Australian Government

Department of Health
Therapeutic Goods Administration

Application Audit – Level 2 (compulsory)
Initial Clinical Assessment (Triage) report

TRIM Reference: D17-772783

Application ID(s):	1. DV-2017-DA-12695-1 s.22
Submission ID:	1. & 2. DA-2017-05038-1 s.22
Applicant's submission:	Note: The Five (5) applications are supported by the same CER: Intellis Neurostimulation System Clinical Evaluation Report, Version 4.0, dated 10 August 2017, Reference: NDHF 1463-132221. Version. 4.0 Intellis Neurostimulation System Clinical Evaluation Report NDHF 1463-132221 1. Introduction This report documents the results of the clinical evaluation for Medtronic's new Intellis™ rechargeable neurostimulation system, hereafter referred to as the Intellis system, in accordance with guidelines provided by MEDDEV 2.7.1 Rev 3. The Intellis neurostimulators are based upon the market-released Restore family of implantable neurostimulators (INS), particularly the commercially available Model 97714 RestoreSensor SureScan MRI neurostimulator which is the predicate device for the Intellis INS. The following neurostimulators and components are considered within this review: • Model 97715 Intellis Implantable Neurostimulator with AdaptiveStim Technology s.22 • Model 97725 Wireless External Neurostimulator (ENS) Therefore, clinical screening for the 5 applications has been grouped. Complete Data Submissions: 1. & 2. DA-2017-05038-1 = D17-769000 s.22 CER – D17-769000, page 211/479 Clinical expert CV (Profs.22) - D17-769000, page 458/479

	Endorsement by clinical expert - D17-795914 Risk Management Reports: 1. & 2. DA-2017-05038-1 = D17-769000, page 197/479 s.22 [redacted] Device Labels: 1. DA-2017-05038-1 = D17-769000, page 24/479 s.22 [redacted] IFUs: 1. & 2. DA-2017-05038-1 • IFU for Model 97715 s.22 [redacted] = D17-769000, page 28/479 • Information for Prescribers = D17-769000, page 56/479 • System Eligibility Battery Longevity = D17-769000, page 86/479 • MRI Guidelines = D17-769000, page 160/479 s.22 [redacted]
Sponsor:	Medtronic Australasia Pty Ltd
Manufacturer:	Medtronic Inc (United States Of America)[9913]

The Device(s)

1.	Unique Product Identifier(s)	1. Intellis AdaptiveStim Neurostimulator 97715 s.22 [redacted]
2.	GMDN code and term	1. & 2. - Stimulator, electrical, analgesic, spinal cord [36007] s.22 [redacted]
3.	The description of the Device(s) (if required)	An overview of the components of the Intellis rechargeable neurostimulation system is provided within the CER in Table 1 - D17-769000, page 218/479.

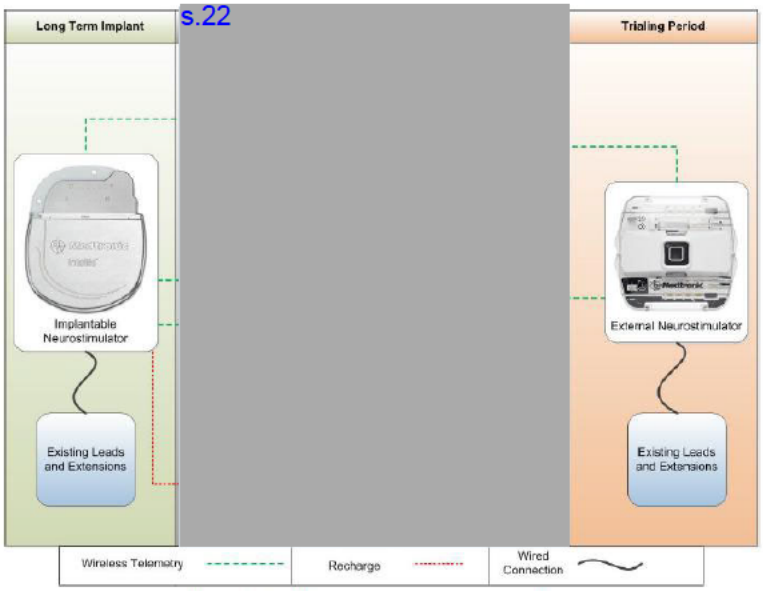


Figure 1 Intellis system component interactions

Device descriptions of each component:
As per CER - D17-769000, page 220/479.
Intellis Implantable Neurostimulator (INS) – Model 97715

The Intellis Implantable Neurostimulator (INS) is a sterile, implantable, multi-programmable, rechargeable device that delivers stimulation through one or more leads. The stimulation settings are programmed using a clinician programmer or patient programmer/controller and are stored in the INS. Radiofrequency (RF) telemetry is used to communicate the settings from the programmers to the INS. The Model 97715 Intellis INS has the AdaptiveStim feature enabled s.22 *. A photograph of the Intellis neurostimulator front and back is provided in Figure 2.*



Figure 2 Model 97715 s.2 Intellis Implantable Neurostimulator

s.22

s.22

		s.22
4.	General specialty category the Device(s) belongs to[1]	☐Anaesthesiology[2] ☐Cardiovascular ☐Ear, Nose, and Throat ☐Gastroenterology and Urology ☐Plastic Surgery ☐Immunology ☒Neurology ☐Obstetrical and Gynaecological ☐Ophthalmic ☐Orthopaedic ☐Radiology ☐None of the above, specify:
5.	Is the device:	☒AIMD (RE: Applications 1 & 2) ☐Passive implantable device ☐Surgically invasive medical devices intended for long-term use ☒None of the above (RE: Applications 3, 4 & 5)

[1] Examples of the Device Classification Panels, credit to the US FDA website: https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/ClassifyYourDevice/ucm051530.htm.

[2] Refer the 'Clinical evidence guidelines: Medical devices' for the requirements for specific categories of medical devices: https://www.tga.gov.au/publication/clinical-evidence-guidelines-medical-devices

6.	The intended purpose(s)[3]	**Intended use of the <u>Intellis Neurostimulation System</u>** as per the CER -D17-769000, page 258/479: *The Medtronic SCS/PNS Therapy Systems are used in the management of the following medical conditions:* *Pain of the trunk, posterior trunk, and/or limbs* *Conditions often treated with the SCS/PNS system include pain in the trunk and/or limbs due to, but not limited to, Failed Back Surgery Syndrome (FBSS) and Complex Regional Pain Syndrome (CRPS).* • *Failed Back Surgery Syndrome is a condition of persistent pain in the legs and/or lower back after previous successful spinal surgery.* • *Complex Regional Pain Syndrome is a combination of neuropathic pain and dysfunction of the sympathetic nervous system comprising symptoms such as edema, vasomotor and sudomotor dysfunction occurring after a noxious event or nerve injury. CRPS Type I is typically associated with regional pain, sensory changes, abnormality of temperature, and edema after a noxious event. CRPS Type II includes all of the above along with peripheral nerve lesions.* *Indications for use in the product labeling* *Spinal Cord Stimulation (SCS)* *Neurostimulation for Spinal Cord Stimulation (SCS)–Medtronic SCS neurostimulation system is indicated for SCS as an aid in the management of chronic, intractable pain of the trunk and/or limbs.* *Peripheral Nerve Stimulation (PNS)* *Neurostimulation for Peripheral Nerve Stimulation (PNS) using percutaneous leads – A Medtronic PNS neurostimulation system is indicated for PNS as an aid in the management of chronic, intractable pain of the posterior trunk.* *Neurostimulation for Peripheral Nerve Stimulation (PNS) using surgical leads – A Medtronic PNS neurostimulation system is indicated for PNS as an aid in the management of chronic, intractable pain of the trunk and/or limbs.* **Intended purpose for each component** <u>1. Intellis AdaptiveStim Neurostimulator 97715</u> As per the Application: *Intellis AdaptiveStim Neurostimulator Model 97715 is a sterile, implantable, multi-programmable, rechargeable neurostimulator for the management of chronic, intractable pain of the trunk and/or limbs.*

[3] Essential principle 14 of Schedule 1 of the *Therapeutic Goods (Medical Devices) Regulations 2002*: Every medical device 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.

		s.22
		As per IFU (D17-769000, page 34/479): *Refer to the indications sheet for indications and related information.* However, changes to the indications sheet are noted in the in CER D17-769000, page 277/479: *Neurostimulation for Spinal Cord Stimulation (SCS)–Medtronic SCS neurostimulation system is indicated for SCS as an aid in the management of chronic, intractable pain of the trunk and/or limbs, ~~peripheral vascular disease, or intractable angina pectoris~~.* Comment from Clinical Assessor (Medical Officer): The indications sheet is required in order to confirm that the IP/indications proposed as part of this application is the same as that outlined in the IFU (or indications sheet). In particular, we need to clarify whether the proposed indications are restricted to SCS (similar to FDA PMA supplement) or if the applicant is also proposed PNS stimulation (based on the broader system indication outlined above).
		s.22

<table>
<tr><td></td><td></td><td>s.22</td></tr>
<tr><td>7.</td><td>Indications for the use of the Device(s)</td><td>See Questions 6</td></tr>
<tr><td>8.</td><td>Is the Device an existing or novel technology?</td><td>☒Existing ☐Novel
Comment if required:</td></tr>
<tr><td>9.</td><td>Is the Device intended to be used as a component/part of the system (e.g. pacemaker and leads or component of a joint replacement system)</td><td>☒YES ☐NO (IF 'NO' GO TO Paragraph 11)
Comment if required:
As per CER (D17-769000, page 279/479):
Intellis is a rechargeable neurostimulation system that is based on the Restore family rechargeable neurostimulation system and is designed to work with all of Medtronic's commercially available neurostimulation leads/extensions/accessory kits.</td></tr>
<tr><td>10.</td><td>Have the other devices from the same system been already included in the ARTG?</td><td>☒YES ☐NO
Comment if required:
<table>
<tr><th>ARTG</th><th>Class</th><th>ARTG Label</th><th>Manufacturer</th><th>Sponsor</th><th>Intended purpose</th></tr>
<tr><td>293256</td><td>IIB</td><td>Stimulator, electrical, analgesic, spinal cord</td><td>Medtronic Inc</td><td>Medtronic Australasia Pty Ltd</td><td>Model 97725 Wireless External Neurostimulator is a multi-programmable device used for intraoperative testing during lead placement and for trial stimulation outside of the operating room.

