Medical Device Application

ARTG No : 118441

Class IIb
Status : Approved

Application Change history

Application Progress Date	
Date received:	09/04/2005

Review Information	
Review flag:	
Auto review required:	No

Device Product Characteristics

Is the device, or any form of the device, supplied sterile: Yes
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
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

Application Summary	
Application ID:	DV-20050405-DA-002067-2
Submission ID:	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
Sponsor name:	Eska Australia
Sponsor ID:	45270
Agent name:	SPECTRUM TECHNOLOGY PTY LTD
Contact details :	[redacted]
Contact email:	[redacted]

Manufacturer Information	
Manufacturer's evidence:	DV-20050329-MC-001787-2 : hp/eska implants/various 01 Goto
Manufacturer name:	Eska Implants GmbH and Co (Germany)[45325]
Assessment route:	Council Directive 93/42/EEC (MDD)
Assessment body:	Dekra Certification GmbH [0124]
GMDN code:	Prosthesis, internal, joint, hip, femoral component[35666]
GMDN description:	A component of a total hip joint prosthesis that is used to replace the femoral head and, in some designs, the femoral neck. The component may have a trunnion at the proximal end or a head. The device may be of metal, carbon or ceramic material and may consist of a number of parts. In addition there may be devices, e.g. screws, that augment the fixation to the body. The design of the component may be constrained or unconstrained. It may also be used with or without bone cement.
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 Category Terms	
Device category 1:	Non-active implantable devices

Attached Documentation

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