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	118441
Product ID	199051

Application Details	
Application identifier:	DV-20050405-DA-002067-2
Submission identifier:	DV-2005-1454
Sponsor's own reference:	hp/eska/ Genius Hip system adapter hip stem 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 component of a total hip jopint prosthesis that is used to replace the femoral head and in some instances the femoral neck

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, femoral component[35666]

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 10:50:55 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