References:
DV-2017-DA-12700-1</td></tr>
</table></td></tr>
<tr><td>11.</td><td>Are there any known predicate device(s) included in the ARTG (e.g. from the same family of devices)</td><td>☒YES ☐NO
Comment if required:
As per CER Table 25 (D17-769000, page 280/479) the predicate devices for the Intellis system components are:
<table>
<tr><th>Predicate system component</th><th>Intellis system component</th></tr>
</table></td></tr>
</table>

		RestoreSensor SureScan MRI Model 97714 Implantable Neurostimulator 1. Intellis AdaptiveStim Neurostimulator 97715 s.22 Predicates devices in the ARTG: **ARTG** | **Class** | **ARTG Label** | **Manufacturer** | **Sponsor** | **Intended purpose** 215750 | AIMD | RestoreSensor SureScan MRI 97714 - Stimulator, electrical, analgesic, spinal cord | Medtronic Inc | Medtronic Australasia Pty Ltd | The Medtronic RestoreSensor SureScan MRI 97714 is a multi-program Neurostimulator and is part of a neurostimulation system for Spinal Cord Stimulation or Peripheral Nerve Stimulation for use in pain therapy. **References:** DV-2013-DA-01529-2 2013/003264 s.22
12.	Is there the same device included by a different sponsor?	☐YES ☒NO Comment if required: **If this Application is from a different sponsor, this information is FOR INTERNAL USE ONLY**
13.	Is there any other information that can assist in assessing this particular Application?	☐YES ☒NO Comment if required:

The regulatory history of the Device(s) in other countries

14.	EC Certificate (Notified Body, date of issue and the scope)	1. & 2. - s.22 for 'Implantable Muscle-/Neurostimulator systems' – - D17-685392

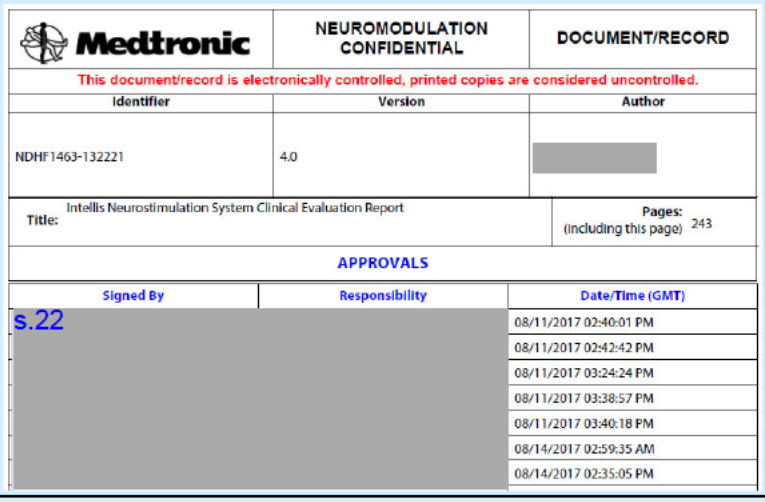
		Attachment for Certificate no [redacted] Product: Implantable Muscle- / Neurostimulator Systems Test Report No.: [redacted] Model: Model No: Variant: Intellis Implantable Neurostimulator With AdaptiveStim® Technology 97715 MR Conditional [redacted] s.22 [redacted]
15.	Has the Device been approved by the US FDA (PMA or 510K)?	☒YES ☐NO ☐Not known Comment if required: Unable to find using search terms: Intellis, neurostimulation, neurostimulator, Medtronic Inc, Medtronic Australasia Comment from Clinical Assessor (Medical Officer): It appears that a PMA supplement was granted for the Intellis ™ Implantable Neurostimulation System in July 2017 (P840001, S344). Reference to the SCS but not the PNS stimulator.
16.	Has the Device been approved by the Health Canada	☐YES ☒NO ☐Not known Comment if required: Unable to find using search terms: Medtronic Inc, Intellis, Device model numbers.
17.	Has the Device been approved in Japan	☐YES ☐NO ☒Not known Comment if required:

The clinical evidence provided by the applicant

18.	Has a Clinical Evaluation Report (CER) been provided[4]	☒YES ☐NO
19.	Has the CER been dated?	☒YES ☐NO

[4] Clause 8.4(1)(c) of Schedule 3 of the *Therapeutic Goods (Medical Devices) Regulations 2002*: a written report by an expert in the relevant field, being a report that contains a critical evaluation of all the clinical investigation data held in relation to the device.

20.	Does the CER provide up-to-date information (i.e. it is dated within the last two years)?	☒YES ☐NO Comment if required: CER (D17-769000, page 210/479) signed and dated 14 August 2017
21.	Has the clinical data been evaluated by competent clinical experts	☒YES ☐NO Comment if required: Updated endorsement by clinical expert - D17-795914
22.	Has CV been provided to demonstrate the competency of the clinical expert[5]?	☒YES ☐NO Comment if required: Overview of Expert Reviewer Quals - D17-769000, page 389/479 Clinical expert CV (Prof s.22 - D17-769000, page 458/479
23.	Has the CER been signed/endorsed by the clinical expert?	☒YES ☐NO Comment if required: Prof s.22 was Neurosurgeon. Assoc. Prof Neurosurgery, Vice Chairman Department of s.22 . It is noted that Prof retired . However, as per CER, D17-769000, page 389/479: *Retired from his medical practice, he continues to perform implantations for these indications on request in the* Based on Prof 's qualifications and clinical experience, he is deemed to be a competent clinical expert.
24.	What is the form of the clinical evidence provided[6]?	☐**Clinical investigation data**



Medtronic | NEUROMODULATION CONFIDENTIAL | DOCUMENT/RECORD

This document/record is electronically controlled, printed copies are considered uncontrolled.

Identifier	Version	Author
NDHF1463-132221	4.0	

Title: Intellis Neurostimulation System Clinical Evaluation Report — Pages: (including this page) 243

APPROVALS

Signed By	Responsibility	Date/Time (GMT)
s.22		08/11/2017 02:40:01 PM
		08/11/2017 02:42:42 PM
		08/11/2017 03:24:24 PM
		08/11/2017 03:38:57 PM
		08/11/2017 03:40:18 PM
		08/14/2017 02:59:35 AM
		08/14/2017 02:35:05 PM

[5] Clause 8.6(1) of Schedule 3 of the *Therapeutic Goods (Medical Devices) Regulations 2002*: The manufacturer of a kind of medical device must ensure that the clinical data is evaluated by competent clinical experts.

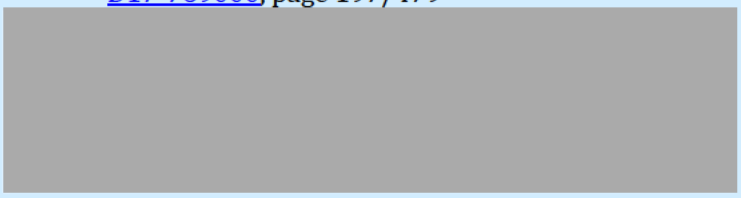
		☒Literature review **☐Both**
25.	How the clinical evidence was provided?	**☐Direct data for the Device(s)** **☒Clinical evidence for the predicate(s)/comparator(s)** **☐Both**
26.	Has a comparative table between the Device and the claimed predicate/comparator device(s) and/or explanation to demonstrate substantial clinical equivalence been provided?	☒YES ☐NO ☐N/A Comment if required: Ref: CER, D17-769000, page 279/479
27.	Has provided analysis **sufficiently demonstrated substantial equivalence**?	☐YES ☒NO ☐N/A Comment if required: Although pages 222-242 compare biological and technical features of the subject device and the predicates, there is no detailed comparison of clinical equivalence. In order to demonstrate substantial equivalence, there should a detailed comparison of clinical indications, anatomical sites and patient populations (not merely a statement saying that they are the same), as well as a discussion as to why any differences are not likely to impact on the clinical safety and performance of the subject devices.
28.	Has any data **from the clinical trial(s)/study** for the Device and/or the claimed predicate(s)/comparator(s) been provided?	☒YES ☐NO ☐N/A Comment if required:
29.	What sort of clinical trial/study the data has been provided for?	☒Randomised Control Trial ☐Non-randomised cohort study ☐Case-control study ☐Single-arm (case-series); multi-site ☒Single-arm (case-series); single-site ☐None of the above Comment if required: SubQStim I Study - CER, D17-769000, page 353/479 • Prospective randomized controlled study of subcutaneous nerve stimulation for back pain due to Failed Back Surgery Syndrome (FBSS). SubQ Stim II Study - CER, D17-769000, page 355/479 • Prospective, randomized, controlled study to evaluate the safety and efficacy of subcutaneous nerve stimulation.

[6] Clauses 8.3(1)(a) and 8.4 of Schedule 3: The manufacturer of a kind of medical device must obtain clinical data in relation to the device in the form of either or both of the following: (a) clinical investigation data; (b) a literature review.

		s.22 Pre-Clinical Testing - CER, D17-769000, page 289/479
30.	Has **any post-market data** for the Device and/or the claimed predicate(s)/comparator(s) been provided?	☒YES ☐NO ☐N/A Comment if required: Clinical experience: CER, D17-769000, page 339/479 • Discussion of post-market registry data for predicate devices with the AdpativeStime technology - Model 37714 RestoreSensor neurostimulator and the Model 97714RestoreSensor SureScan MRI neurostimulator. Post market clinical follow-up: CER, D17-769000, page 383/479
31.	Are there **any records of adverse events/complaints** for the Device and/or the claimed predicate(s)/comparator(s)?	☐YES ☐NO ☒N/A Comment if required: Page 288/479 states that the subject devices (system) have not been commercially released. Whilst this may have been the case at the time the CER was finalised, the fact that the subject devices appear to have an EC certificate and an FDA PMA supplement raise the question of whether the devices have been marketed and used in a clinical setting since the CER was finalised in August 2017. If so, it is expected that some post-marketing data for the subject devices (system) be available to support this application.
32.	Has comparison adverse event/complaint rate analysis been provided?	☒YES ☐NO ☐N/A Comment if required: Information pertaining to registry data for the predicates was provided on pages 339-353/479. Until claims of substantial equivalence have been assessed and are accepted, this data is of limited relevance.
33.	Has the **literature review** been provided for the Device and/or the claimed predicate(s)/comparator(s)[7]?	☐The Device ☒Predicate/Comparator ☐Both ☐N/A Comment if required: Ref: CER, D17-769000, page 311/479
34.	What sort of literature review has been provided?	☐Published literature on the Device ☒Published literature on the predicate and/or comparator device(s) ☐Unpublished scientific literature ☐General broad search on the Device Comment if required: The literature and clinical studies should be reviewed as part of a full clinical assessment once the claims of substantial equivalence have been accepted.
35.	Does the CER claim MRI Safe or MRI Conditional status of	☒YES ☐NO ☐N/A Comment if required:

[7] Clauses 8.3(1)(b) and 8.5 of Schedule 3: As above, Literature review.

