



Medical Device Application

ARTG No : 118427

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-002074-2

Submission ID: DV-2005-1454

Sponsor's own reference: hp/eska/ modular hip-system CUT 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 :

Contact email:

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, total[36315]

GMDN description: A device to replace the articulation of the hip joint usually consisting of femoral and acetabular matching components. There may also be additional devices, e.g. screws and bolts, in accordance with the design of the total replacement. Materials include metals, polymers and ceramics. The device(s) may be implanted with or without bone cement.

Intended purpose : A device to replace the articulation of the hip joint usually consisting of femoral and acetabular matching components.

Device Category Terms

Device category 1: Non-active implantable devices

Attached Documentation

History

14/04/2005 10:49:09 AM Approved.

Review Completed - Accepted, 14/04/2005)

Record

Date

Fee: 670 Date Paid: 12/04/2005

Date 14/04/2005
Decision:

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