly indicate which clinical studies pertain to the Eon and/or Genesis IPG devices.

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[REDACTED]

In light of the fact that both the Proclaim 5 Elite IPG Model 3660 and the Proclaim 7 Elite Model 3662 devices obtained the [REDACTED] post-market surveillance data for the subject devices, if available, would assist the TGA assessor in the evaluation of their safety.

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[REDACTED]

While MRI safety information has been clearly presented under the 'Warnings' heading of the Clinician's Manual, which states that patients with an implanted neurostimulation system should not be subjected to MRI (page 2, Clinicians Manual), the device labels provided in the submission do not include the MR Unsafe icon. This should be rectified by the applicant.

The Risk Management Report provided in the submission appears to relate to the Orion Neuro Hibrid IPG, rather than the subject Proclaim Elite IPG devices. As per Essential Principle 9.2, 'Minimisation of risks associated with use of medical devices', the submission must provide documentation that demonstrates the risks associated with the use of the subject Proclaim Elite IPG devices, and how these risks have been mitigated as far as possible.

A Risk Assessment Report specific to the subject devices must be provided so that the TGA assessor can be confident that the risk management process is based on clinical evidence.

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On balance, the applicant has not provided sufficient clinical evidence to demonstrate performance and safety of the device.

The applicant is requested to provide the following information.

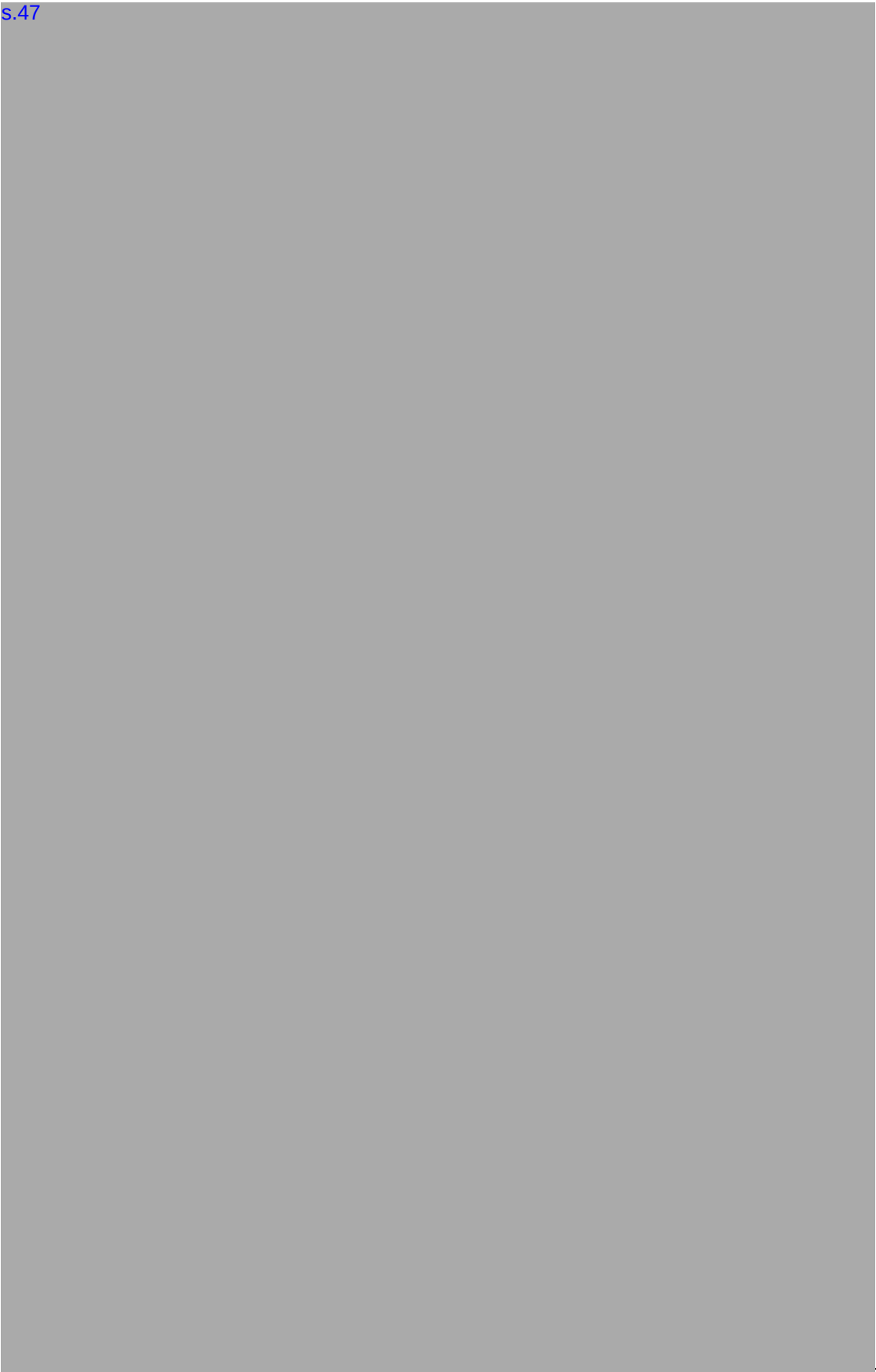
TGA Question 1

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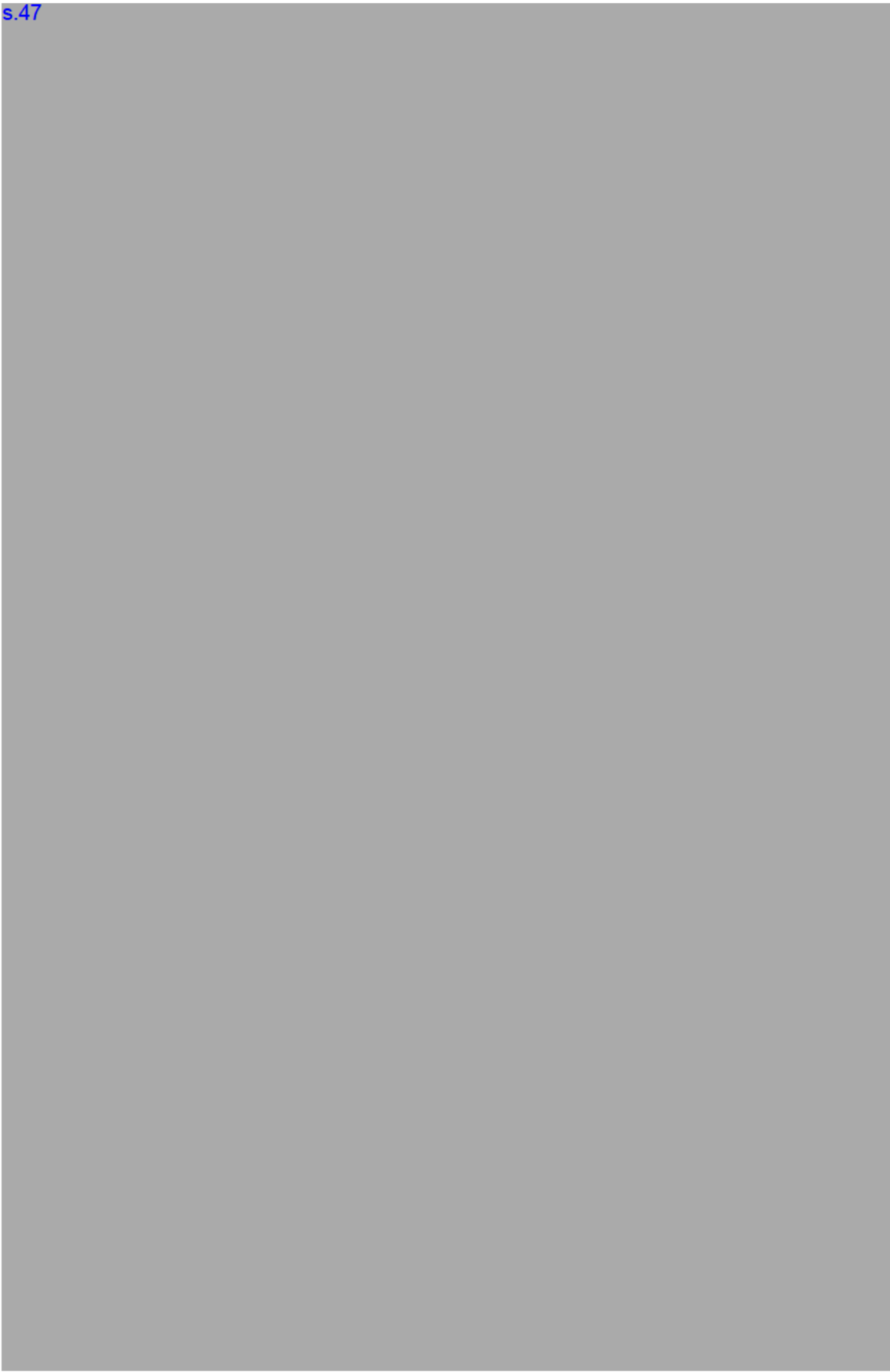
[REDACTED]