	the Device?	MRI Compatibility: MR conditional as per CER, D17-769000, page 243/479. 1. Intellis AdaptiveStim Neurostimulator 97715 s. [redacted] s.22 [redacted]
36.	Is the same indicated in the manufacturer's IFU and on the label?	☒YES ☐NO ☐N/A Comment if required: The Device labels do not have the MR Unsafe/conditional warning. However, as per EP 13.2 if it not practicable to provide the information on the Device label under clause 13.3 the information must be provided on a leaflet supplied with the device. (see question 37)
37.	Does the IFU contain the expected MRI Safety statement?	☒YES ☐NO ☐N/A Comment if required: • MRI Guidelines provided = D17-769000, page 160/479 **Neurostimulator model numbers** The neurostimulator model numbers listed herein are MR Conditional. Do not use model numbers alone to determine which MRI scan conditions to use in these MRI guidelines. Always begin with the "START HERE – Eligibility identification" section of this manual and **use the yes/no identification checklist that starts on page 10** to determine the patient's MRI scan-type eligibility and the appropriate scan conditions to use for the patient's implanted Medtronic neurostimulation system for chronic pain. **Precautions** **External devices are MR Unsafe in the scanner (magnet) room** – Do not allow the following Medtronic external control devices into the MRI scanner (magnet) room. These devices contain ferromagnetic material, which can be affected by the MRI magnet. These devices are MR **Unsafe**: ▪ Patient control device ▪ Recharger ▪ External neurostimulator ▪ Clinician programmer In addition: • IFU for Model 97715 [redacted] includes MRI information see = D17-769000, page 41/479 • Information for Prescribers = D17-769000, page 56/479 and System Eligibility Battery Longevity = D17-769000, page 86/479 include the following statement: *Refer to the MRI Guidelines for Medtronic Neurostimulation Systems for Chronic Pain instructions for use manual for the MRI conditions and MRI-specific warnings and precautions for conducting an MRI scan.* s.22 [redacted]
38.	Is an ASTM testing report	☐YES ☒NO ☐N/A

	provided?	Comment if required: Pre-clinical MRI compatibility testing - D17-769000, page 290/479 As per D17-769000, page 243/479: *From an MRI standpoint, the Intellis system is technically equivalent to the RestoreSensor SureScan MRI system. The Intellis system incorporates the same SureScan MRI technology and labeling MRI Scan conditions as the RestoreSensor SureScan MRI system that allows full body coils to be used to scan any part of the body. This is not a new feature and is not featured in clinically relevant risk items in Table 28. The MRI compatibility testing to establish full-body MRI eligibility is discussed in section 5.1 Pre-clinical summary.* The RestoreSensor SureScan MRI system was assessed by a clinical assessor 15 April 2013 - R13/326645.
39.	Does the risk analysis include tables to enlist possible risks and measures to manage those risks?	☒YES ☐NO Comment if required: Risk Management Reports provided: 1. & 2. DA-2017-05038-1 (Report#:NDHF1245-152839) = D17-769000, page 197/479 
40.	Does the IFU contain the information on the use of the Device, appropriate warnings, precautions, and complications consistently with the supporting evidence provided in the CER and Risk Management Report?	☐YES ☒NO Comment if required: The IFU will require further evaluation as part of a full clinical assessment. The IFU refers to an indication sheet – this should be provided so that the clinical assessor can confirm the indications (including whether or not the devices are used for the broader system claim of PNS stimulation). It is noted that angina pectoris was removed as an indication and with this, a warning for angina pertoris patients regarding AMI. As part of the full clinical assessment, consideration should be given to whether or not such a warning still warrants inclusion within the IFU (for example, educating patients to differentiate between acute and chronic pain and seeking treatment when serious pain symptoms may suggest AMI).

DAVS Assessor's comments:
The subject device for which this assessment has been done have been referred to as 'The Device' in the comments and recommendations below.

- The Device does not appear to have US FDA or Health Canada approval.
- The CER is up-to-date, authored, endorsed and signed by a Clinical Expert. A CV for the Clinical Expert has been provided.
- Post market information has been provided.
- Risk management Plan along with design, use and process FMEA tables has been provided.

- The implantable Intellis AdaptiveStim Neurostimulator 97715 s.22 [redacted] are labelled as MR Conditional. [redacted]

DAVS Assessor:

Name:	s.22 [redacted]	**Date:**	21/09/2017
Signature:	Signed Electronically		

Comments from Clinical assessor (Medical Officer):

Given that claims of substantial equivalence require further scrutiny and there is no post-marketing data available for the subject devices, a full clinical assessment is recommended.

Information to facilitate the full clinical assessment:

Confirmation regarding the indications (as per the IFU/and or indications sheet). In particular, are the proposed indications restricted to SCS (similar to FDA PMA supplement) or do they include PNS stimulation.

In order to demonstrate substantial equivalence with the predicates, there should a detailed comparison of clinical indications, anatomical sites and patient populations (not merely a statement saying that they are the same), as well as a discussion as to why any differences are not likely to impact on the clinical safety and performance of the subject devices.

Confirmation as to whether the subject devices have been marketed and used in a clinical setting since the CER was finalised in August 2017. If so, post-market data for the subject devices (system) should be provided.

Does the submitted clinical evidence provide verification of the conformance with the requirements of the essential principle 14 of Schedule 1 and Part 8 of Schedule 3 of the *Therapeutic Goods (Medical Devices) Regulations 2002?*	**☐YES/☒NO**

Clinical assessor:

Name:	s.22 [redacted]	**Date:**	27/09/2017
Signature:	Signed Electronically		

Endorsed by (if required):

Name:		**Date:**	Click here to enter a date.
Signature:	Signed Electronically		

Australian Government
Department of Health
Therapeutic Goods Administration

Application Audit - Level 2
Clinical Assessment – 1st Round

TRIM Reference: D17-772876

To be completed by DAVS Assessor:

Device UPI:	1. Intellis AdaptiveStim Neurostimulator 97715 s.22
Sponsor:	Medtronic Australasia Pty Ltd
Manufacturer:	Medtronic Inc (United States Of America)[9913]
Application ID:	1. DV-2017-DA-12695-1 s.22
Submission ID:	1&2. DA-2017-05038-1 s.22
DAVS Assessor:	s.22
Application TRIM	1. E17-29210 2. E17-29218 3. E17-29279 4. E17-31116 5. E17-29270
Sponsor's submission TRIM Ref.:	**Initial Data Submitted** Complete Data Submissions: 1. & 2. DA-2017-05038-1 = D17-769000 s.22 Note: The Five (5) applications are supported by the same CER: Intellis Neurostimulation System Clinical Evaluation Report, Version 4.0, dated 10 August 2017, Reference: NDHF 1463-132221. CER – D17-769000, page 211/479 Clinical expert CV (Prof s.22 - D17-7690000, page 458/479 Endorsement by clinical expert - D17-795914 Risk Management Reports: 1. & 2. DA-2017-05038-1 = D17-769000, page 197/479 s.22

	5. [redacted] Device Labels: 1. DA-2017-05038-1 = D17-769000, page 24/479 s.22 [redacted] IFUs: 1. & 2. DA-2017-05038-1 • IFU for Model 97715 s.22 = D17-769000, page 28/479 • Information for Prescribers = D17-769000, page 56/479 • System Eligibility Battery Longevity = D17-769000, page 86/479 • MRI Guidelines = D17-769000, page 160/479 s.22 [redacted] **New Data Submitted (for all 5 applications, not assessed in clinical screening)** D17-892685 - Coverletter (page 3/100) - Intended use/Indications (page 5/100) - Substantial equivalence (page 86/100) - Post-market data (page 90/100)
Date submitted to TGA:	08/08/2017
Date Referred to Clinical Section:	30/10/2017
Screening for clinical data:	Has screening been completed? Yes ☒ No ☐ If '*YES*': 27/09/2017 Name of the assessor: s.22 [redacted] Did the screening identify any issues? Yes ☒ No ☐ If '*YES*': TRIM reference for Screening Report: D17-772783 Outcome of clinical screening: *Given that claims of substantial equivalence require further scrutiny and there is no post-marketing data available for the subject devices, a full clinical assessment is recommended.* *Information to facilitate the full clinical assessment:* *Confirmation regarding the indications (as per the IFU/and or indications sheet). In particular, are the proposed indications restricted to SCS (similar to FDA PMA supplement) or do they include PNS*

	stimulation. *In order to demonstrate substantial equivalence with the predicates, there should a detailed comparison of clinical indications, anatomical sites and patient populations (not merely a statement saying that they are the same), as well as a discussion as to why any differences are not likely to impact on the clinical safety and performance of the subject devices.* *Confirmation as to whether the subject devices have been marketed and used in a clinical setting since the CER was finalised in August 2017. If so, post-market data for the subject devices (system) should be provided.*
Clinical Round:	**1** Initial clinical assessment report: D17-772783

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**

Comments & Rationale:

Device description

This is a first round of assessment for the UPI's mentioned in the table above (the Devices), manufactured by Medtronic Inc. (United States of America).

The Devices are components of Intellis rechargeable neurostimulation system.

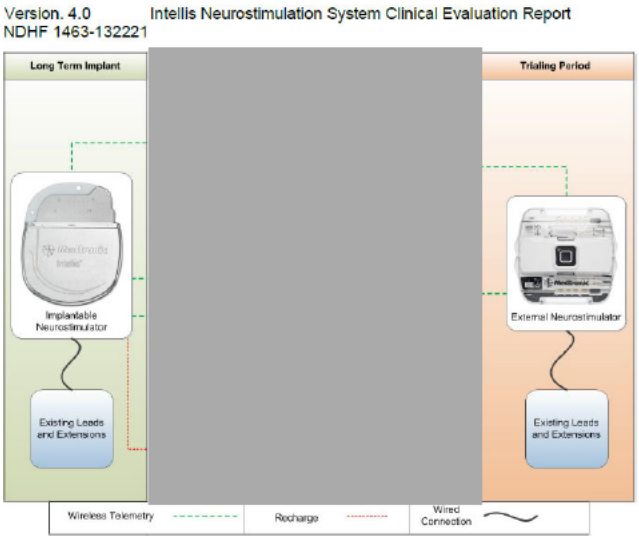


Figure 1 Intellis system component interactions



Figure 2 Model 97715 [redacted]ntellis Implantable Neurostimulator

The implantable neurostimulators (models 97715 [redacted] (INS) are sterile implantable, multi-programmable, rechargeable device that delivers stimulation through one or more leads. The stimulation settings are programmed using a clinician programmer or patient programmer/controller and are stored in the neurostimulator. RF telemetry communicates the

settings from the programmers to the neurostimulators. Model 97715 Intellis INS has the AdaptiveStim[1] feature enabled [redacted].

s.22 [redacted]

The initial assessment done on the data to assess the type and quality of data, revealed that the indications suggested that the Devices are indicated to be used for spinal cord stimulation as well as the peripheral nervous stimulation.

