Medical Device Application

ARTG No : 121184

Class IIb
Status : Approved

Application Change history

Application Progress Date	
Date received:	20/07/2005
Review Information	
Review flag:	Request to cancel ARTG entry
Auto review required:	No

Device Product Characteristics

Application Summary	
Application ID:	DV-20050706-DA-005740-1
Submission ID:	DV-2005-3600
Sponsor's own reference:	Charite Artificial Disc
Application for:	
Will you be applying for listing of this product or procedure in the Medicare Benefit Schedule (MBS)?	○ Yes ○ No
Will you be applying for listing of this product on the Prosthesis List?	○ Yes ○ No
Will you be applying for listing of this product on the Co-dependent or hybrid technology application list?	○ Yes ○ No
Sponsor name:	Johnson & Johnson Medical Pty Ltd T/A Depuy Australia
Sponsor ID:	10380
Agent name:	
Contact details :	[redacted]
Contact email:	

Manufacturer Information	
Manufacturer's evidence:	021112-WEBE-5FT7L4 : DePuy Spine Inc Annex II Goto
Manufacturer name:	Depuy Spine Inc (United States Of America)[42419]
Assessment route:	Council Directive 93/42/EEC (MDD)
Assessment body:	BSI Product Services [0086]
GMDN code:	Prosthesis, internal, spine, disc[34163]
GMDN description:	A device that replaces or restores the platelike structure between two moving vertebrae. It may be made of metal, polymer, other artificial or biological materials or be a combination of these.
Intended purpose :	Indicated for spinal arthroplasty in skeletally mature patients with degenarative disc disease (DDD)at one level from L4-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies.

Device Category Terms	
Device category 1:	Non-active implantable devices

Payment Information	
Payment type:	Cheque
Cheque number:	XXX
Bank:	Citibank

Attached Documentation

History

08/08/2005 4:07:45 PM Approved.

Review Completed - Accepted, 08/08/2005)

Record		Date	
Fee:	670	Date Paid:	04/08/2005
		Date Decision:	08/08/2005

Start Dates		Finish Dates		Working Days
Application Received	20/07/2005	Payment Received	04/08/2005	11

Payment Received	04/08/2005	Application Decision	08/08/2005	13
			Total Working Days	24

Medical Device Application

Class IIb
Status : Approved

Application Change history

Application Progress Date	
Date received:	20/07/2005
Review Information	
Review flag:	Request to cancel ARTG entry
Auto review required:	No

ARTG & Product ID	
ARTG ID	121184
Product ID	203043

Application Details	
Application identifier:	DV-20050706-DA-005740-1
Submission identifier:	DV-2005-3600
Sponsor's own reference:	Charite Artificial Disc
Application for:	
Will you be applying for listing of this product or procedure in the Medicare Benefit Schedule (MBS)?	○ Yes ○ No
Will you be applying for listing of this product on the Prosthesis List?	○ Yes ○ No
Will you be applying for listing of this product on the Co-dependent or hybrid technology application list?	○ Yes ○ No
Cancel ARTG - product:	Current DePuy listing AUSTL: 96121 Device number: 115765 Obsolete listing AUSTL: 51002 Device number: 144133. This AUSTL was purchased by DePuy Spinal and registered under AUSTL number 96121.

Sponsor Details	
Sponsor name:	Johnson & Johnson Medical Pty Ltd T/A Depuy Australia
Contact details:	[redacted]

Contact email:	[redacted]

Class Details

Class:	Class IIb
Intended purpose:	Indicated for spinal arthroplasty in skeletally mature patients with degenarative disc disease (DDD)at one level from L4-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies.