[REDACTED]

S.47



s.47



Applicant response

The applicant states that the [s.22](#) has directly examined the existent literature on this topic [s.47](#)

Assessor comments

The response is acceptable provided [s.22](#) can be demonstrated to be suitably qualified to be the clinical expert for this application. A CV will be requested from the applicant.

TGA Question 3

[s.47](#)

Applicant response

[s.47](#)

Assessor comments

The response is acceptable.

TGA Question 4

Inclusion of the MR unsafe icon on all device labelling;

Applicant response

It is stated that the current Proclaim IFU (Clinician's Manual) includes the following warning in regard to use in the MR environment:

Patients with an implanted neurostimulation system should not be subjected to MRI because the electromagnetic field generated by an MRI may damage the device electronics and induce voltage through the lead that could jolt or shock the patient.

The applicant states that the IFU will be updated to include the MR unsafe symbol and descriptive text in the symbol table as per ASTM F2503-13, although no date is given. However, the applicant expressed the opinion that since the *TGA Position on the Requirements for MRI Labelling* is currently under consultation, a reasonable transition period should be allowed for new labelling requirements to allow manufacturers to update product labelling in an orderly manner while still allowing the product to be supplied in the interim.

The clinical assessor was informed by the coordinating assessor that the applicant has indicated a timeframe of approximately 6 months to include the MR-unsafe icon onto the labelling and within the IFU.

Assessor comments

The response is acceptable.

TGA Question 5

A Risk Management Report specific to the Proclaim 5 Elite IPG Model 3660 and the Proclaim 7 Elite IPG Model 3662, including any relevant risk management standard operating procedures, any hazard analysis documents, FMECA documents. These documents should name and classify specific risks, detail how those risks have been mitigated, and how the risk management process is informed by clinical evidence.

Applicant response

The applicant provided the following risk management documents.

Risk Management Process Procedure

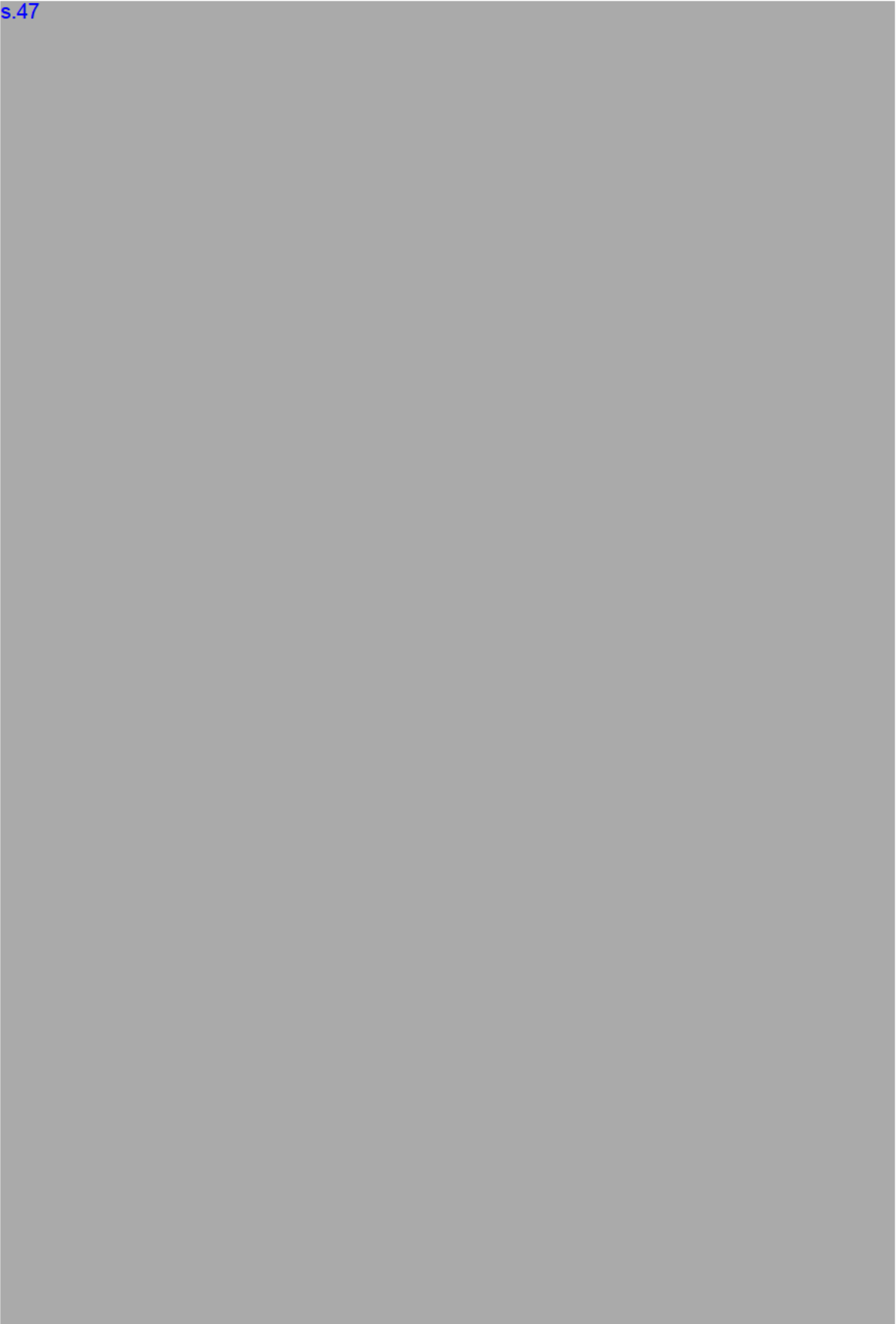
This competently presented document describes the risk management process as a standard operating procedure for medical devices produced by various stated facilities of the manufacturer, covering the entire product lifecycle. The document covers management responsibilities, definition of terms, associated documents (including ISO 14971, IEC 60601-1 and IEC 62304), personnel requirements, risk management file contents, risk management process flow chart, risk management process steps (including risk planning, risk analysis and risk control, completeness of risk control, overall risk acceptability, and overall risk/benefit evaluation), and production / post-production information.