The applicant has now however clarified that the Devices are not intended to be used for peripheral nervous stimulation and only for spinal cord stimulation. The peripheral nervous use is yet to be approved by the notified body and will be submitted for approval in future (to the TGA).

[1] AdaptiveStim technology incorporates a 3-axis accelerometer that senses body position and automatically adjusts stimulation for that position to a level defined by the patient and physician. The system is designed to provide automatic therapy adjustment for 6 positions and this feature is customised for each patient.

Intended purpose:
The intended purpose for the Intellis Neurostimulation System in the CER is stated as:
"*The Medtronic SCS/PNS Therapy Systems are used in the management of the following medical conditions:*
Pain of the trunk, posterior trunk, and/or limbs
Conditions often treated with the SCS/PNS system include pain in the trunk and/or limbs due to, but not limited to, Failed Back Surgery Syndrome (FBSS) and Complex Regional Pain Syndrome (CRPS).

- *Failed Back Surgery Syndrome is a condition of persistent pain in the legs and/or lower back after previous successful spinal surgery.*
- *Complex Regional Pain Syndrome is a combination of neuropathic pain and dysfunction of the sympathetic nervous system comprising symptoms such as edema, vasomotor and sudomotor dysfunction occurring after a noxious event or nerve injury. CRPS Type I is typically associated with regional pain, sensory changes, abnormality of temperature, and edema after a noxious event. CRPS Type II includes all of the above along with peripheral nerve lesions.*"

The individual intended purposes for each of the components are mentioned in the TGA eBS Device application forms for each of the applications.

Contraindications:
The contraindications stated in the IFU are:
Diathermy - Do not use shortwave diathermy, microwave diathermy or therapeutic ultrasound diathermy (all now referred to as diathermy) on patients implanted with a neurostimulation system. Energy from diathermy can be transferred through the implanted system and can cause tissue damage at the location of the implanted electrodes, resulting in severe injury or death. Refer to Appendix A: Electromagnetic interference for further information.

There is also detailed information in relation to electromagnetic interference, case damage, neurostimulator interaction with implanted cardiac devices; there is also a mention of safety and effectiveness not being established for pregnancy, unborn foetus, or delivery and paediatric use (under 18 years of age).

Status in other countries:

1. Has the device(s) been approved by the US FDA/Health Canada?
☒ **YES** ☐ **NO** ☐ **NOT KNOWN**

☐ **Tick if further information is required.**

The Intellis Implantable Neurostimulation system was granted a PMA supplement in July 2017 (P840001, S344) which refers to the spinal cord stimulation (SCS) but not the peripheral nervous stimulator (PNS).

The predicate device components (for RestoreSensor SureScan system) are already on the ARTG since 2013 – ARTG 215750, 214421, and 104700.

Clinical expert and overview of clinical data:
1. Has appropriate CER been provided?
☒ **YES** ☐ **NO** ☐ **Provided but NOT acceptable**

☐ **Tick if further information is required.**

The detailed CER has been provided initially and includes the claims for substantial equivalence with previous generation devices by the same manufacturer. Additional information has also been now provided to elaborate on the equivalence claims.

2. Has the clinical data been evaluated by a competent clinical expert?

☒ **YES** ☐ **NO** ☐ **Clinical expert but NOT acceptable**

☐ **Tick if further information is required.**

The CER has been endorsed by Prof [redacted] whose CV has been provided. Prof. [redacted] was a Neurosurgeon. Assoc. Prof Neurosurgery, Vice Chairman Department of Neurosurgery [redacted]. He is now retired [redacted] from his medical practice but the CV states that he continues to perform implantations for these indications on request in [redacted]. Based on his qualifications and clinical experience, Prof [redacted] is deemed to be an appropriate clinical expert for the Devices.

Assessment of clinical data:

1. Has *clinical investigation data* for the device(s) been included in the CER?

☐ **YES** ☒ **NO**

☐ **Tick if further information is required.**

The approach to providing clinical evidence is to present substantial equivalence between the Devices and the previous generation devices by Medtronic and present the clinical study data for those equivalent devices.

The SubQStim studies and s.22 [redacted] have been discussed in the CER but will not be assessed since the SubQStim studies discuss the peripheral nerve stimulation [redacted]. Both of these indications are not applicable to the Devices.

The CER also explains that a pre-market clinical study is assessed to not be warranted for the Devices (Intellis Neurostimulators in particular) since the incremental changes to the devices have been demonstrated by objective evidence in the CER to be equivalent to the previous systems. The only element of implanted neurostimulation system which changed is the neurostimulator and there are no changes to other elements including the leads, optional extensions or the anchors.

2. Has *clinical equivalence* been claimed with a comparator/predicate device(s)?

☒ **YES** ☐ **NO**

☐ **Tick if further information is required.**

The substantial equivalence for the Devices (Intellis Neurostimulation System) has been claimed with RestoreSensor SureScan MRI. The physical, technical and bilogical characteristics have been explained to be similar for the RestoreSensor SureScan MRI and the Intellis System. Additionally clinical and patient related characteristics are also explained in additional information, to be similar. The equivalence in this case is acceptable.

3. Has a *literature review* been included in the CER?

☒ **YES** ☐ **NO**

☐ **Tick if further information is required.**

A general discussion has been provided in addition to the studies described further below. The general discussion provides a background and rationale to the merits and uses of SCS for back pain and failed back surgery syndrome (FBSS); also mentioning the PROCESS trial that discusses the benefits of SCS for chronic intractable pain, and which was a Medtronic-sponsored randomised, controlled, multicentre process trial to compare SCS to conventional medical management in FBSS patients.

The clinical studies that have been presented are not for spinal cord stimulation (SCS) use but for peripheral nervous stimulation, as well as for the external stimulator; both of these aspects are not under assessment and therefore these studies are not being taken into consideration.

The literature review is stated to be focused on five areas out of which AdaptiveStim technology, SCS constant current for chronic pain, Medtronic clinician and patient programmers and recharge systems and Neurostimulation trialing systems for pain are the most relevant to the Devices.
Comparison between the Intellis system and other competitor systems has also been provided for relevant factors.

Literature review has also been provided in relation to the predicate and comparator systems and provides a reference to performance and safety.

- Schultz et al. (2012): SCS for chronic pain using RestoreSensor; randomised multicentre, open-label crossover study; 79 subjects; 12 weeks follow-up; 86.5% subjects achieved improved pain relief with no loss of convenience or improved convenience with AdaptiveStim in comparison to manual programming adjustments; 2.8% reported worsened pain relief with position-adaptive stimulation; 66 patients reported 239 adverse events (74 device-related)
- Schade et al. (2011): SCS for chronic pain/investigational adaptive stimulation external programmer Restore and Restore Advanced; prospective, multi-centre, open label, randomised trial at 2 centres; 20 patients (15 enrolled with complete data/acute in-clinic follow-up; no significant changes in impedance seen across patients; 6 adverse events reported as unrelated to study procedures or research device, 3 impedance out of range; 2 worsening of pre-existing conditions (congestive heart failure and connective tissue disorder); no deaths or unanticipated adverse device effects reported.

Post-market experience:

1. Has CER included post-market data for the device or comparator/predicate device?

☒ YES ☐ NO

☐ Tick if further information is required.

The applicant has clarified that the Devices are new to the global market and no meaningful post market data is available. The first implant worldwide occurred in the USA on 11 September 2017 and to date no complaints have been received in relation to any of the components of the Devices.

Data has also been provided for post-market studies on the predicate device system (RestoreSensor). The data from the following registries has been presented:

- Implantable Systems Performance Registry (ISPR): was voluntarily created by Medtronic Neuromodulation; to actively monitor the performance of commercially available products);

s47G

s47G



Table 44 Device Events experienced with RestoreSensor systems

s47G



s47G

[redacted]

The MRI-related events are also stated to have been captured by the ISPR and PSR. The ISPR does not specifically categorize events by their association with an MRI scan; however, the adhoc data query conducted to investigate whether any events reported were indicated to be associated with an MRI scan, revealed the following as in the table below. It is also explained that data in relation to MRI scans was not collected in the ISPR.

Table 45 MRI-related events in ISPR

Patient ID	Event date	Device diagnosis	Clinical diagnosis	Description	Product performance related?
110240346	2015-03-04		inadequate paresthesia coverage	change in paresthesia coverage after mri done. resulted in inadequate paresthesia coverage.	Non-product Performance related (censoring)

s47G

[redacted]

s47G



Instructions for Use (IFU), labelling:

1. Are the claims in the IFU supported by clinical evidence provided to the TGA?

☒ YES ☐ NO

☐ Tick if further information is required.

The IFU specifically is called "Medtronic Pain Therapy-Using Intellis™ neurostimulation system for chronic pain", which indicates that the IFU is applicable to the Intellis system models only.

The applicant has explained that they intend to propose the extended indication and use of the Devices in the peripheral nervous stimulation in future submission.

The multilingual indications sheet that has been submitted includes the SCS indications separately.

It is stated in the applicant's response that:

However, during CER review in Europe, the European Notified Body raised questions about the existing level of evidence in SCS for the indications of peripheral vascular disease and intractable angina pectoris. Since this question was at the therapy level and there was a second CER under review for product recertification, the manufacturer asked that this issue be resolved under the recertification CER and offered to temporarily remove those indications from the Intellis indication statement pending satisfactory resolution of the issue with the notified body. That issue has recently been resolved, and a future submission to TGA will request restoration of those indications with some negotiated modifications.

This clinical assessor agrees with the applicant that the indications for use be restricted to SCS (with PNS use removed) for this application. The applicant agrees that PNS use will be removed from the indication statement.

2. Does information provided with the device contain all necessary warnings and precautions as per the clinical evidence provided to the TGA?

☒ YES ☐ NO

☐ Tick if further information is required.

3. Does the IFU include any information in relation to its use in an MR environment?

☒ YES ☐ NO

☒ Tick if further information is required.

The IFU includes the following statement in relation to the use of the Devices in an MR environment. The statements differentiate between the external removable components being MR Unsafe and the implantable components being MR Conditional. In addition to the statements below, the IFU also includes the following statement at the start:
"*Refer to the MRI Guidelines for Medtronic Neurostimulation Systems for Chronic Pain instructions for use manual for the MRI conditions and MRI-specific warnings and precautions for conducting an MRI scan.*"

Neurostimulator model numbers

MR

The neurostimulator model numbers listed herein are MR Conditional. Do not use model numbers alone to determine which MRI scan conditions to use in these MRI guidelines. Always begin with the "START HERE – Eligibility identification" section of this manual and use the yes/no identification checklist that starts on page 10 to determine the patient's MRI scan-type eligibility and the appropriate scan conditions to use for the patient's implanted Medtronic neurostimulation system for chronic pain.