Device Product Characteristics

Is the device, or any form of the device, supplied sterile:	Yes
Sterilisation Method:	
Is the device intended to be invasive:	Yes
s the device, or any form of the device, intended for single use:	Yes
Is the device an active device:	No
Does the device contain material or ingredients of microbial origin:	No
Does the device contain material or ingredients of recombinant origin:	No
Does the device contain material or ingredients manufactured or formulated using a genetically modified organism:	No
Does the device contain material or ingredients of Human Origin:	No
Does the device contain Human Blood or its components:	No
Does the device consist of:	Single product only
Does the device contain material or ingredients of Animal Origin rendered non-viable	No
Animal Species:	
Country of Origin:	
Does any component in the procedure, kit or system contain material or ingredients of Animal Origin rendered non-viable:	No
Is the device medicated:	No
Is the device formulated:	No
Does the product contain a medicine that is supplied separately in the Australian Market:	No
Does the product contain a medical device which incorporates a medicine as an integral part and that has an action ancillary to the device:	No
Does the device contain a metal on metal bearing:	
I declare that this device contains only components that are medical devices which have been individually certified.	No

Manufacturer Details

Manufacturer evidence	021112-WEBE-5FT7L4 : DePuy Spine Inc Annex II

number:

Manufacturer name:	Depuy Spine Inc (United States Of America)[42419]
Manufacturer address as on evidence:	325 Paramount Drive Raynham Massachusetts 02767 United States Of America S [104406]

GMDNS Code and Description

GMDNS code and description:	Prosthesis, internal, spine, disc[34163]

Device Category Terms

Device category 1:	Non-active implantable devices
Device category 2:	
Device category 3:	

Product Details

UPI (Unique product identifier):	
Total number of devices covered:	
Functional decription:	

Variant List

#	Variant type	Variant range

Standard Conditions

Non Standard Conditions

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

To remove, enter item #

Declaration

(a) devices of the kind in question are medical devices; and
(b) devices of that kind are intended for a specified purpose, as ascertained under The definition of a medical device; and
(c) the kind of device is correctly classified according to the medical device classifications; and
(d) devices of that kind comply with the essential principles; and
(e) I:
(i) have available sufficient information to substantiate that compliance with the essential principles; or

(ii) have procedures in place, to ensure that such information can be obtained from the manufacturer within the period specified in the regulations; and

(f) an appropriate conformity assessment procedure has been applied to devices of that kind; and

(g) I:

(i) have available sufficient information to substantiate the application of those conformity assessment procedures; or

(ii) have procedures in place, to ensure that such information can be obtained from the manufacturer within the period specified in the regulations; and

(h) devices of that kind comply with every requirement (if any) relating to advertising applicable under the regulations; and

(i) devices of that kind do not contain substances that are prohibited imports for the purposes of the Customs Act 1901; and

(ia) devices of that kind are not to be used exclusively for one or more of the purposes specified under section 41BEA; and

(j) the information included in or with the application is complete and correct.

I understand the consequences of making a false declaration, as outlined below.

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

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

Signatory name of the person submitting the application.:

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History

08/08/2005 4:07:45 PM Approved.