Risk Management Report

This document covers the subject IPGs and several accessories including tunnelling tool, torque wrench, port plug, and pocket sizer, summarising the risk management activities conducted per the above SOP.

Hazards are rated as Acceptable, Acceptable* (risks reduced to ALARP after mitigation measures including design changes, additional protective measures in the device or in the manufacturing process, and/or providing additional information for safety), and Unacceptable. There were no unacceptable hazards identified for the subject devices. The risk analysis results are summarised as follows.

s.47



Design FMECA Orion IPG and accessories

There were 163 acceptable, 107 acceptable* and no unacceptable risks identified. Two of the acceptable* risks were originally unacceptable but categorised as acceptable* with risk benefit analysis. These pertain to the electrosurgery related risks addressed in the hazard analysis document with appropriate mitigation measures. All other risks identified are consistent with the findings of the literature review.

Software FMECA Orion IPG

It is stated that no unacceptable (after mitigations) software failure modes were identified, therefore no risk benefit analysis is needed. The Software FMECA risk table and the Software FMECA list of mitigations (Appendices A and B) are not included. (They are stated as "Excel Files" that have not been submitted.

eIFU AFMECA

It is stated that electronic Instructions for Use (eIFU) have a single internet location to provide access to the IFU for customer convenience. This risk assessment report describes the risks of not having physical indications for use in the sales packaging for all currently available neuromodulation models.

The assessor notes that this relates to the physical format of the Instructions for Use supplied with the subject devices and is outside the scope of this clinical assessment.

Assessor comments

The submitted risk management documents are acceptable and demonstrate adequate risk mitigation measures and acceptable residual risks for the safety and performance of the subject devices, provided the Software FMECA risk table and Software FMECA list of mitigations as described above are submitted and found satisfactory.

The clinical assessor defers to the delegate with regard to the acceptability of use of an electronic IFU for this device system [s.47](#).

Is additional clinical data required?	YES
---------------------------------------	-----

Specific Questions to be asked:

- Provide direct post-market surveillance data for the subject devices, including the complaint data analysis mentioned in the hazard analysis report (68-4167 Rev. G; page 4 under "Complaint Data Review") where a total of [s.47](#) were included.
- Provide a CV for [s.22](#) to demonstrate suitability as clinical expert for this application.
- [s.22](#)

Name & Dated Signature of Clinical Assessor:

Name:		Date:	
Signature:			

Attachment B**Clinical Evidence required to substantiate compliance of the kind of device with the essential principles, including requirements set out under Schedule 1 and Part 8 of Schedule 3 of the Therapeutic Goods (Medical Devices) Regulations 2002**

All medical devices supplied in Australia must comply with relevant legislative provisions. One of these is compliance with the essential principles. These are set out in Schedule 1 of the *Therapeutic Goods (Medical Devices) Regulations 2002* (the Regulations).

Clinical Evidence

Essential principle 14 of Schedule 1 of the Regulations states that each medical device requires appropriate clinical evidence.

Regulation 3.11 - stipulates that in addition to the conformity assessment procedures that are applied to a medical device, clinical evaluation procedures must also be applied to the device, for the purpose of demonstrating that the device complies with the applicable provisions of the essential principles, in particular:

- Principle 1 - Use of medical device not to compromise health and safety;
- Principle 3 - Medical devices to be suitable for intended purpose;
- Principle 6 - Benefits of the medical devices to outweigh undesirable effects.

Part 8 of Schedule 3 of the Regulations provides requirements for the clinical data that the manufacturer of a kind of medical device must obtain and evaluate in relation to the kind of device.

What you need to do

In order to demonstrate compliance with the abovementioned requirements, you need to provide the clinical data in the format specified below.

Refer the last two pages of this Attachment for further information about the requirements for clinical evidence.

Fill in the Clinical Evaluation Report (CER) Checklist and provide it as the first page for your clinical evidence submission.

CLINICAL EVALUATION REPORT (CER) CHECKLIST

[To be completed by the sponsor. It is a requirement that you check that all aspects of the CER are complete and correct prior to submission the clinical evidence to the TGA]

1. Specify the avenue(s) the manufacturer has selected to meet the requirements of Clause 14 (Clinical Evidence) of Schedule 1 and Part 8 (Clinical Evaluation Procedures) of Schedule 3 of the *Therapeutic Goods (Medical Devices) Regulations 2002*?

☐ Full Study Report(s) for the device or comparator(s)*

* Bear in mind a comparator MUST be clinically justified in the expert report.

☐ Literature review*

* A fully documented search strategy MUST be included in the expert report (i.e. databases searched, search terms used, inclusion and exclusion criteria to a level of detail that can be reproduced).

☐ Clinical Justification*

* Note that this avenue is only valid in some instances, i.e. a change of no clinical impact to a current device might be one instance.

If there are none of the above avenues used, the submission is incomplete and would not have adequate clinical data.

2. Has the manufacturer provided a clinical expert C.V. with the CER or sufficient documentation so that a judgement can be made about the “expert’s” status?

☐ Yes

If not, the submission is incomplete and may result in a delay in processing.

3. Does the nominated clinical expert have relevant clinical qualifications and experience with the use of the device under assessment in a clinical setting?

☐ Yes – the clinical expert has relevant qualifications and experience*

* A clinical expert should be clinically qualified and be able to comment upon the use of the device for its intended purpose. For example, an engineering degree is inadequate.

If not, the submission is incomplete.

4. Has the manufacturer submitted post market data within the CER for this device or its comparators (if relevant)?

☐ Yes

☐ No – If available, consider adding this information as it provides some extra data about real-world use of the device(s).

5. Does the submission have adequate indexing and pagination such that the totality of clinical evidence documentation can be readily identified and assessed? Please note that there should typically only be ONE CER encompassing the clinical evidence available for the device(s).

☐ Yes

☐ No*

*If not, difficulty with evaluation and requests for additional information may occur, delaying the finalisation of the submission.

Sponsor name:	
Title:	
Signature:	
Date:	

FURTHER INFORMATION

The Clinical Evaluation Report

- All clinical submissions MUST contain a Clinical Evaluation Report. This report MUST contain a summary presentation of all relevant clinical evidence for the device(s) under assessment, including clinical trial reports, published literature, post-market data and any clinical justification arguments. The author MUST provide a critique of those data and describe WHY those data support safety and performance for the specific device(s) when used as intended.
- All clinical data should typically be encompassed by ONE Clinical Evaluation Report. Multiple Clinical Evaluation Report documents would be a rarity and typically not an acceptable format for submission.
- The Clinical Evaluation Report MUST be authorised by a 'competent clinical expert'; in other words, an individual with clinical qualifications relevant to the device and its use, who also has experience in the use of the device in a clinical setting.
- The appropriateness of the clinical expert will clearly vary depending upon the nature of the device and the intended purpose(s).
- Full curriculum vitae for such an expert or other documentation to enable verification of their suitability is also a necessary component of the clinical evidence submission.

