# Medical Device Application

## Class IIb
## Status : Approved

**Application Change history**

| Application Progress Date | |
|---|---|
| Date received: | 09/04/2005 |
| **Review Information** | |
| Review flag: | |
| Auto review required: | No |

| ARTG & Product ID | |
|---|---|
| ARTG ID | 118429 |
| Product ID | 199039 |

| Application Details | |
|---|---|
| Application identifier: | DV-20050405-DA-002078-2 |
| Submission identifier: | DV-2005-1454 |
| Sponsor's own reference: | hp/eska/ metal on metal 012 |
| 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 |
| Cancel ARTG - product: | |

| Sponsor Details | |
|---|---|
| Agent name: | SPECTRUM TECHNOLOGY PTY LTD |
| Sponsor name: | Eska Australia |
| Contact details: | [redacted] |

| | |
|---|---|
| Contact email: | [redacted] |

| **Class Details** | |
|---|---|
| Class: | Class IIb |
| Intended purpose: | A component of a total hip joint prosthesis that is used to replace the acetabular comprising of an inner and outer shell - metal on metal |

| **Device Product Characteristics** | |
|---|---|
| Is the device, or any form of the device, supplied sterile: | Yes |
| Sterilisation Method: | |
| Is the device intended to be invasive: | Yes |
| s 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 |
| Animal Species: | |
| Country of Origin: | |
| 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 |
| Does the device contain a metal on metal bearing: | |
| I declare that this device contains only components that are medical devices which have been individually certified. | No |

| **Manufacturer Details** | |
|---|---|
| Manufacturer evidence number: | DV-20050329-MC-001787-2 : hp/eska implants/various 01 |
| Manufacturer name: | Eska Implants GmbH and Co (Germany)[45325] |

| | |
|---|---|
| Manufacturer address as on evidence: | GrapengieBerstraBe 34 Lubeck D-23556 Germany S [ 147473] |

| GMDNS Code and Description | |
|---|---|
| GMDNS code and description: | Prosthesis, internal, joint, hip, acetabular component[35661] |

| Device Category Terms | |
|---|---|
| Device category 1: | Non-active implantable devices |
| Device category 2: | |
| Device category 3: | |

| Product Details | |
|---|---|
| UPI (Unique product identifier): | |
| Total number of devices covered: | |
| Functional decription: | |

**Variant List**

| # | Variant type | Variant range |
|---|---|---|

**Standard Conditions**

**Non Standard Conditions**

Note: A non standard conditions must not contain semi colons.

To remove, enter item #

**Declaration**

(a) devices of the kind in question are medical devices; and
(b) devices of that kind are intended for a specified purpose, as ascertained under The definition of a medical device; and
(c) the kind of device is correctly classified according to the medical device classifications; and
(d) devices of that kind comply with the essential principles; and
(e) I:
(i) have available sufficient information to substantiate that compliance with the essential principles; or

(ii) have procedures in place, to ensure that such information can be obtained from the manufacturer within the period specified in the regulations; and

(f) an appropriate conformity assessment procedure has been applied to devices of that kind; and

(g) I:

(i) have available sufficient information to substantiate the application of those conformity assessment procedures; or

(ii) have procedures in place, to ensure that such information can be obtained from the manufacturer within the period specified in the regulations; and

(h) devices of that kind comply with every requirement (if any) relating to advertising applicable under the regulations; and

(i) devices of that kind do not contain substances that are prohibited imports for the purposes of the Customs Act 1901; and

(ia) devices of that kind are not to be used exclusively for one or more of the purposes specified under section 41BEA; and

(j) the information included in or with the application is complete and correct.

I understand the consequences of making a false declaration, as outlined below.

In electronically submitting this application to TGA, I hereby declare that in relation to this medical device the information given in this application and the above statements on this declaration form are current and correct.

PLEASE NOTE:
A false declaration will result in the device entry being removed/cancelled from the ARTG.

Signatory name of the person submitting the application.:

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**History**

14/04/2005 10:49:27 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 |