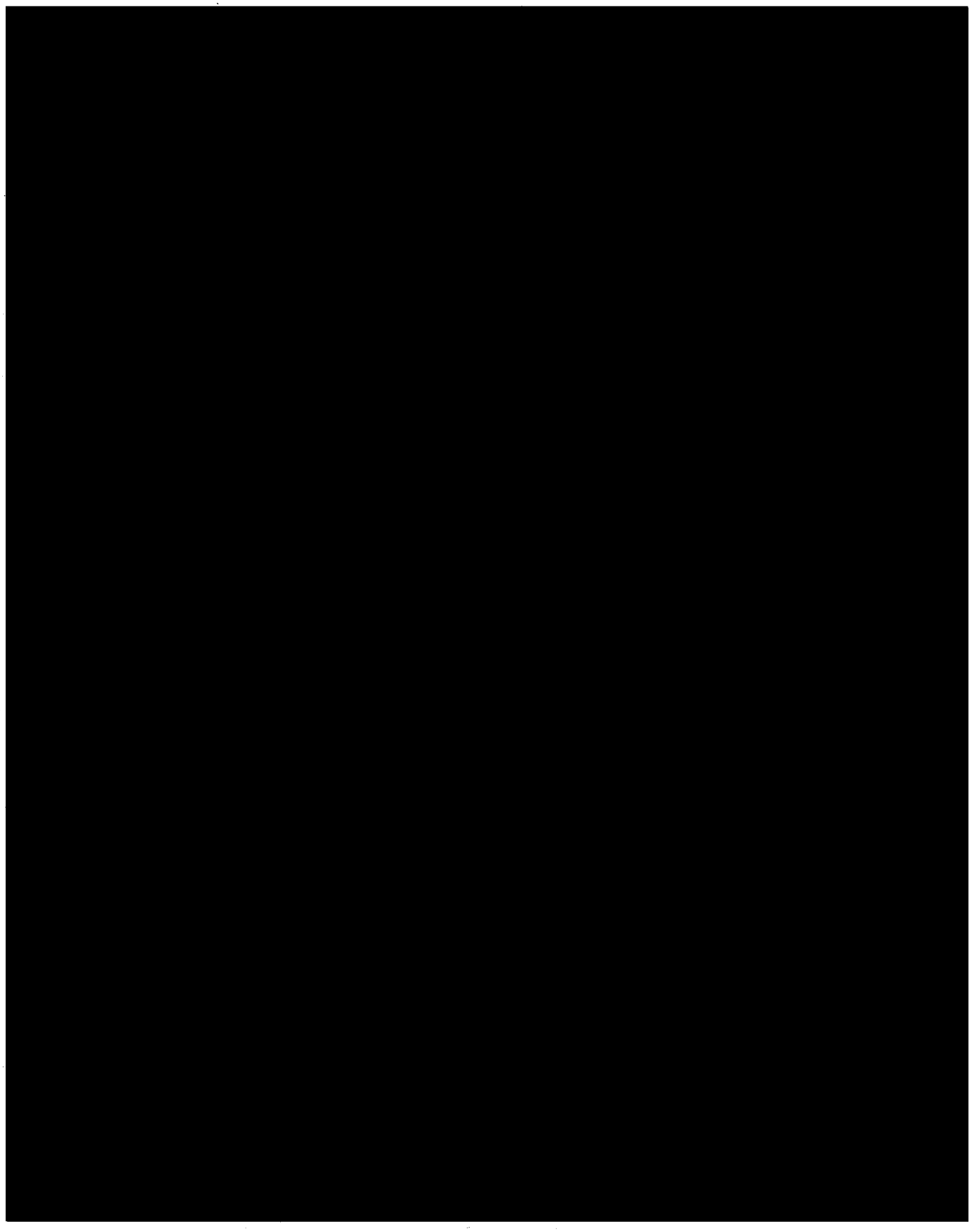
Review Completed - Accepted, 08/08/2005)

Record		Date	
Fee	670	Date Paid	04/08/2005
		Date Decision	08/08/2005

Start Dates		Finish Dates		Working Days
Application Received	20/07/2005	Payment Received	04/08/2005	11
Payment Received	04/08/2005	Application Decision	08/08/2005	13
			Total Working Days	24

Manufacturer Evidence

Status : Approved



[redacted]

Notification details

Evidence identifier:	021112-WEBE-5FT7L4
Submission identifier:	DM-2011-02562-7
Version number:	20
Sponsor's own reference:	DePuy Spine Inc Annex II [CE53820]

Sponsor details

Agent name:	
Sponsor name:	Johnson & Johnson Medical Pty Ltd T/A Depuy Australia
Contact details:	[redacted]

Certification details

Manufacturer name:	Depuy Spine Inc (United States Of America)[42419]
Manufacturer address as on certification:	325 Paramount Drive Raynham Massachusetts 02767 United States Of America

Type of product:

○ This certification is to support an application for an in vitro diagnostic medical device (IVD)
● This certification is to support an application for a medical device that is not an in vitro diagnostic medical device (IVD)

Certificate issued under:	Council Directive 93/42/EEC (MDD)
Conformity assessment procedure:	Schedule 3 Part 1 (Annex II)
Source of certification:	BSI Product Services [0086] Lookup
Certificate number:	CE 53820
Certificate issue date: (dd/mm/yyyy)	04/04/2000
Certificate expiry date: (dd/mm/yyyy)	03/03/2015
Certificate re-issue date: (dd/mm/yyyy)	12/04/2011

Restrictions on scope:

Restriction on conformity assessment procedure:
Full Quality Assurance Certificate.
Note: For Class III a Design Examination Certificate must be submitted with the Device Application.