The Clinical Data

Clinical data can take many forms depending upon the device, its development programme, and whether it is a new or novel device, or simply another iteration of a previous model. Data may be provided in one of several forms, and can include full clinical trial reports, published and unpublished literature, clinical justifications and post-market data. The following describes these data types more fully:

Clinical Study Reports

- Full clinical study reports for the device(s) under assessment used in the indications claimed.

Clinical Study Reports for a Similar Device

- Full study reports similar device(s), with a reasoned clinical argument why the safety and performance of that device may be taken to support the device under assessment [paying particular note to the intended purpose(s)]. Full study reports refers to complete study reports will all related documentation, not publications or journal articles. It is acknowledged that full study reports may only be summarised in the CER.

Documented Literature Search

- A documented literature search with a review of the publications retrieved. Such a review would discuss and critique the use of these devices in the publications, and why they support safety and performance for the device(s) under assessment. Particular attention should be paid to the intended purposes for the device(s) under assessment and those of the devices revealed by the literature search.

The following shall be taken into account:

- The documented search strategy should include information such as the databases searched, search terms used and any inclusion and exclusion criteria applied, in sufficient detail to enable the search to be reproduced if desired. This is necessary to enable an assessment of whether or not the review adequately searched current available published literature about the device(s) under assessment.
- A critical discussion of the literature revealed by the search strategy must be undertaken with particular emphasis on how the publications demonstrate safety and performance of the device under assessment for the indications claimed (i.e. in terms of similarity, predicates, the actual device, etc.).
- If there are no actual clinical data for the specific device, depending upon the nature of it and the reasons for submission, it may be possible to provide a full clinical justification for why clinical evidence is not required.

- Typically, a justification may reference the clinical safety and performance data of a 'predicate' or similar marketed device and critically examine each change or difference in terms of materials, design, clinical use, and their likely impact on safety and performance.
- A justification may also take the form of a minor change to a currently approved device, where the change is considered too minor to have any clinical impact, and this is justified by the clinical expert.
- If it can be established via justification that changes do not pose any clinical impact on safety and performance, a clinical justification can, in some circumstances, suffice for clinical evidence.
- Post-market data can be a valuable addition to the clinical evidence in a submission. These data should typically at least provide world-wide distribution numbers of the relevant device(s) since launch, as well as complaints and adverse events reported to the manufacturer. Complaint and adverse event rates should be given, and where the clinical expert deems it relevant, MDRs and other adverse event and complaint data should be discussed and critiqued to enable an understanding of the safety profile of the relevant device(s) in a 'real-world' setting.

Format

The documentation must be presented in a particular format. The following principles apply:

- Submissions must be appropriately paginated and indexed so that the totality of information can be seen, as well as each part of it easily identified.
- If the sponsor chooses to provide the submission electronically, this must be provided on a CD, separate from all other submitted information.
- The form of the electronic submission MUST enable easy referencing and provide a clear indication of the extent of the clinical documentation submitted. i.e. a cover letter with a clear list and location of all clinical documents, or an index as part of a PDF as two examples.

Attachment C**Request for reconsideration of an initial decision**

This decision is a reviewable initial decision under section 60 of the Act. Under section 60, a person whose interests are affected by a 'reviewable' initial decision, can seek reconsideration of the initial decision.

As this document constitutes written notice of the making of an initial decision being given by the Secretary, a request for reconsideration of this initial decision must be given to the Minister within 90 days and be accompanied by any information that you wish to have considered. A request for reconsideration given to the Minister outside the statutory 90 day reconsideration period cannot be accepted.

The Minister may either personally undertake a request for reconsideration of an initial decision or delegate to an officer of the Department with the appropriate delegation.

Under section 60(3A) of the Act, the Minister (or the Minister's delegate) is not able to consider any information provided after the notification is made of a request for reconsideration of an initial decision unless the information is provided in response to a request from the Minister (or the Minister's delegate), or it is information that indicates that the quality, safety or efficacy of the relevant therapeutic goods is unacceptable.

Guidelines for requesting reconsideration of an initial decision

A request for reconsideration should be made in writing, signed and dated by the person requesting reconsideration, should be titled "**Request for Reconsideration Under Section 60 of the Therapeutic Goods Act 1989**" and should include the following:

- a copy of the initial decision notification letter (or other evidence of notification);
- identify, and describe with as much specificity as possible, which component(s) of the initial decision should be reconsidered and set out the reasons why reconsideration is requested;
- any information/documentation in support of the request, clearly labelled to correspond with (any or each of) the reasons why reconsideration is requested; and
- an email address nominated for the purposes of receiving correspondence in relation to the request for reconsideration.

All requests for reconsideration should be given to the Minister by email:

Email: **'minister.ley@health.gov.au'** and **'decision.review@tga.gov.au'**

Where a request for reconsideration includes dossiers (or similar bulk material) that cannot easily be attached to the request given by email, the supporting documentation and original (signed) request for reconsideration can then be sent by express post or registered mail to:

Mail: **Minister for Health
Suite M1 41
c/- Parliament House
CANBERRA ACT 2600**

Subject to the *Administrative Appeals Tribunal Act 1975* (AAT Act), if you are dissatisfied with the decision upon reconsideration by the Minister (or the Minister's delegate), you can apply to the Administrative Appeals Tribunal (AAT) for a review of that decision upon reconsideration.

NOTE: This initial decision remains in effect unless and until it is revoked or revoked and substituted by the Minister (or the Minister's delegate) as a result of a request for reconsideration under section 60 of the Act OR is set aside, varied or remitted by the AAT or is otherwise overturned or stayed.



Australian Government

Department of Health

Therapeutic Goods Administration

Application Audit - Level 2 Clinical Assessment – 3rd Round

TRIM Reference: R16/588595

To be completed by DAVS Assessor:

Device UPI:	Proclaim 5 Elite IPG, Model 3660, Proclaim 7 Elite IPG, Model 3662
Sponsor:	St Jude Medical Australia Pty Ltd
Manufacturer:	St Jude Medical (United States Of America)
Application ID:	DV-2015-DA-14695-1, DV-2015-DA-14698-1
Submission ID:	DA-2015-06754-1
DAVS Assessor:	s.22
Application TRIM	2015/026929 DATA R15/728632 1 st round clinical assessment report: R15/746510 Sponsors response to 1 st round (data): R16/529842 2 nd round clinical assessment report (R16/566200) Sponsor's response to round 2 clinical assessment: <u>R16/588560</u> (email attachments)
Sponsor's submission TRIM Ref.:	Sponsor's response to round 2 clinical assessment: <u>R16/588560</u> (<u>email attachments</u>)
Date submitted to TGA:	5/08/2016
Date Referred to Clinical Section:	5/08/2016
Screening for clinical data:	<u>Has screening been completed?</u> Yes ☐ No ☐ If <u>'YES'</u>: Click here to enter a date. <u>Name of the assessor:</u> Did the screening identify any issues? Yes ☐ No ☐ If <u>'YES'</u>: TRIM reference for Screening Report: R16/xxxxx Note: if no issues have been identified, there is no need for a screening report
Clinical Round:	<u>3</u> 1 st round clinical assessment report: R15/746510 2 nd round clinical assessment report (R16/566200)

To be completed by Clinical Assessor:

Does the submitted clinical data meet the requirements of essential principle 14 of Schedule 1 and Part 8 of Schedule 3 of the <i>Therapeutic Goods (Medical Devices) Regulations 2002</i>?	☐ YES / ☒ NO
--	---

Background

This is the 3rd Round Clinical Assessment for the Proclaim 5 Elite IPG (model 3660) and the Proclaim 7 Elite IPG (model 3662). This assessment will focus solely on whether the recommendations outlined in 2nd Round Clinical Assessment (see bolded text below) have been adequately addressed by the applicant.

