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	118425
Product ID	199035

Application Details	
Application identifier:	DV-20050405-DA-002070-2
Submission identifier:	DV-2005-1454
Sponsor's own reference:	hp/eska/ Genius Hip cranial shell 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:	[redacted]

Contact email:	[redacted]

Class Details	
Class:	Class IIb
Intended purpose:	A device that may be in the form of an acetabular support ring, sheet or mesh and is sed in the situation of a damaged acetabulum in order to support a replacement acetabular component

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 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 support component[33179]

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

14/04/2005 10:48:54 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