Attached documentation:

Attached documents	Updated EC Certificate - Annex II EC Cert. DS CE 53820 Exp 03 Mar 2

Supporting documents:

#	Document Type	Description	Method
1.	Addition of GMDN code(s)	Word Document	Fax

Related Active ARTG Entry Information:

[redacted]

121184	Depuy Australia Pty Ltd - Prosthesis, internal, spine, disc

[redacted]

History

CN=Cathie Stoffell/OU=TGA/O=Health

Certificate

Full Quality Assurance

No. CE 53820

Issued to:

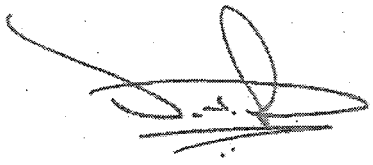
DePuy Spine
325 Paramount Drive
Raynham
Massachusetts
02767
USA

In respect of:

The design, development and manufacture of spinal implant systems and instrumentation systems, bovine-derived bone graft material, spinal cement delivery systems and accessory needles

on the basis of our examination under the requirements of Council Directive 93/42/EEC, Annex II, Section 3.2.

For and on behalf of the British Standards Institution, a Notified Body for the above Directive (Notified Body Number 0086):



[redacted]

First Issued: **4 Mar 2000** Date: **12 Apr 2011**

Expiration Date: **3 Mar 2015**

Conditions of Approval
Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

raising standards worldwide™

The British Standards Institution, Kitemark House, Maylands Avenue, Hemel Hempstead, HP2 4SQ United Kingdom Tel: +44 (0)8450 765600 Web: www.bsigroup.com
The British Standards Institution is incorporated by Royal Charter. Principal Office: 389 Chiswick High Road, London W4 4AL UK. Tel: +44 (0)20 8996 9000

Certificate

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No. **CE 53820**
Date: **12 Apr 2011**
Issued to: **DePuy Spine**
Raynham
USA

Subcontractor	Service(s) supplied
Leoni Studer AG Studer Hard 4658 Däniken Switzerland	Sterilization
DePuy International Limited St Anthony's Road Leeds United Kingdom LS11 8DT	EU Representative
DePuy Motion SARL Chemin Blanc 38 CH-2400 Le Locle Switzerland	Manufacture
DePuy Spine SARL Chemin Blanc 36 CH 2400 Le Locle Switzerland	Design Manufacture
DePuy (Ireland) Loughbeg Ringaskiddy Cork Ireland	Manufacture

Certificate

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No. **CE 53820**
Date: **12 Apr 2011**
Issued to: **DePuy Spine**
Raynham
USA

Subcontractor	Service(s) supplied
DePuy Spine 365 Ravendale Road Mountain View CA 94043 USA	Manufacture
BeamOne LLC 9020 Activity Road, Suite D San Diego CA 92126 USA	Sterilization
Isotron PLC Marcus Close Tilehurst Reading Berkshire RG30 4EA United Kingdom	Sterilization
DePuy Inc. 50 Scotland Park Drive Bridgewater Massachusetts USA 02324	Distribution Packaging Inspection

Certificate

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No.	**CE 53820**
Date:	**12 Apr 2011**
Issued to:	**DePuy Spine**
	Raynham
	USA

Subcontractor	Service(s) supplied
Steris Isomedix Services 435 Whitney Street Northborough Massachusetts 01532 USA	ETO Sterilization Gamma Sterilization
Kensey Nash Corporation 735 Pennsylvania Ave. Exton PA 19341 USA	Animal substances
Mediplast Israel Ltd. 7 Ha'yarkon Street P. O. Box 13214 Industrial Zone Yavne 81227 Israel	Sterilization
Sor-Van Irradiation Ltd. Kiryat Soreq PO Box 214 Yavne 81800 Israel	Sterilization