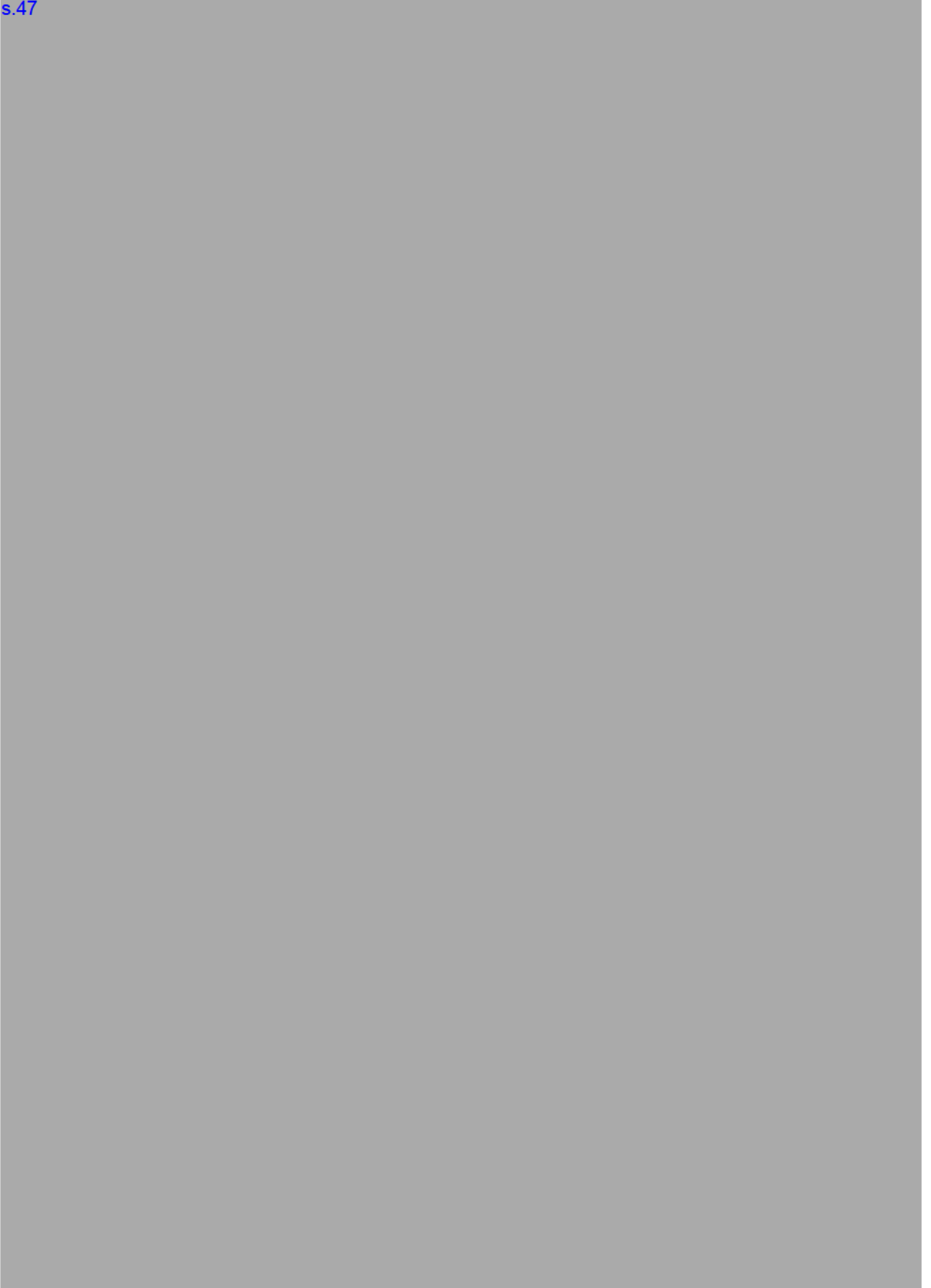
- 1. Provide direct post-market surveillance data for the subject devices, including the complaint data analysis mentioned in the hazard analysis report (68-4167 Rev. G; page 4 under “Complaint Data Review”) where a total of s.47 fielded units [REDACTED] were included.**

As per the applicant’s response letter dated 04 August 2016, the applicant confirmed that the two Proclaim IPG models subject to this assessment, namely 3660 and 3662 have been commercially marketing in the European Union s.47 [REDACTED]. The cover letter contained the following table which outlined the number of devices supplied (but not necessarily used) per geographical distribution. It should be noted that the sales are not reported separately for the two models subject to this assessment.

s.47



s.47



s.47

2. Provide a CV for [s.22](#) to demonstrate suitability as clinical expert for this application.

A CV was submitted as part of the applicant's response documentation. The CV for [s.22](#) demonstrated that [s.22](#) has formal qualifications in anaesthesiology and pain medicine/management. [s.22](#) is considered to be an appropriately qualified clinical expert.

s.47

Conclusions

The information provided in response to the second and third recommendations appear reasonable at this time. Information pertaining to the first recommendation however requires additional information.

Recommendations

s.47



Name, date and signature of Clinical Assessor:

Name:	s.22	Date:	09/08/2016
Signature:			

From: s.22
To: "
Subject: s41JA Request for Additional Information - DA-2015-06754-1 - Proclaim 5 and 7 Elite IPGs Models 3660 and 3662 - St Jude Medical Australia Pty Ltd [SEC=UNCLASSIFIED]
Date: Tuesday, 9 August 2016 4:21:56 PM
Attachments: [Request for reconsideration of an initial decision.pdf](#)

Hi s.22,

As a delegate of the Secretary of the Department of Health (the Secretary) for the purposes of section 41JA of the *Therapeutic Goods Act 1989* (the Act), I have made a decision to request information in relation to applications DV-2015-DA-14698-1 and DV-2015-DA-14695-1 for the inclusion of the kind of medical device: *Proclaim 5 and 7 Elite IPGs Models 3660 and 3662* in the Australian Register of Therapeutic Goods (ARTG).

Information is requested by no later than close of Business 6 September 2016.

The clinical assessment has been completed on the data provided on 5th August 2016 and the clinical assessor has raised the following questions:

s.47



Information required:

- 1) Amended clinical evidence report (CER) or an addendum to the CER that addresses the 3 questions listed above.
- 2) Signed and endorsed copy of the CER or the addendum to the CER by a relevant clinical expert that addresses the 3 questions listed above.