Precautions

MR **External devices are MR Unsafe in the scanner (magnet) room** – Do not allow the following Medtronic external control devices into the MRI scanner (magnet) room. These devices contain ferromagnetic material, which can be affected by the MRI magnet. These devices are MR **Unsafe**:

- Patient control device
- Recharger
- External neurostimulator
- Clinician programmer

From an MRI standpoint, the Intellis system is technically equivalent to the RestoreSensor SureScan MRI system. The Intellis system incorporates the same SureScan MRI technology and labeling MRI Scan conditions as the RestoreSensor SureScan MRI system that allows full body coils to be used to scan any part of the body. This is not a new feature and is not featured in clinically relevant risk items in Table 28.

The implant manual details appropriately what components get heated and what components should and shouldn't be exposed to MR environment. It also details how the implantable components should be handled where possible to minimize heating. The detailed instructions are well written and informative.

However, there is no ASTM testing report for the implantable neurostimulator components for Intellis and the IFU does not appear to have the standard expected safety statement in the IFU (which has been explained in the questions at the end of this report). The ASTM testing report is required to confirm that the results of the testing have been used to deduce the MR safety statement which is to be included in the IFU.

The current data also mentions that all testing was conducted on the Model 97715 INS (one of the Devices). Both the INS models in the Devices, are compatible with all Medtronic commercially available leads but full body scan eligibility is available only when used with the Vectris SureScan MRI leads and the Specify SureScan MRI surgical leads.

Risk Management:

1. Has Risk Management Report been provided?

☒ YES ☐ NO

☐ Tick if further information is required.

The FMEA analysis tables have not been provided and are required.

2. Have risks associated with the use of the device as identified in the CER, been adequately reflected in the Risk management documentation?

☐ YES ☒ NO

☒ Tick if further information is required.

The FMEA analysis tables have not been provided and are required.

3. Do the risk management activities demonstrate that the appropriate procedures have been implemented by the manufacturer to address potential risks associated with the use of the device, which are identified in the CER at this point?

☐ YES ☒ NO

☒ Tick if further information is required.

The FMEA analysis tables have not been provided and are required.

Conclusions and Recommendations:

The applicant has provided detailed information to explain the risks and benefits of spinal cord stimulation in general, and of use of the predicate devices in particular. The predicate devices are already on the ARTG and the post-market data for those has been provided in detail.

Based on the evidence provided at this stage, only certain issues remain to be addressed, pending which the Devices can be deemed to demonstrate compliance with the essential principles.

The IFU explains MR related use by referring to user manual. The user manual discusses the same in detail; however, the IFU does not include the detailed standard MR safety statement as explained below. Also, the ASTM testing report for validating those claims (and to replicate the results and values in the expected MR safety statement), has not been provided.

The detailed FMEA analysis tables for risk management have not been provided.

As stated in the applicant's response, the indications for use should be restricted to SCS (with PNS use removed) for this application. The applicant agrees that PNS use will be removed from the indication statement.

Is additional clinical data required?	**YES**

What, if any, additional clinical data or information is required:

- Provide (a preferably stand-alone document) complete IFU for the Devices which includes complete MR Conditional safety statement in accordance with the format as follows:

  "The patient with the implanted <*device name*> can undergo an MRI scan under following conditions:
  - Static magnetic field strength <*specify field strength here*>
  - Maximum spatial gradient field of <*x* gauss/cm or *x* T/m>
  - Maximum MR System reported, whole-body-averaged Specific Absorption Rate (SAR) for 15 minutes of scanning <*x* W/kg> at <*specified magnetic field strengths*> produced a maximum temperature increase of <*x*°C> during 15 minutes of MRI;
  - In non-clinical testing, the image artefact caused by the device extends approximately <*specify the artefact size in mm*>from the implanted device when imaged with a gradient echo sequence and a <*specify static magnetic field strength* here> MRI system

  In non-clinical testing, the magnetically induced displacement force and magnetically induced torque were tested and no clinically significant displacement or torque was measured"
- Provide the ASTM testing report for the implantable components of the Devices which validates the results and the values that would be included in the MR safety statement in the IFU.
- Provide the detailed FMEA risk analysis tables for risk management.

Name & Dated Signature of Author:

Name:	s.22	**Date:**	8 December 2017
Signature:	Signed Electronically		

Endorsed by:

Name:	s.22	**Date:**	13 December 2017
Signature:	Signed electronically		

Australian Government
Department of Health
Therapeutic Goods Administration

Application Audit - Level 2
Clinical Assessment – 2nd Round

TRIM Reference: D18-10030440

To be completed by DAVS Assessor:

Device UPI:	1. Intellis AdaptiveStim Neurostimulator 97715 s.22
Sponsor:	Medtronic Australasia Pty Ltd
Manufacturer:	Medtronic Inc (United States Of America)[9913]
Application ID:	1. DV-2017-DA-12695-1 s.22
Submission ID:	1&2. DA-2017-05038-1 s.22
DAVS Assessor:	s.22
Application TRIM	1. E17-29210 2. E17-29218 3. E17-29279 4. E17-31116 5. E17-29270

Sponsor's submission TRIM Ref.:	• Clinical Screening Report Completed - D17-772783
	• S41JA based on Clinical Screening Report - D17-789711
	
	• Round 1 Clinical Assessment - D17-772876
	  ○ Provide the ASTM testing report for the implantable components of the Devices which validates the results and the values that would be included in the MR safety statement in the IFU.
	  ○ Provide the detailed FMEA risk analysis tables for risk management.
	
	• Section 41JA Based on Rd 1 Clinical Assessment - D17-809120
	  ○ Data submitted under S41JA – 08/01/2018
	  ○ **TO BE ASSESSED UNDER Round 2 Clinical Assessment**
	  ○ D18-10025973
	  ○ Cover letter dicusses the submission – Pages 28 - 33
	  ○ ASTM testing – Attachement 1 to Attachment 10 – Pages 34 – 233.
	  ○ FMEA tables - Attachment 11 to Attachment 14 – Pages

	234 – 401. **NOTE – THE APPLICATION MUST BE APPROVED BY 25 JANURARY 2018 IN ORDER TO BE INCLUDED ON THE PROTHESIS LIST FOR REIMBURSEMENT.**
Date submitted to TGA:	8/01/2018
Date Referred to Clinical Section:	11/01/2018
Screening for clinical data:	Has screening been completed? Yes ☒ No ☐ If '*YES*': Click here to enter a date. Name of the assessor: Did the screening identify any issues? Yes ☒ No ☐ If '*YES*': TRIM reference for Screening Report: **See Round 1 Report for more detailed information** D17-772876
Clinical Round:	Round 2

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**

Comments & Rationale:
This is the second round of assessment for the devices above (the Devices). The applicant was required to provide clarification in relation to certain issues identified in the forts round of clinical assessment.

MR Conditional Claims:
The implantable components of the Devices viz. Intellis AdaptiveStim Neurostimulator 97715 s.22 (Intellis Neurostimulators), are claimed to be MR Conditional. The applicant was asked to provide ASTM testing report to validate the same. The applicant was also asked to include the standard MR statement in the IFU to list the conditions (gradient and field strength specifications, heating, and image artifact).

The response document that has been provided includes a cover letter and attachments. The cover letter explains that the current format followed by the applicant covers these aspects, except the image artifact, and has been approved by s.22 and) and are approved globally. The excerpt below is for the information now added for image artifact.

Table 1. [a]Maximum artifact

Device	1.5 T
Intellis neurostimulator	12.2 cm × 15.9 cm

[a] The measurements reported in Table 1 represent the maximum dimensions of the artifact obscuring the underlying tissue, with the implantable device in the artifact's center.

The letter further argues that these requirements as requested by the TGA are only for passive implantables and not active ones (which the Intellis Neurostimulators are). Therefore the data provided in the MR guidelines with the addendum for image artifact is sufficient and is supported by the ASTM testing reports (which have also been provided).

The ASTM testing reports and the MR guideline document for the Devices are consistent and satisfactory.

FMEA Analysis for risk management:

The detailed FMEA analysis tables have now been provided and reflect the known and potential risks associated with the use of the Devices, as well as the measures taken to mitigate those risks.

Conclusions and Recommendations:

The applicant has provided the response to the concerns raised in the first round of assessment and the response is deemed to be satisfactory.

The Devices demonstrate compliance with the essential principles 1, 3, 6 and 14.

Is additional clinical data required?	**NO**

What, if any, additional clinical data or information is required:

Name & Dated Signature of Assessor:

Name:	s.22	**Date:**	12 January 2018
Signature:	Signed Electronically		

Australian Government

Department of Health

Therapeutic Goods Administration

Initial Clinical Assessment (Triage) report

TRIM Reference: D19-6063267

Application ID(s):	DV-2019-CR-11240-1
Submission ID:	DA-2019-04933-1
Applicant's submission:	TRIM: attachment in D19-6032867
Sponsor:	Medtronic Australasia Pty Ltd
Manufacturer:	Medtronic Inc
Reason for Audit:	Extension of intended purpose for ARTG Number 298746 s.22 Original assessment reports in E17-29270

The Device(s)

1.	Unique Product Identifier(s)	- Intellis AdaptiveStim Implantable Neurostimulator 97715 s.22
2.	GMDN code and term	36007 Stimulator, electrical, analgesic, spinal cord
3.	The description of the Device(s) (if required)	The Medtronic SCS/PNS system uses an implantable multi-programmable neurostimulation system to deliver electrical stimulation to selected areas of the spinal cord or selected areas of the peripheral nervous system for indicated patients. The implanted system consists of an implantable neurostimulator and lead(s), and an extension may be needed that connects the lead to the neurostimulator. An external physician programmer is used to non-invasively set or adjust patient stimulation parameters. Patients may also make stimulation adjustments, based on their pain needs and physician prescribed programming options, via the external patient programmer/controller. The therapy has evolved over time and has also led to additions to the product portfolio. The Medtronic SCS/PNS therapy system provides a portfolio of leads for both percutaneous and surgical placement. Percutaneous leads are available with 4 or 8 electrode options while surgical leads have two 16 electrode configurations (2x8 and 5-6-5).

