Medical Device Application

ARTG No : 118425

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-002070-2
Submission ID:	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
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, acetabular support component[33179]
GMDN description:	A device that may be in the form of an acetabular support ring, sheet or mesh. It is used in the situation of a damaged acetabulum in order to support a replacement acetabular component. The device may be of metal or polymer material.
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 Category Terms	
Device category 1:	Non-active implantable devices

Attached Documentation

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