Based on the above, I have come to the view that the clinical evidence provided to the TGA is not sufficient to demonstrate compliance of the Devices (*Proclaim 5 and 7 Elite IPGs Models 3660 and 3662*) with the essential principle 14 for the purposes of demonstrating that the Devices complies/comply with the essential principle 1 (identification of benefits and risks associated with the use of the Devices), essential principle 3 (use of the Devices for its intended purposes), and essential principle 6 (acceptability of any side effects associated with the use of the Devices); and/or conformance with part 8 of Schedule 3 of the Regulations.

Therefore, you need to provide further information to substantiate compliance of the Devices with the essential principles.

The information should be provided in either of the following formats:

- a) An electronic copy (in the form of a CD or DVD containing all of the relevant material) – **[Preferred Method]**

Note: Responses that contain 15 pages or more of the data/information must **not** be sent

to the TGA as email attachments. The submitted electronic information must be complete and clearly tabulated and titled.

OR:

- b) A single hard copy of the information (two-sided print is acceptable).
 - Standard A4 paper must be used for all information (where possible). The margin should be sufficiently large that information is not obscured through binding.
 - The information must be supplied in loose-leaf binders. Plastic sleeves or stapled material should be avoided.
 - The information must be sectioned for ease of reference, and a table of contents provided which details the content of the binder(s).

Review of the decision

Should you wish to seek a review of my decision to require you to provide information/documents about the Device, your rights of review are outlined in [Attachment](#) to this email.

Best regards,

[s.22](#)

Devices Applications and Verification Section

Medical Devices Branch

Therapeutic Goods Administration

devices@tga.gov.au



Australian Government
Department of Health
 Therapeutic Goods Administration

Request for reconsideration of an initial decision

This decision is a reviewable initial decision under section 60 of the Act. Under section 60, a person whose interests are affected by a 'reviewable' initial decision, can seek reconsideration of the initial decision.

As this document constitutes written notice of the making of an initial decision being given by the Secretary, a request for reconsideration of this initial decision must be given to the Minister within 90 days and be accompanied by any information that you wish to have considered. A request for reconsideration given to the Minister outside the statutory 90 day reconsideration period cannot be accepted.

The Minister may either personally undertake a request for reconsideration of an initial decision or delegate to an officer of the Department with the appropriate delegation.

Under section 60(3A) of the Act, the Minister (or the Minister's delegate) is not able to consider any information provided after the notification is made of a request for reconsideration of an initial decision unless the information is provided in response to a request from the Minister (or the Minister's delegate), or it is information that indicates that the quality, safety or efficacy of the relevant therapeutic goods is unacceptable.

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- a copy of the initial decision notification letter (or other evidence of notification);
- identify, and describe with as much specificity as possible, which component(s) of the initial decision should be reconsidered and set out the reasons why reconsideration is requested;
- any information/documentation in support of the request, clearly labelled to correspond with (any or each of) the reasons why reconsideration is requested; and
- an email address nominated for the purposes of receiving correspondence in relation to the request for reconsideration.

All requests for reconsideration should be given to the Minister by email:

Email: **'minister.ley@health.gov.au'** and **'decision.review@tga.gov.au'**

Where a request for reconsideration includes dossiers (or similar bulk material) that cannot easily be attached to the request given by email, the supporting documentation and original (signed) request for reconsideration can then be sent by express post or registered mail to:

Mail: **Minister for Health**
Suite M1 41
c/- Parliament House
CANBERRA ACT 2600

Subject to the *Administrative Appeals Tribunal Act 1975* (AAT Act), if you are dissatisfied with the decision upon reconsideration by the Minister (or the Minister's delegate), you can apply to the Administrative Appeals Tribunal (AAT) for a review of that decision upon reconsideration.

NOTE: This initial decision remains in effect unless and until it is revoked or revoked and substituted by the Minister (or the Minister's delegate) as a result of a request for reconsideration under section 60 of the Act OR is set aside, varied or remitted by the AAT or is otherwise overturned or stayed.



Australian Government

Department of Health

Therapeutic Goods Administration

Application Audit - Level 2 Clinical Assessment – 4th Round

TRIM Reference: R16/601745

To be completed by DAVS Assessor:

Device UPI :	Proclaim 5 Elite IPG, Model 3660, Proclaim 7 Elite IPG, Model 3662
Sponsor:	St Jude Medical Australia Pty Ltd
Manufacturer:	St Jude Medical (United States Of America)
Application ID:	DV-2015-DA-14695-1, DV-2015-DA-14698-1
Submission ID:	DA-2015-06754-1
DAVS Assessor:	s.22
Application TRIM	2015/026929 DATA R15/728632 1 st round clinical assessment report: R15/746510 Sponsors response to 1 st round (data): R16/529842 2 nd round clinical assessment report (R16/566200) Sponsor's response to round 2 clinical assessment: R16/588560 (email attachments) 3 rd Round clinical assessment report (R16/588595) Sponsor's response to round 3 clinical assessment: <u>R16/601674</u> (email attachments)
Sponsor's submission TRIM Ref.:	Sponsor's response to round 3: <u>R16/601674</u> (email attachments)
Date submitted to TGA:	10/08/2016
Date Referred to Clinical Section:	10/08/2016
Screening for clinical data:	<u>Has screening been completed?</u> Yes ☐ No ☐ If 'YES': Click here to enter a date. <u>Name of the assessor:</u> Did the screening identify any issues? Yes ☐ No ☐ If 'YES': TRIM reference for Screening Report: R16/xxxxx <i>Note: if no issues have been identified, there is no need for a screening report</i>
Clinical Round:	4 1 st round clinical assessment report: R15/746510 2 nd round clinical assessment report (R16/566200) 3 rd round clinical assessment report (R16/588595)

To be completed by Clinical Assessor:

Does the submitted clinical data meet the requirements of essential principle 14 of Schedule 1 and Part 8 of Schedule 3 of the *Therapeutic Goods (Medical Devices) Regulations 2002*?

☒ YES / ☐ NO

Background

This is the 4th Round Clinical Assessment for the Proclaim 5 Elite IPG (model 3660) and the Proclaim 7 Elite IPG (model 3662). The 3rd Round Clinical Assessment requested the provision of additional information pertaining to the death/s reported in the applicant's previous response letter (see bolded text below).

s.47

s.47

Conclusions

s.47

Is additional clinical data required?

NO

s.47 there are no further questions from the clinical assessor at this time.

Note for the post-market team: as part of the mandatory annual reporting process, please consider specifically reviewing the complaint rates s.47 (as outlined in the 3rd and 4th Round Clinical Assessments).

Name, date and signature of Clinical Assessor:

Name:	s.22	Date:	10/08/2016
Signature:			



Australian Government
Department of Health
Therapeutic Goods Administration

TGA use only

This form is classified 'For official use only'.

For guidance on how to treat information : see <<http://www.tga.gov.au/about/tga-information-to.htm>>.

