



# 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 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, 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

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            |