



Medical Device Application

Class IIb
Status : Approved

Application Change history

Application Progress Date

Date received: 09/04/2005

Review Information

Review flag:

Auto review required: No

ARTG & Product ID

ARTG ID 118426

Product ID 199036

Application Details

Application identifier: DV-20050405-DA-002073-2

Submission identifier: DV-2005-1454

Sponsor's own reference: hp/eska/ genius hip metal shell type 2000 01

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: SPECTRUM TECHNOLOGY PTY LTD

Sponsor name: Eska Australia

Contact details:

Contact email:

Class Details

Class: Class IIb

Intended purpose: A component of a total hip joint prosthesis that is used to replace or repair the acetabulum and may include an inner liner.

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: 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 number: DV-20050329-MC-001787-2 : hp/eska implants/various 01

Manufacturer name: Eska Implants GmbH and Co (Germany)[45325]

Manufacturer address as on evidence: GrapengieBerstraBe 34 Lubeck D-23556 Germany S [147473]

GMDNS Code and Description

GMDNS code and description: Prosthesis, internal, joint, hip, acetabular component[35661]

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 description:

Variant List

#	Variant type	Variant range
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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	
14/04/2005 10:49:01 AM Approved.	
Review Completed - Accepted, 14/04/2005)	

Record	Date
Fee 670	Date Paid 12/04/2005
	Date Decision 14/04/2005

Start Dates		Finish Dates		Working Days
Application Received	09/04/2005	Payment Received	12/04/2005	1
Payment Received	12/04/2005	Application Decision	14/04/2005	3
Total Working Days				4