Application Audit Checklist (Level 2)

Submission ID:	DA-2015-06754-1
Application ID:	DV-2015-DA-14695-1
TRIM Reference:	2015/026929

Sponsor Name:	St Jude Medical Australia Pty Ltd
Manufacturer Name:	St Jude Medical (United States Of America)[40287]
UPI/Sponsor's reference:	Proclaim 5 Elite IPG, Model 3660
Classification:	Class AIMD
GMDN Term & Code:	Stimulator, electrical, analgesic, spinal cord[36007]

OUTCOME OF THE ASSESSMENT/RECOMMENDATION: INCLUDE KIND OF DEVICE IN ARTG

Instruction: Please complete **each** checklist question by clicking on the appropriate checkbox. Please **provide all relevant information**, including images (snapshot/snipping tool), references to the documents provided and page numbers and/or subtitles in the document to explain/support each point.

Description of the kind of device (please include images and references to the relevant documents if required):

This neurostimulation system is designed to deliver low-intensity electrical impulses to nerve structures. This implantable pulse generator (IPG) is an electronic device designed to be connected to one or more extensions or leads with up to 16 electrodes total. It is powered by a hermetically sealed battery within a titanium case and uses microelectronic circuitry to generate constant-current electrical stimulation. The IPG can deliver stimulation with a single program or with multiple programs. Each program can provide stimulation to a single anatomical area or to multiple areas. The IPG communicates wirelessly with system programmers and controllers, and IPGs are available in small and large sizes to accommodate different power needs. The IPG is available in two sizes: model # 3660 (small) and model # 3662 (large) to accommodate for different power requirements (R15/728632). This application covers **Proclaim 5 Elite IPG, Model 3660**.

Application ID: DV-2015-DA-14698-1 covers the device Proclaim 7 Elite IPG, Model 3662.



Functional description: The IPG is designed to be connected to one or more extensions or leads with up to 16 electrodes total. It is powered by a hermetically sealed battery within a titanium case and uses microelectronic circuitry to generate constant-current electrical stimulation. The IPG can deliver stimulation with a single program or with multiple programs to a single anatomical area or to multiple

PO Box 100 Woden ACT 2606 ABN 40 939 406 804

Phone: 1800 020 653 Fax: 02 6203 1605 Email: info@tga.gov.au <http://www.tga.gov.au>

Reference/Publication #

areas. The IPG communicates wirelessly with system programmers & controllers. Can be substantiated from provided information (R15/728632) – Acceptable.

GENERAL INFORMATION	
Application was selected for audit	☒ YES ☐ NO If 'YES': ☒ s.41FH(1)(a) ☐ s.41FH(1)(b)
Date of s.41FH selection notice	04.09.2015 (TRIM: R15/699244)

Part 1 –Application

Information provided in the application - Manufacturer's Evidence	
1.1 Manufacturer's Evidence ID:	DV-2015-MC-11365-1
Certificate issued by (Notified body/MRA/TGA Conformity Assessment Certificates)	Notified body
s.47 	

Information provided in and with the application	Yes	No	NA ¹
1.2 Is application effective?	☒	☐	
Is application made in accordance with subsection 41FC(1) of the TG Act (i.e. in	☒	☐	

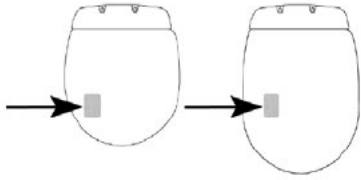
¹ NA means – 'Not applicable' and/or 'Not enough information to be assessed'

Information provided in and with the application		Yes	No	NA ¹													
accordance with the form and manner approved)?																	
Is this medical device one of the kind specified under MD Regulation 4.1 made for the purposes of section 41EA that requires the manufacturer to have a TGA conformity assessment certificate before an application for inclusion of that device in ARTG can be made, and no such certificate is in force?		☐	☒														
Does the application contain information that is false or misleading in a material particular (e.g. fraud certificate)?		☐	☒														
1.3	Was application made for a kind of device?	☒	☐														
Is the device nomenclature system codes (GMDN) the relevant preferred term/collective term for the devices of the kind (Regulation 1.7)? - Stimulator, electrical, analgesic, spinal cord[36007] consistent with the DoC (R15/728632) and intended purpose		☒	☐														
For Class III, AIMD and Class 4IVD, does the unique product identifier (UPI) stated in the application accurately identify the devices of the kind? - Consistent with the DE Certificate (R15/684062), DoC (R15/728632) and product information (R15/728632)		☒	☐														
For Class III, AIMD and Class 4IVD, are the variants stated in the application correct according to the information provided? - Nil variant (as 1 device) <table border="1" data-bbox="252 1122 1147 1256"> <thead> <tr> <th colspan="3">Variant List</th> </tr> <tr> <th>#</th> <th>Variant type</th> <th>Variant range</th> </tr> </thead> <tbody> <tr> <td>1.</td> <td>Nil variant (as 1 device)</td> <td>3660</td> </tr> </tbody> </table> <table border="1" data-bbox="252 1294 1098 1357"> <thead> <tr> <th>Product Description</th> <th>Model Number</th> </tr> </thead> <tbody> <tr> <td>Proclaim™ 5 Elite Implantable Pulse Generator</td> <td>3660</td> </tr> </tbody> </table>		Variant List			#	Variant type	Variant range	1.	Nil variant (as 1 device)	3660	Product Description	Model Number	Proclaim™ 5 Elite Implantable Pulse Generator	3660	☒	☐	
Variant List																	
#	Variant type	Variant range															
1.	Nil variant (as 1 device)	3660															
Product Description	Model Number																
Proclaim™ 5 Elite Implantable Pulse Generator	3660																
1.4	Was <u>any other</u> information provided <u>with the application</u> ?	☒	☐	☐													
Certificate (e.g. Design-Examination Certificate or Type Examination Certificate Certificates appropriate for Class III/AIMD device)		☒	☐														
Declaration of Conformity - R15/728632		☒	☐														
Labelling for the medical device - R15/728632		☒	☐														
Instructions for use (IFU) - R15/728632		☒	☐														
Any other information (e.g. data from the National Joint Replacement Registry)		☐	☒														
1.5	Is there any other information/device characteristics that need to be considered in the application (e.g. the device is a procedure pack/sterile/active, etc)? Sterile, invasive, single-use, active	☒	☐	☐													

Information provided in and with the application		Yes	No	NA ¹
1.6	Are there any known concerns about the device (specifically or in general, e.g. vaginal mesh)	☐	☒	☐

Part 2 –Audit Assessment

Are certifications made under section 41FD of the <i>Therapeutic Goods Act 1989</i> correct in relation to the kind of device?		Yes	No	NA
2.1	Paragraph 41FD(a) – Is product in the application a medical device according to section 41BD of the Act?	☒	☐	
2.2	Paragraph 41FD(b) – Are devices of the kind intended to be used for a purpose as ascertained under subsection 41BD(2)? – Is the intended purpose stated in the application correct according to the information provided with the device? <i>intended purpose</i> means the purpose for which the manufacturer of the device intends it to be used, as ascertained from the information provided with the device, including on or in any one or more of the following: labelling; the instructions for use of the device; any advertising material relating to the device; and technical documentation describing mechanism of action of the device. – Confirmed based on the IFU (R15/728632)	☒	☐	
2.3	Paragraph 41FD(c) – Is the kind of device correctly classified according to the medical device classifications (medical devices are classified based on its intended purpose, refer Division 3.1 and Schedule 2 or Schedule 2A for IVD of MD Regulations)? – Rule 5.7(1): An active implantable medical device is classified as Class AIMD	☒	☐	
2.4	Paragraphs 41FD(d) and (e) – Essential Principles (Schedule 1 of the MD Regulations) • Paragraphs 41FD(d) – Are devices of the kind comply with the essential principles? • Paragraphs 41FD(e) – Does the applicant have available sufficient information to substantiate compliance or have procedures in place, including a written agreement with the manufacturer, to ensure that information can be obtained within the period specified in the regulations?	☒	☐	☐
	• Essential Principle 13 – Manufacturer's name and address – consistent with the EC Certificate – Sterilization method used is EO – consistent with IFU (page 5/80, R15/728632)	☒	☐	☐

