



Medical Device Application

Class IIb Status : Approved

Application Change history

Application Progress Date

Date received: 29/06/2004

Review Information

Review flag:

Auto review required: No

ARTG & Product ID

ARTG ID: 106749

Product ID: 185194

Application Details

Application identifier: 040629-WEBE-62E7Q6

Submission identifier: DV-2004-2352

Sponsor's own reference: **Corin**-Orthopaedic systems - ligaments

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:

Sponsor Details

Agent name: Asia Pacific Total Product Management

Sponsor name: Corin Australia Pty Ltd

Contact details: XXXXXXXXXX

Contact email: [REDACTED]@yahoo.com

Class Details

Class:	Class IIb
Intended purpose:	Medical devices used in various orthopaedic procedures to replace or repair a missing or damaged ligamentous structure in order to restore natural function. Made from synthetic absorbable or non-absorbable materials.

Device Product Characteristics

Is the device, or any form of the device, supplied sterile:	Yes
Sterilisation Method:	
Is the device intended to be invasive:	Yes
Is the device, or any form of the device, intended for single use:	Yes
Is the device an active device:	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:	Products packaged as a system
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 number: 040609-WEBE-5ZS25A : Corin- Orthopaedics - Class 2b - Systems and Implantable Accessories

Manufacturer name: Corin Medical A Division Of Corin Ltd (England)[32592]

Manufacturer address as on evidence: CIRENCESTER United Kingdom S [94807]

GMDNS Code and Description

GMDNS code and description: Prosthesis, internal, ligament[35717]

Device Category Terms

Device category 1: Non-active implantable devices

Device category 2:

Device category 3:

UPI (Unique product identifier):

Total number of devices covered:

Functional description:

Variant List

#	Variant type	Variant range
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Device system name if applicable:

Standard Conditions

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

The standard conditions that are imposed under section 41FO of the Therapeutic Goods Act 1989 when kinds of medical devices are included in the Register are set out in paragraphs 62 to 67.

For a medical device included in the Register under Chapter 4 and imported into Australia, the Sponsor must ensure that information about the Sponsor is provided in such a way as to allow the sponsor to be identified.

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

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

The sponsor shall provide to the Director, Office of Devices, Blood and Tissues, Therapeutic Goods Administration, three consecutive reports which include information of a kind specified in Regulation 5.8 that arises during the reporting period, concerning Class III, Class AIMD or implantable Class IIb medical devices. The reporting period for the first report commences on the date of inclusion and is to be at least a period of six months but not more than 18 months ending on 1 October. For subsequent reports the reporting period is 12 months ending on 1 October.

Where a medical device included in the Register, contains a substance which is included in the Fourth Schedule to the Customs (Prohibited Imports) Regulations or the Eighth Schedule to the Customs (Prohibited Exports) Regulations the Sponsor shall, at the time of importation or exportation of the medical device, be in

possession of a licence and a permission for importation or exportation of each consignment of the goods as required by those regulations.

A sponsor shall ensure that a medical device within their control is stored and transported in accordance with the instructions and information provided by the manufacturer.

Non Standard Conditions

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

To remove, enter item #

Declaration

41FD Matters to be certified:

The applicant must certify that:

- (a) devices of the kind in question are medical devices; and
- (b) devices of that kind are intended for a specified purpose, as ascertained under subsection 41BD(2); 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) the applicant:
 - (i) has available sufficient information to substantiate that compliance with the essential principles; or
 - (ii) has procedures in place, including a written agreement with the manufacturer of the kind of devices setting out the matters required by the regulations, to ensure that such information can be obtained from the manufacturer within the period specified in the regulations; and
- (f) either:
 - (i) an appropriate conformity assessment procedure has been applied to devices of that kind; or
 - (ii) requirements, comparable to the conformity assessment procedures, have been applied to devices of that kind; and
- (g) the applicant:
 - (i) has available sufficient information to substantiate the application of the procedures referred to in subparagraph (f)(i) or the requirements referred to in subparagraph (f) (ii); or
 - (ii) has procedures in place, including a written agreement with the manufacturer of the kind of devices setting out the matters required by the regulations, to ensure that such information can be obtained from the manufacturer within the period specified in the regulations; and
- (h) both of the following are complied with in relation to devices of that kind:
 - (i) the applicable provisions of the Therapeutic Goods Advertising Code;
 - (ii) the other requirements (if any) relating to advertising applicable under Part 5-1 or 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.

Note: See section 41BH for when a medical device complies with the essential principles, section 41BI for when conformity assessment procedures are taken not to have been applied to a medical device and section 41BIA for when requirements comparable to those procedures are taken not to have been applied to a medical device.

41FDA Basis of certification of conformity assessment procedures

When certifying the matter referred to in paragraph 41FD(f), the applicant must also state that the certification of the matter is based:

- (a) on a conformity assessment certificate that is in force; or
- (b) on an Australian conformity assessment body certificate that is in force; or
- (c) on an overseas regulator conformity assessment document that is in force.

This is in accordance with Therapeutic Goods (Medical Devices—Information that Must Accompany Application for Inclusion in the Register) Determination.

IMPORTANT - It is taken that the person, who is stated in this application as the contact person, has authorised and electronically signed the declaration under section 41FD of the Act, as provided above, on behalf of the sponsor.

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

5/08/2004 5:10:37 PM [REDACTED] Approved.

Record

Date

Start Dates	Finish Dates	Working Days		
Application Received	29/06/2004	Payment Received	16/07/2004	13
Payment Received		Application Decision	05/08/2004	28
Total Working Days				40