Medical Device Application

Class III
Status: Approved

Application Change history

2015/027230 s22 [redacted] 3/09/2015)

Application Progress Date	
Date received:	30/09/2016
Review Information	
Review flag:	Class or Type requires review
Auto review required:	No

ARTG & Product ID	
ARTG ID:	280883
Product ID:	559546

Application Details	
Application identifier:	DV-2015-DA-15058-1
Submission identifier:	DA-2015-06850-1
Sponsor's own reference:	WIRION Embolic Protection System
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
Cancel ARTG - product:	
Is this application supported by EU MDR/IVDR certification?	

Sponsor Details

Agent name:	Five Corners Pty Ltd
Sponsor name:	MD Solutions Australasia Pty Ltd
Contact details:	s22 [redacted]
Contact email:	s22 [redacted]

Class Details	
This application is to:	
Class:	Class III

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:	
Does the device consist of:	Products packaged as a system
Does the device contain material or ingredients of Animal Origin rendered non-viable	
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:	
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
Is this a Class IIb spinal fusion device:	
Is the device software:	

Manufacturer Details	
Manufacturer evidence number:	DV-2015-MC-15059-1 :Gardia Medical Annex II EC Certificate
Manufacturer name:	Gardia Medical Ltd (Israel)[63140]
Manufacturer address as on evidence:	2 Ha-Eshel Street Caesarea Industrial Park 38900 Israel S [210024]

GMDNS Code and Description	
GMDNS code and description:	Emboli capture guidewire[44841]

Device Category Terms	
Device category 1:	Single-use devices
Device category 2:	
Device category 3:	

Product Details	
Unique Product Identifier (UPI):	WIRION Embolic Protection System
Total number of devices covered:	1
Functional description:	The WIRION Embolic Protection System is a temporary embolic protection system, filtering distal to the intervention site. It is provided sterile and for single use. The system is a rapid exchange, pre-loaded filter that can be used with commercially available 0.014" guide wires.

Variant List

#	Variant type	Variant range
1.	Nil variant (as 1 device)	0

Device Details	
Device system name if applicable:	

Standard Conditions

The standard conditions that are imposed under section 41FO of the Therapeutic Goods Act 1989 when kinds of medical devices are included in the Register are as set out in the following paragraphs.
Each sponsor shall retain records of the distribution of all of the sponsor's medical devices included in the Register under Chapter 4. In the case of records relating to a Class AIMD medical device, Class III medical device, or Class IIb medical device that is an implantable medical device, the distribution records shall be retained for a minimum period of 10 years. In the case of records relating to any other device, the distribution records shall be retained for a minimum period of 5 years.
Where a medical device included in the Register, contains a substance which is included in the Fourth Schedule to the Customs (Prohibited Imports) Regulations or the Eighth Schedule to the Customs (Prohibited

Exports) Regulations the Sponsor shall, at the time of importation or exportation of the medical device, be in possession of a licence and a permission for importation or exportation of each consignment of the goods as required by those regulations.
The automatic conditions applicable to the inclusion of all kinds of medical devices in the Register are as specified in section 41FN of the Therapeutic Goods Act 1989.
For a medical device included in the Register under Chapter 4 and imported into Australia, the Sponsor must ensure that information about the Sponsor is provided in such a way as to allow the sponsor to be identified.
A sponsor shall ensure that a medical device within their control is stored and transported in accordance with the instructions and information provided by the manufacturer.
It is a condition of inclusion in the ARTG that the sponsor of a medical device that is an AIMD, Class III or implantable Class IIb provides three consecutive annual reports to the Head of the Office of Product Review, Therapeutic Goods Administration following inclusion of the device in the ARTG (as specified in 5.8 of the regulations). Annual reports are due on 1 October each year. Reports should be for the period 1 July to 30 June. The first report following the date of inclusion in the ARTG must be for a period of at least six months but no longer than 18 months. Subsequent reports are to be provided on 1 October for a further 2 years. The annual report must include all complaints and adverse events received by the manufacturer relating to problems with the use of the device that have been received by them over the year. For orthopaedic implant prosthesis that have been re-classified from Class IIb to Class III medical devices, annual report information must be submitted if the device meets either of the following criteria: I.The device was subject to a TGA application audit based on revision rate when the device transitioned from Class IIb to Class III; and/or II.No devices were supplied to the Australian marketplace before 30 June 2012. As per the standard automatic condition, annual reports should be submitted each year for the first three years of inclusion as a Class III medical device on the ARTG.
The sponsor of a medical device included in the Register under Chapter 4 shall keep an up to date log of information of the kind specified in Regulation 5.8.

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

30/09/2016 11:03:09 AM Approved.
Payment notification mail has been sent to PDC on 3/09/2015
Review Completed - Accepted, 30/09/2016)

Record		Date	
Fee	1265	Date Paid	01/09/2015
		Date Decision	30/09/2016

Start Dates		Finish Dates		Working Days
Application Received	30/09/2016	Payment Received	01/09/2015	0
			Total Working Days	0