Are certifications made under section 41FD of the <i>Therapeutic Goods Act 1989</i> correct in relation to the kind of device?	Yes	No	NA
• <u>Regulation 10.2</u> s.47 	☒	☐	☐
• <u>Essential Principle 14 (and conformance with Part 8 of Schedule 3)</u> - 1st round clinical assessment report (R15/746510): NO - 2nd round clinical assessment report (R16/566200): NO - Sponsor stated that 'The manufacturer has indicated a timeframe of approximately 6 months to include the MR symbol onto the labelling and within the IFU' (R16/530046) which is considered acceptable by the clinical assessor - 3rd round clinical assessment report (R16/588595): No - 4th round clinical assessment (R16/601745): Yes - Conclusion: the submitted clinical data meet the requirements of essential principle 14 of Schedule 1 and Part 8 of Schedule 3 of the Therapeutic Goods (Medical Devices) Regulations 2002	☒	☐	☐
• <u>Essential Principles – Part 1 of Schedule 1 - a risk management report</u> - R15/728632 and R16/529842	☒	☐	☐
• <u>Essential Principle – other</u> - Requirement under EP 12.13 (Active implantable medical devices) has been met (Section 3.1, page: 7/80, Trim reference: R15/728632). The code is able to be read without a need for a surgery. Identifying the IPG Before implanting the IPG, you can view the model number engraved on the IPG. After implantation, you can identify the IPG using a radiopaque identification tag that you can view with standard X-ray procedures. The tag, which is located in the lower left corner of the IPG when the logo side of the IPG is facing toward you, contains a code in the following format: SJM/L/V. SJM designates St. Jude Medical as the manufacturer; L/V is a letter and a number combination that identifies the model family (see the following figure). For the Proclaim™ IPG, the code is SJM A1. To determine the exact model IPG that is implanted, use the clinician programmer app to communicate with the IPG and view IPG information. See the clinician's manual for the clinician programmer for instructions. Figure 1. Location of the IPG code on a small IPG (left) and large IPG (right) 	☒	☐	☐

Are certifications made under section 41FD of the <i>Therapeutic Goods Act 1989</i> correct in relation to the kind of device?		Yes	No	NA
• Paragraphs 41FD(f) and (g) – conformity assessment procedures • Paragraphs 41FD(f) – Has the appropriate conformity assessment procedure been applied to the kind of device? • Paragraphs 41FD(e) – Does the applicant have available sufficient information to substantiate the application of the conformity assessment procedures or have procedures in place, including a written agreement with the manufacturer of the kind of device, to ensure that information can be obtained from the manufacturer within the period specified in the regulations?	s.47	☒	☐	☐
• Is the device in the application a medical device used for a special purpose (according to Regulation 3.10) (e.g. procedure pack)?		☐	☒	
• Provide information about conformity assessment procedure that has been applied to the kind of device - See comments above under section 1.1 & 1.4.				
• Does the procedure meet the minimum requirements that must be applied to the device of this classification according to Division 3.2 (if the kind of device in the application is not a device to be used for a special purpose, refer MD Regulations 3.6 – 3.9B and Schedule 3 of the MD Regulations; for the device used for a special purpose – refer Part 7 of Schedule 3 of the MD Regulations).		☒	☐	
• Has declaration of conformity (DoC) been made in accordance with Schedule 3 of MD Regulations? - DoC (Trim: R15/728632) - DoC is made in accordance with Clause 1.8 of Schedule 3 of the Regulations. TRIM Reference: R15/728632. UPI, manufacturer's name and address, CAPs, etc. are consistent with the information provided. - Signed by s.22 authorised by the manufacturer (Dated 14.09.2015) - Includes a list of standards and products.		☒	☐	☐
2.5 Paragraphs 41FD(h) – Does the submitted information demonstrate compliance with the applicable provisions of the Therapeutic Goods Advertising Code and other requirements (if any) relating to advertising? <i>Note: if advertising is only aimed at health professionals these requirements are not applicable.</i>		☐	☐	☒
2.6 Paragraphs 41FD(i) – Do devices of the kind contain substances that are prohibited imports under the Customs Act 1901?		☐	☒	☐
2.7 Paragraphs 41FD(ia) – FOR IVD only - Are devices of that kind intended to be used exclusively for one or more of the purposes specified under section 41BEA?		☐	☐	☒
2.8 Paragraphs 41FD(j) – Is the information included in and with the application complete and correct?		☒	☐	

Part 3 –Audit Assessment

Is there anything else relevant to the assessment of the application?		Yes	No	NA
2.9	Has all information been provided?	☒	☐	

Is there anything else relevant to the assessment of the application?	Yes	No	NA
2.10 Are there any other information/concerns that need to be considered/assessed?	☐	☒	☐

Additional comments (if required)

Assessor's name:	s.22	Position number:	Contractor/ NA
Signature	Signed electronically	Date	10.08.2016

Delegate's checklist	
Do you have delegation for the purposes of section 41FI of the Act (~~or under section 41FF if application is finalised without the audit~~)?	☒ Yes ☐ No
Have you checked that all requirements set out under section 41FI (~~or section 41FF if application is finalised without the audit~~) have been considered and met in making this decision?	☒ Yes ☐ No
Specify other if required:	☐ Yes ☒ No
Other: section 41FL and subsection 41FJ(a)	☒ Yes ☐ No

Delegate's decision	
REQUIRE FURTHER INFORMATION under section 41JA of the Act	☐ Yes ☒ No
INCLUDE KIND OF DEVICE IN ARTG	☒ Yes ☐ No
IMPOSE CONDITIONS under section 41FO of the Act	☐ Yes ☒ No
Other: section 41FL and subsection 41FJ(a)	☒ Yes ☐ No

Comments (if required)

Audit has been conducted in relation to the following matters:

- (a) whether the application is in accordance with Subdivision A; and
- (b) whether matters as to which the applicant has certified under section 41FD are correct.

Following consideration of the information provided, I am satisfied to all aspects considered during the audit.

Therefore, as a delegate of the Secretary of the Department of Health for the purposes of subsection 41FI(2) of the *Therapeutic Goods Act 1989* I have made a decision to include the kind of devices in the ARTG.

Also as a delegate for the purposes of section 41FL and subsection 41FJ(a), I decided to assign a unique device number to the kind of device in the ARTG and notify the applicant in writing of my decision (email will be sent by TBS).

Delegate's name:	s.22	Position number:	s.22
Signature	Signed electronically	Date	10 August 2016



Please make sure you have provided Alt text on all form fields, including the check boxes:

Right click→Properties→Add Help Text...