		Model97715 Intellis with AdaptiveStimTechnology  The Intellis Implantable Neurostimulator (INS) is a sterile, implantable, multi-programmable, rechargeable device that delivers stimulation through one or more leads. The stimulation settings are programmed using a clinician programmer or patient programmer/controller and are stored in the INS. Radiofrequency (RF) telemetry is used to communicate the settings from the programmers to the INS. The Model 97715 Intellis INS has the AdaptiveStim feature. Package Contents: • Neurostimulator • Torque wrench • Pocket sizer • Bore plugs (2) • Registration • Product literature • Registration form • Patient identification card s.22
4.	General specialty category the Device(s) belongs to[1]	☐Anaesthesiology[2] ☐Cardiovascular ☐Ear, Nose, and Throat ☐Gastroenterology and Urology ☐Plastic Surgery ☐Immunology ☒Neurology ☐Obstetrical and Gynaecological ☐Ophthalmic ☐Orthopaedic ☐Radiology ☐None of the above, specify:
5.	Is the device:	☒AIMD ☐Passive implantable device ☐Surgically invasive medical devices intended for long-term use ☐Device used for surgical intervention ☐None of the above
6.	The intended purpose(s)[3]	As per the Application: Intended purpose for current entries: The Intellis Implantable Neurostimulator is a sterile, implantable, multi-programmable, rechargeable device that

[1] Examples of the Device Classification Panels, credit to the US FDA website: https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/ClassifyYourDevice/ucm051530.htm.

[2] Refer the 'Clinical evidence guidelines: Medical devices' for the requirements for specific categories of medical devices: https://www.tga.gov.au/publication/clinical-evidence-guidelines-medical-devices

[3] Essential principle 14 of Schedule 1 of the *Therapeutic Goods (Medical Devices) Regulations 2002*: Every medical device 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.

		delivers stimulation through one or more leads. The stimulation settings are programmed using a clinician programmer or patient programmer/controller. The Radiofrequency (RF) telemetry is used to communicate to the clinician and patient programmers. The AdaptiveStim technology detects the patient's body position orientation and adjusts stimulation accordingly. s.22 <u>Proposed extension to the intended purpose for both:</u> Peripheral Nerve Stimulation (PNS)using surgical leads is indicated as an aid in the management of chronic, intractable pain of the trunk and/or limbs.; Peripheral Nerve Stimulation (PNS) using percutaneous leads is indicated as an aid in the management of chronic, intractable pain of the posterior trunk. As per the information provided with the Device (s) (e.g. IFU): **Neurostimulation for Peripheral Nerve Stimulation (PNS) using percutaneous leads -** A Medtronic PNS neurostimulation system is indicated for PNS as an aid in the management of chronic, intractable pain of the posterior trunk. **Neurostimulation for Peripheral Nerve Stimulation (PNS) using surgical leads –** A Medtronic PNS neurostimulation system is indicated for PNS as an aid in the management of chronic, intractable pain of the trunk and/or limbs. The application is for an extension to the existing ARTG-listed indications of spinal cord stimulation (SCS) as an aid in the management of trunk or limb pain, angina, and peripheral vascular disease (PVD). The CER states that the proposed extended indication is: • Peripheral Nerve Stimulation (PNS) using percutaneous leads … as an aid in the management of chronic, intractable pain of the posterior trunk. The IFU additionally states: - • Peripheral Nerve Stimulation (PNS) using surgical leads … as an aid in the management of chronic, intractable pain of the trunk and/or limbs.

		Clarification will be sought from the Sponsor regarding the above discrepancy. Further detail is sought on the surgical procedure and the target nerves.
7.	Indications for the use of the Device(s)	Same as above
8.	Is the Device an existing or novel technology?	☒Existing ☐Novel Comment if required:
9.	Is the Device intended to be used as a component/part of the system (e.g. pacemaker and leads or component of a joint replacement system)	☒YES ☐NO (IF 'NO' GO TO Paragraph 11) Comment if required: *Intellis is a rechargeable neurostimulation system that is based on the Restore family rechargeable neurostimulation system and is designed to work with all of Medtronic's commercially available neurostimulation leads/extensions/accessory kits. (from original assessment in 2017).* The current CER does mention the controller and kit that the Devices must be used with.
10.	Have the other devices from the same system been already included in the ARTG?	☒YES ☐NO Comment if required:
11.	Are there any known predicate device(s) included in the ARTG (e.g. from the same family of devices)	☐YES ☒NO Comment if required:
12.	Is there the same device included by a different sponsor?	☐YES ☒NO Comment if required:
13.	Is there any other information that can assist in assessing this particular Application?	☐YES ☒NO Comment if required:

The regulatory history of the Device(s) in other countries

14.	EC Certificate (Notified Body, date of issue and the scope)	TUV SUD: s.22 Issued first: Aug 2017
15.	Has the Device been approved by the US FDA (PMA or 510K)?	☒YES ☐NO ☐Not known Comment if required: It appears that a PMA supplements have been granted for the Intellis ™ Implantable Neurostimulation System in May-July 2019 (P840001) and could be the PNS stimulator update along with the original SCS Stimulator. The aforementioned PMA supplements do not appear to relate to the proposed extended indication(s). Clarification is sought from the Sponsor regarding FDA approval for the proposed indication(s).
16.	Has the Device been approved by the Health Canada	☐YES ☐NO ☐Not known

		Comment if required: Unable to find using search terms: Medtronic Inc, Intellis, Device model numbers
17.	Has the Device been approved in Japan	☐YES ☐NO ☒Not known Comment if required:

The clinical evidence provided by the applicant

18.	Has a Clinical Evaluation Report (CER) been provided[4]	☒YES ☐NO Page 105/448
19.	Has the CER been dated?	☒YES ☐NO Dec 2018
20.	Does the CER provide up-to-date information (i.e. it is dated within the last two years)?	☒YES ☐NO Comment if required:
21.	Has the clinical data been evaluated by competent clinical experts	☒YES ☐NO Comment if required:
22.	Has CV been provided to demonstrate the competency of the clinical expert[5]?	☒YES ☐NO Comment if required: Page 417/448: CV for s.22 has been provided. He is a qualified and experienced Neurosurgeon and is deemed to be a suitable clinical expert for the Devices.
23.	Has the CER been signed/endorsed by the clinical expert?	☒YES ☐NO Comment if required:
24.	What is the form of the clinical evidence provided[6]?	☒**Clinical investigation data** ☒**Literature review** ☐**Both**
25.	How the clinical evidence was provided?	☐**Direct data for the Device(s)** ☐**Clinical evidence for the predicate(s)/comparator(s)** ☒**Both**
26.	Has a comparative table between the Device and the claimed predicate/comparator device(s) and/or explanation to demonstrate substantial clinical equivalence been provided?	☐YES ☒NO ☐N/A Comment if required:

[4] Clause 8.4(1)(c) of Schedule 3 of the *Therapeutic Goods (Medical Devices) Regulations 2002*: a written report by an expert in the relevant field, being a report that contains a critical evaluation of all the clinical investigation data held in relation to the device.
[5] Clause 8.6(1) of Schedule 3 of the *Therapeutic Goods (Medical Devices) Regulations 2002*: The manufacturer of a kind of medical device must ensure that the clinical data is evaluated by competent clinical experts.
[6] Clauses 8.3(1)(a) and 8.4 of Schedule 3: The manufacturer of a kind of medical device must obtain clinical data in relation to the device in the form of either or both of the following: (a) clinical investigation data; (b) a literature review.

27.	Has provided analysis **sufficiently demonstrated substantial equivalence**?	☐YES ☐NO ☒N/A Comment if required:
28.	Has any data **from the clinical trial(s)/study** for the Device and/or the claimed predicate(s)/comparator(s) been provided?	☒YES ☐NO ☐N/A Comment if required: SubQStim I The only clinical trial data on the proposed extended indications(s) is from the SubQStim I study, an open-label RCT comparing treatment of posterior trunk pain with a Medtronic peripheral nerve stimulator (PNS) and Optimised Medical Management (OMM) to OMM alone. Patients were followed for 9 months to assess a primary efficacy measure was the proportion of patients with a >=50% reduction in back pain intensity as rated on the Visual Analogue Scale (VAS). The various secondary efficacy measures include ODI, EQLFD, SF-36 and patient global impression of change. The study did not meet the enrolment target, enrolling 162 of and intended 400 patients and randomising 116 into the ITT population of whom 56 were in the PNS+OMM arm. The final per protocol population consisted of 65 patients. Baseline pain score between arms were similar. The primary endpoint was met, with 34% in the Device treatment arm meeting a 50% improvement in VAS compared to 2% in the control arm, p<0.001. All secondary measures demonstrated a statistically significant difference in favour of the PNS+OMM arm. In terms of safety, the PNS+OMM arm had fewer AEs (33% vs 53%). Hardware and stimulation related adverse events accounted for <5% of total AEs. Pain in the extremity and back pain were common complaints, occurring in 5% and 7%, respectively. A breakdown of these events between groups is not given; further information is requested from the Sponsor. It is unclear whether the trial implanted the subject devices or predecessor models and clarification is sought from the Sponsor. Further information is sought on patient withdrawals and treatment-arm specific demographics and adverse events. SubQStim II The SubQStim II trial, which had planned to compare treatment of post-surgical back pain by PNS with a sham stimulation, was abandoned due to insufficient numbers. 62 patients were

		implanted and randomised. The primary efficacy measures were not assessed due to lack of power. The safety analysis captured 143 AEs, 67 of which were evaluated as device-related and included burning sensation (6.6%), back pain (3.3%), and implant site pain (4.9%). There were 16 SAEs that included AF, implant site pain, burning sensation implant site infection, sensation of pressure, sensory disturbance, dermatitis, and muscle spasms.
29.	What sort of clinical trial/study the data has been provided for?	☒Randomised Control Trial (open label) ☐Non-randomised cohort study ☐Case-control study ☐Single-arm (case-series); multi-site ☐Single-arm (case-series); single-site ☐None of the above Comment if required:
30.	Has **any post-market data** for the Device and/or the claimed predicate(s)/comparator(s) been provided?	☒YES ☐NO ☐N/A Comment if required: Page 168/448: post-market surveillance Page 172/448: Post-market studies
31.	Are there **any records of adverse events/complaints** for the Device and/or the claimed predicate(s)/comparator(s)?	☐YES ☐NO ☐N/A Comment if required: s47G [redacted]
32.	Has comparison adverse event/complaint rate analysis been provided?	☐YES ☐NO ☐N/A Comment if required:

33.	Has the **literature review** been provided for the Device and/or the claimed predicate(s)/comparator(s)[7]?	☐The Device ☐Predicate/Comparator ☐Both ☐N/A Comment if required: Page 153/448: discusses use of PNS Page 156/448: State of the art for Trialing Page 167/448: scientific literature review
34.	What sort of literature review has been provided?	☐Published literature on the Device ☒Published literature on the predicate and/or comparator device(s) ☐Unpublished scientific literature ☐General broad search on the Device Comment if required: One study was identified as relevant to the proposed indication extension. Guentchev et al (2017) describe a single arm study of 17 patients treated with PNS using a predecessor model for sacroiliac joint pain. The patients were initially given a 7-day trial, from which 16 patients achieved a >50% reduction in pain and were followed for a further 36 months. 14 patients completed 12 months' follow-up, at which point the mean VAS score had reduced from 8.8 to 1.3. The patient cohort declined to be assessed by the ODI due to its lengthy nature. One patient experienced treatment failure. Only 3 patients made it to final follow-up. Regarding PNS as a treatment modality, the CER states "there are currently no known guidelines recommending the therapy." (Page 153 of the combined document that includes the CER)
35.	Does the CER claim MRI Safe or MRI Conditional status of the Device?	☒YES ☐NO ☐N/A Comment if required: The MR Conditional claims were assessed and deemed acceptable during the initial assessment of the Devices.
36.	Is the same indicated in the manufacturer's IFU and on the label?	☒YES ☐NO ☐N/A Comment if required:
37.	Does the IFU contain the expected MRI Safety statement?	☒YES ☐NO ☐N/A Comment if required:
38.	Is an ASTM testing report provided?	☐YES ☐NO ☒N/A Comment if required:
39.	Does the risk analysis include tables to enlist possible risks and measures to manage those risks?	☒YES ☐NO Comment if required: Page 21/448

[7] Clauses 8.3(1)(b) and 8.5 of Schedule 3: As above, Literature review.

