# Medical Device Application

**ARTG No : 201852**

## Class IIb
## Status: Approved

### Application Change history

| Application Progress Date | |
|---|---|
| Date received: | 01/10/2012 |

| 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 consist of: Products packaged as a system
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
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-2012-DA-15188-1 |
| Submission ID: | DA-2012-05726-1 |
| Sponsor's own reference: | sinus-Venous Stent |
| Application for: | Medical Device - Included |
| 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: | Pyramed Pty Ltd |
| Sponsor ID: | 47995 |
| Agent name: | 47G [redacted] |
| Contact details: | s22 [redacted] |
| Contact email: | s22 [redacted] |

| **Manufacturer Information** | |
|---|---|
| Manufacturer's evidence: | DV-20061110-MC-027677-11 :Optimed Annex II 50066-16-05 Goto |
| Manufacturer name: | Optimed Medizinische Instrumente (Germany)[28983] |
| Assessment route: | Council Directive 93/42/EEC (MDD) |
| Assessment body: | Dekra Certification GmbH [0124] |
| GMDN code: | Iliofemoral vein stent[58057] |
| GMDN description: | A sterile expandable tubular device intended to be implanted in an iliofemoral vein to maintain patency and improve luminal diameter in patients with symptomatic venous outflow obstruction. It is inserted and advanced to the site of implantation with a dedicated catheter where it self-expands upon release. The device is typically made of Nitinol and has a radiopaque marker for visualization; it is available in a variety of diameters and lengths. |
| Intended purpose: | Intended to be implanted in an iliofemoral vein to maintain patency and improve luminal diameter in patients with symptomatic venous outflow obstruction. To be used to treat symptomatic obstructions of the femoral vein or iliac vein. |

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

**Attached Documentation**

**History**

11/10/2012 2:05:08 PM Approved.

Payment notification mail has been sent to PDC on 4/10/2012
Review Completed - Accepted, 11/10/2012)
Decision notification mail has been sent to PDC on 12/10/2012

| **Record** | **Date** |
|---|---|

| | | | |
|---|---|---|---|
| Fee: | 890 | Date Paid: | 02/10/2012 |
| | | Date Decision: | 11/10/2012 |

| Start Dates | | Finish Dates | | Working Days |
|---|---|---|---|---|
| Application Received | 01/10/2012 | Payment Received | 02/10/2012 | 1 |
| Payment Received | 02/10/2012 | Application Decision | 11/10/2012 | 8 |
| | | | Total Working Days | 9 |