



# Medical Device Application

ARTG No : 118426

## 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-002073-2

Submission ID: DV-2005-1454

Sponsor's own reference: hp/eska/ genius hip metal shell type 2000 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  Yes  No  
of this product on the  
Prosthesis List?

Will you be applying for listing  Yes  No  
of this product on the  
Co-dependent or hybrid  
technology application list?

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 component[35661]

GMDN description: A sterile implantable principal component of a total hip prosthesis (acetabular component) designed to replace or repair the acetabulum. The component is of a one-piece construction and is made of a combination of metal, ceramic, and/or polyethylene (PE), or all-metal or ceramic material; it may include fixation devices (e.g., screws) for attachment to the body.

Intended purpose : A component of a total hip joint prosthesis that is used to replace or repair the acetabulum and may include an inner liner.

#### Device Category Terms

Device category 1: Non-active implantable devices

#### Attached Documentation

#### History

14/04/2005 10:49:01 AM Approved.

Review Completed - Accepted, 14/04/2005)

#### Record

#### Date

Fee: Date Paid: 12/04/2005

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Date 14/04/2005  
Decision:

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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

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