40.	Does the IFU contain the information on the use of the Device, appropriate warnings, precautions, and complications consistently with the supporting evidence provided in the CER and Risk Management Report?	☐YES ☐NO Comment if required: Page 18/448 This only includes the amendment. Original complete IFU and other related documents for MR Conditional use etc. have been assessed during first evaluation.

DAVS Assessor's comments:

- Device has USFDA approval but no MDALL approval
- CER up-to-date; signed and endorsed by a clinical expert. CV for expert provided
- Post-market data provided
- Risk Management and FMEA provided
- Device makes MR Conditional claims; IFU includes appropriate statement and has been assessed during previous assessment of these Devices.

The Devices have been on the ARTG since 2017. Original assessment reports are in E17-29270 . The applicant now wishes to extend the intended purpose to include the use for Peripheral Nerve Stimulation.

DAVS Assessor:

Name:	s.22	**Date:**	9 September 2019
Signature:	Signed Electronically		

Comments from Clinical assessor (Medical Officer):

Concise Summary

The Devices are currently ARTG listed as Spinal Cord Stimulators (SCS). The Sponsor proposes extending the indication to include Peripheral Nerve Stimulation (PNS). There are numerous deficiencies in the application, including inconsistency in the indication for use. The evidence base to support Device efficacy is weak. Further information is requested from the Sponsor.

Summary

The Devices are the Intellis AdaptiveStim Implantable Neurostimulator s.22

The application is for an extension to the existing ARTG-listed indications of spinal cord stimulation (SCS) as an aid in the management of trunk or limb pain, angina, and peripheral vascular disease (PVD). The proposed extended indication is not clear; the CER states peripheral nerve stimulation (PNS) as an aid in the management of chronic intractable pain of the posterior trunk, whilst the IFU additionally states for trunk and/or limb pain. Clarification is requested from the Sponsor on the proposed extended indication(s). The risk analysis will not be fully assessed by the TGA Clinical Assessor until the proposed indication(s) for use are clarified.

It is unclear whether the subject devices are approved for the proposed extended indication(s) by the FDA. Clarification from the Sponsor is sought.

Insufficient information is provided regarding the procedure and the target nerves. Further information is requested from the Sponsor.

The only robust clinical trial data is from an open-label RCT comparing the Device to optimised medical management in the treatment of posterior trunk pain over 9 months. The trial did not meet enrolment targets but was sufficiently powered to meet the primary efficacy endpoints. Insufficient detail is provided regarding patient withdrawals, treatment-arm specific demographics and adverse events, and the neurostimulators models used in the trial.

s47G

One single arm observational study (n=17) was identified in the literature search, in which the majority of patients withdrew before the final 36-month follow-up and refused to complete the disability index questionnaire due to its length. The results do not refute the Sponsor's claim of safety and performance but add little weight to the body of evidence.

The post market data for the subject devices is not delineated by year, region, or indication for use, and further information is requested from the Sponsor. The total complaint rate is 18%, the MAUDE complaint rate is 8% and Device survival is 97% at 4 years.

Recommendations for the sponsor

Regarding the proposed extended indication(s) for use, the CER proposes:

- **Neurostimulation for Peripheral Nerve Stimulation (PNS) using percutaneous leads:** Medtronic PNS neurostimulation system is indicated for PNS as an aid in the management of chronic, intractable pain of the posterior trunk.

The IFU *additionally* proposes: -

- **Neurostimulation for Peripheral Nerve Stimulation (PNS) using surgical leads –** A Medtronic PNS neurostimulation system is indicated for PNS as an aid in the management of chronic, intractable pain of the trunk and/or limbs.

Clarify the above discrepancy. If the proposed indication(s) include treatment of chronic, intractable pain of the limbs as stated in the IFU, provide evidence for the performance and safety for that indication.

Clarify whether the subject devices are approved by the FDA for the proposed extended indication(s).

Provide information on the surgical procedure for lead and Device placement. Clarify the set of peripheral nerves which can be stimulated and whether the risk profile varies according to the target nerve.

Provide a detailed report on the SubQStim I trial, including information on the device models implanted, patient withdrawals, the censoring strategy employed, and a comparison of the study arms in terms of demographics and adverse event profiles.

Clarify if there is any evidence in support of Device performance for the proposed extended indication(s) beyond the SubQStim I and the study by Guentchev et al (2017).

Provide post market data (including sales and complaints) for the subject devices delineated by the proposed indication(s) for use, and year and region of sale.

Does the submitted clinical evidence provide verification of the conformance with the requirements of the essential principle 14 of Schedule 1 and Part 8 of Schedule 3 of the *Therapeutic Goods (Medical Devices) Regulations 2002?*	**☐YES/☒NO**

Clinical assessor:

Name:	s.22	**Date:**	25/11/2019
Signature:	Signed Electronically		

Endorsed by (if required):

Name:	s.22	**Date:**	26/11/2019
Signature:	Signed Electronically		

Clinical Assessment - Round 2

s41JA	TRIM: D20-400998
Information provided in response to the previous round	TRIM: D20-433665

Comments and assessment:

Regarding the discrepancy between the indication in the CER and IFU, the indications using the surgical leads for treatment of chronic intractable pain of the limbs have been retracted. The questions around the surgical procedure for surgical lead placement are no longer relevant. Nonetheless, the Sponsor has provided a description of the percutaneous lead placement through provision of a surgical manual. The percutaneous leads target unnamed small fibres. The procedure essentially amounts to tunnelling the lead with the provided needle through the subcutaneous layer to the implanted stimulator.

The extended indications are not yet FDA approved.

Further information on the main clinical study has been received. The RestoreAdvanced, PrimeAdvanced, RestoreUlta and RestoreSensor models were used, which purportedly deliver the same output as the subject device. In terms of demographics, the control and active treatment arms are well matched, with no significant differences noted, including in the severity and duration of back pain. Withdrawals were fairly even between groups, slightly more in the control arm. Total withdrawals are >20%, in part due to withdrawals at study closure. Efficacy endpoints were met ('responder' rates) in the ITT and PP sets (see table, below); similarly for the various secondary endpoints including ODI. 193 AEs occurred (103 in the active arm); 2.2% were therapy related, 2.7% were hardware related. The most common AE was back pain (7%) and pain in extremity (5.2%). 4 infections, 3 lead fractures and 2 lead dislocations occurred. No lead erosions or deaths occurred.

Table 2. Primary Outcome of Responder Rate (≥50% Pain Relief at Nine Months).

Analysis of back pain	SQS + OMM			OMM			Between-group difference *p*-value
	Total (*N*)	Missing (*N*, %)	Responder (*N*, %)	Total (*N*)	Missing (*N*, %)	Responder (*N*, %)	
ITT	56	20 (35.7%)	19 (33.9%)	60	24 (40.0%)	1 (1.7%)	<0.0001
Per-treatment	30	0 (0%)	17 (56.7%)	35	0 (0%)	1 (2.9%)	<0.0001
Modified ITT	56	10 (17.9%)	19 (33.9%)	60	24 (40.0%)	1 (1.7%)	<0.0001

s47G



In summary, the subject device, already ARTG listed for spinal cord stimulation, has demonstrated efficacy in peripheral nerve stimulation for chronic trunk pain in an open label RCT, with primary efficacy endpoints met in the per protocol and intention-to-treat populations. The post market data does not reveal any pressing clinical concerns. The nature of the procedure and placement of a subcutaneous lead, whilst not trivial, introduces far less risk to the patient than the existing ARTG-listed indication of spinal cord stimulation. The Sponsor has adequately addressed deficiencies in the initial submission. No further data will be requested.

Does the submitted clinical evidence provide verification of the conformance with the requirements of the essential principle 14 of Schedule 1 and Part 8 of Schedule 3 of the *Therapeutic Goods (Medical Devices) Regulations 2002?*	**☒YES/☐NO**

Clinical assessor:

Name:	s.22	**Date:**	15/04/2020
Signature:	Signed Electronically		

Endorsed by (if required):

Name:	s.22	**Date:**	21/04/2020
Signature:	Signed Electronically		

FOI 27-3446 - Document 5

Australian Government
Department of Health
Therapeutic Goods Administration

Medical Devices Program

Internal Form			
DAS FORM 4.a	Medical Device Application Without an Audit Assessment Checklist		
Comes under	DAS SOP 4 Assessing an application without an audit		
Applicable to	Devices Applications Section	Authorised by	s.22 Director, DAS
Date issued	21 Jul 2021	Version #	1.0

Application Details

Submission ID	DA-2022-05545-1
Application ID	DV-2022-DA-13755-1
TRIM Reference	E22-588589
Sponsor Name	Medtronic Australasia Pty Ltd
Manufacturer Name:	Medtronic Inc (United States Of America)[9913]
UPI/Sponsor's reference	Intellis AdaptiveStim Implantable Neurostimulator 97715
Classification	Class III (refer to comments below)
GMDN Term & Code	Spinal cord/peripheral nerve implantable analgesic electrical stimulation system pulse generator, implantable [64970] (see comments)

FOI 27-3446 - Document 5

Outcome of the assessment/recommendation:

☐ Seek advice from the delegate

☐ Application has failed preliminary assessment

☐ Sponsor requested to withdraw application

☒ Decision to include kind of device in ARTG according to S41FF

☐ Impose conditions under S41FO

☐ Select application for audit under S41FH

☒ I confirm that I have the appropriate delegation under the *Therapeutic Goods Act 1989*

Description of the device

Please include images and references to the relevant documents if required

The application is for an AIMD to Class III reclassification. The application is intended to re-classify the ARTG entry 298746 to Class III in accordance with the updated classification rule[1].