Certificate

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No. **CE 53820**
Date: **12 Apr 2011**
Issued to: **DePuy Spine**
Raynham
USA

Subcontractor	Service(s) supplied
Beam One LLC 500 West 4th Street Lima OH 45804 USA	Sterilization
RSI Leasing, Inc. dba Sterigenics 7695 Formula Place San Diego California 92121 USA	E beam Sterilization

Certificate

History of Quality Assurance Certificate

Certificate No: CE 53820
Issue Date:
Issued to: DePuy Spine
Raynham
USA

Date	BSI Reference No.	Action
04 March 2000	-	First issue
01 November 2002	-	DePuy Inc (Bridgewater) added as a subcontractor DePuy Acromed, Inc (Jacksonville) removed from the list of subcontractors
21 November 2003	-	Change of company name, change of scope and addition of DePuy Spine (Mountain View), titan Scan Systems (San Diego) and DePuy Spine Inc (Leeds) to the list of subcontractors
18 August 2004	-	Addition of DePuy (Ireland) Limited (Cork), Waldemar Link GmbH & Co. KG (Germany) and Isotron Plc (Reading) to the list of subcontractors
18 April 2005	-	Addition of Ethicon GmbH (Norderstedt), Steris/Isomedix (Massachusetts), and DePuy Spine SARL (Switzerland) as subcontractors and five year renewal
5 May 2005	-	Alignment with CE 79912 following completion of SER for Healos II Devices and addition of Kensey Nash Corporation as a subcontractor for Animal Substances.
19 June 2006	-	Addition of DePuy Orthopaedics New Bedford as a subcontractor for manufacture
20 March 2007	-	Sub-contractor company name change from "Titan Scan Systems" to "BeamOne LLC" and typographical error correction to address of BeamOne LLC

History of Quality Assurance Certificate

Certificate No: CE 53820
Issue Date:
Issued to: DePuy Spine
Raynham
USA

Date	BSI Reference No.	Action
7 April 2008	7177220	Extension to scope to include "Spinal Cement" Addition of subcontractor Disc-o-Tech Medical Technologies Ltd., for the activities of design and manufacture
13 August 2008	7217964	Removal of DePuy Orthopaedics, Inc. from the list of significant subcontractors for manufacturing. Addition of BeamOne to the list of significant subcontractors for sterilization and Symmetry Medical, Inc. to the list of significant subcontractors for manufacturing.
6 October 2008	7265920	Addition of Mediplast Israel Ltd, Sor-Van Radiation Ltd, and Leoni Studer AG Studer Hard to the list of significant subcontractors for sterilization.
27 March 2009	7341322	Addition of DePuy Motion SARL to the list of significant subcontractors for manufacture. Addition of design activity for existing subcontractor DePuy Spine SARL. Addition of Sterigenics, San Diego, to the list of significant subcontractors for E-beam sterilization. Removal of Disc-O-Tech Medical, Symmetry Medical, and DePuy Spine Leeds from the list of significant subcontractors.
26 February 2010	7459365	Certificate renewal Inclusion of 'accessory needles' in the scope Addition of 'DePuy Int. for EU Rep. Deletion of Waldemar Link GmbH & Co., KG & J & J Medical, Germany. Minor changes to several sub contractors' addresses to match their current ISO 13485 certificates.

Certificate

History of Quality Assurance Certificate

Certificate No: CE 53820

Issue Date:

Issued to: DePuy Spine
Raynham
USA

Date	BSI Reference No.	Action
12 April 2011	7652447	Revision of scope, from 'The design, development and manufacture of spinal implant systems and instrumentation systems, synthetic bone graft material, spinal cement and cement delivery systems and accessory needles' to 'The design, development and manufacture of spinal implant systems and instrumentation systems, bovine-derived bone graft material, spinal cement delivery systems and accessory needles.'