The device is an implantable, multi-programmable, rechargeable neurostimulator that delivers stimulation through one or more leads. The device is indicated for SCS as an aid in the management of chronic, intractable pain of the trunk and/or limbs; and stable intractable Angina Pectoris or Peripheral Vascular Disease of Fontaine Stage II or higher in patients who are not candidates for revascularization. Peripheral Nerve Stimulation (PNS) using percutaneous leads is indicated as an aid in the management of chronic, intractable pain of the posterior trunk. The AdaptiveStim technology detects the patient's body position orientation and adjusts stimulation accordingly. The stimulation settings are programmed using a clinician programmer or patient programmer/controller.

[1] https://www.tga.gov.au/resource/reclassification-active-implantable-medical-devices-aimd

FOI 27-3446 - Document 5

Part 1 – Application

Information provided in the application – Manufacturer's Evidence	
Manufacturer's Evidence ID	DV-20050426-MC-002989-1
Conformity assessment document issued by (TGA Conformity Assessment Certificate/Notified body/MDSAP/US FDA/Health Canada/Japan)	Notified body
Regulator/Certification Body name and ID	s.22
Any relevant information (e.g. is certificate current and if it expired, has it been replaced and when; does the scope of the certificate cover the kind of device/was ME stated correctly, and if it was not, has this information been corrected and when; etc.):	**EC Certificate** Full Quality Assurance System Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD), Annex 2 excluding (4) (Other devices than custom made or intended for clinical investigation) s.22 **Manufacturer:** **Medtronic, Inc.** 710 Medtronic Parkway Minneapolis MN 55432 USA **Product:** **Implantable Muscle-/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 devices / device categories in accordance with AIMDD Annex 2. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of the devices / device categories an additional Annex 2 (4) certificate is mandatory. See also notes overleaf. **Report no.:** 713158134 **Valid from:** 2019-10-04 **Valid until:** s.22
Does the Notified Body have accreditation to assess the kind of device (under Medical Devices Directive 93/42/EEC and/or Active implantable medical devices 90/385/EEC or MDR 2017/745?	☒ Yes ☐ No

FOI 27-3446 - Document 5

Information provided in the application – Manufacturer's Evidence	
Any other information if relevant:	

Preliminary assessment	N/A means 'Not application and/or "not enough information to be assessed"
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) Provide relevant information, including Class of the device, classification rule(s) that apply and justification if required below:	☒ Yes ☐ No ☐ N/A
Class III as per classification rule 5.7 (1), Schedule 2 of the MD Regulations.	
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? If it is not, provide relevant information below:	☐ Yes ☐ No ☒ N/A
Is application accompanied by the kind of information and in a form determined for the classification of medical device? (Refer Table 2 of the guidance '*Use of market authorisation evidence from comparable overseas regulators / assessment bodies for medical devices*') If it is not, provide relevant information below:	☒ Yes ☐ No ☐ N/A

Preliminary assessment	N/A means 'Not application and/or "not enough information to be assessed"

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)
s.22

Manufacturer: **Medtronic, Inc.**
710 Medtronic Parkway
Minneapolis, MN 55432
USA

Product: **Implantable Muscle- / 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. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see:
www.tuvsud.com/ps-cert?q=cert:I7 039709 1090 Rev. 01

Report no.: 713197093

Valid from: 2021-03-10
Valid until: s.22

Paragraph 41FD(f) – Have the appropriate conformity assessment procedure or requirements, comparable to the conformity assessment procedure been applied to the kind of device? If not, provide relevant information below:	☒ Yes ☐ No ☐ N/A
Paragraph 41FD(e) – Does the applicant have available sufficient information to substantiate the application of the conformity assessment procedures/ comparable 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? If it is not, provide relevant information below:	☒ Yes ☐ No ☐ N/A
Is the device in the application a medical device used for a special purpose (according to Regulation 3.10), e.g. procedure pack? If so, provide relevant information below:	☐ Yes ☒ No ☐ N/A

FOI 27-3446 - Document 5

Preliminary assessment	N/A means 'Not application and/or "not enough information to be assessed"

FOI 27-3446 - Document 5

Part 2 – Application Assessment

Application assessment	N/A means 'Not application and/or "not enough information to be assessed"
Was the application made for a kind of device?	☒ Yes ☐ No ☐ N/A
Is the device nomenclature system codes (GMDN) the relevant preferred term/collective term for the devices of the kind (Regulation 1.7)? Provide any relevant information below:	☒ Yes ☐ No ☐ N/A
Spinal cord/peripheral nerve implantable analgesic electrical stimulation system pulse generator, implantable [64970] (see comments)	
For Class III and AIMD, does the unique product identifier (UPI) stated in the application accurately identify the devices of the kind? If the UPI does not appear to be correct, provide relevant information (including if it has been amended/corrected in the application, or if other application is required, etc.) below:	☒ Yes ☐ No ☐ N/A

97715 – matches with the Design Examination Certificate

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)

s.22

Model(s): **see below**

Product: **Implantable Muscle- / Neurostimulator Systems**

Test Report No.: 713098675

Model:	Model no.:	Variant:
Intellis Implantable Neurostimulator with AdaptiveStim® Technology	97715	MR Conditional

s.22

FOI 27-3446 - Document 5

Application assessment	N/A means 'Not application and/or "not enough information to be assessed"
For Class III and AIMD, are the variants stated in the application correct according to the information provided? If the variants do not appear to be correct, provide relevant information below:	☒ Yes ☐ No ☐ N/A
Does the intended purpose stated in the application appear to be correct? Does it indicate any concerns? Is it consistent with the GMDN code selected in the application? If no, specify and provide relevant information below:	☒ Yes ☐ No ☐ N/A ☐ Yes ☒ No ☐ N/A ☒ Yes ☐ No ☐ N/A
Are there any other information/device product characteristics that need to be considered in the application (e.g. the device is a procedure pack/sterile/active, etc.)? Are the device characteristics consistent with the intended purpose of the kind of device, GMDN code selected in then application, etc.? If no, specify and provide relevant information below:	☒ Yes ☐ No ☐ N/A ☒ Yes ☐ No ☐ N/A
Intended purpose is appropriate and matches with the ARTG entry 298746.	
Are there any known concerns about the device (specifically or in general) such as the device is a vaginal mesh or EC Certificate was issued by a notified body of concern, e.g. withdrawal from the MDD accreditation). Refer "Hot Topics" R16/869138 Provide relevant information below:	☐ Yes ☒ No ☐ N/A

FOI 27-3446 - Document 5

Information attached with the application	N/A means 'Not application and/or "not enough information to be assessed"
Was any other information provided with the application? If yes, specify and provide relevant information below:	☐ Yes ☒ No ☐ N/A
Declaration of Conformity [Provide the TRIM link] Is the Declaration of Conformity made in accordance to the appropriate Part of Schedule 3 of the MD Regulations and the scope covers the Device? Provide relevant information below:	☐ Yes ☐ No ☒ N/A ☐ Yes ☐ No ☒ N/A
Not requested	
Labelling for the medical device [Provide the TRIM link] Does the labelling comply with EP 13.2 (location) and13.3? Provide relevant information below:	☐ Yes ☐ No ☒ N/A ☐ Yes ☐ No ☒ N/A
Not requested	
Instructions for use (IFU) [Provide the TRIM link] Does the labelling comply with EP 13.2 (location) and13.3? Provide relevant information below:	☐ Yes ☐ No ☒ N/A ☐ Yes ☐ No ☒ N/A
Not requested	
Any other information (e.g. data from the National Joint Replacement Registry). Provide relevant information below:	☐ Yes ☒ No ☐ N/A
Paragraphs 41FD(j) – Is the information included in and with the application complete and correct?	☒ Yes ☐ No ☐ N/A

Additional comments (if required)

Provide relevant information, if not already covered above, or if further clarification is required. For example, if it is recommended to impose a condition, state the proposed draft of the conditions and the reasons why.

The application was submitted with the GMDN code “Stimulator, electrical, analgesic, spinal cord [36007],” which is now obsolete according to the GMDN agency. The sponsor has confirmed that the updated GMDN code is “Spinal cord/peripheral nerve implantable analgesic electrical stimulation system pulse generator, implantable [64970]” (D22-5666593) but was not able to amend the application due to the nature of the reclass application (D22-5676781). Once the application has been approved the new ARTG entry will be amended to have the correct GMDN code.

Assessor’s Name	s.22	Position Level	APS6
Signature	Signed electronically	Date	13/07/2022

FOI 27-3446 - Document 5

Reviewers Recommendation

To be completed by an EL1 when the decision delegate is an EL2

Recommendation	
Pass Preliminary Assessment **Note:** If the application has not passed preliminary assessment, the Secretary is required to give notice of the refusal under section 41FG	☐ Yes ☐ No
Include Kind of Device in ARTG	☐ Yes ☐ No
Impose Conditions under section 41FO of the Act	☐ Yes ☐ No
Other: Procedure following audits – state in the notice reasons for the recommendation	☐ Yes ☐ No

Additional comments (if required)

Provide relevant information, if not already covered above, or if further clarification is required. For example, if it is recommended to impose a condition, state the proposed draft of the conditions and the reasons why.

Reviewer's Name		Position Level	
Signature		Date	

FOI 27-3446 - Document 5

Delegate's Checklist and Decision

Delegate's Checklist	
Do you have delegation for the purposes of section 41FDB of the Act (*Preliminary assessment* of applications)?	☒ Yes ☐ No
Do you have delegation for the purposes of section 41FF if application is finalised without the audit?	☒ Yes ☐ No
Have you checked that all requirements set out under section 41FF have been considered and met in making this decision?	☒ Yes ☐ No
Specify other if required: section 41FO	☐ Yes ☒ No
Other: section 41FL	☒ Yes ☐ No

Delegate's Decision	
Pass Preliminary Assessment **Note:** If the application has not passed preliminary assessment, the Secretary is required to give notice of the refusal under section 41FG	☒ Yes ☐ No
Include Kind of Device in ARTG	☒ Yes ☐ No
Impose Conditions under section 41FO of the Act	☐ Yes ☒ No
Other: section 41FL	☒ Yes ☐ No

Additional comments (if required)

Provide relevant information, if not already covered above, or if further clarification is required. For example, if it is recommended to impose a condition, state the proposed draft of the conditions and the reasons why.

New ARTG entry will have GMDN code amended to "Spinal cord/peripheral nerve implantable analgesic electrical stimulation system pulse generator, implantable [64970]."

Delegate's Name s.22 Position Level APS6

FOI 27-3446 - Document 5

Signature	Signed electronically	Date	13/07/2022

Version history

Version	TRIM Reference	Description of change	Author/s	Effective date
V1.0	D19-5922185	New document. Supersedes R16/879015 Updated to new template: MDB TEMP 2.1.c- Template for a FORM - Version 3.3 Reviewed/updated content to reflect current processes.	s.22	22 Jul 2021