Medical Device Application

Class IIa
Status: Approved

Application Change history

E21-335352 s22 [redacted], 20/07/2021)

Application Progress Date	
Date received:	13/07/2021
Review Information	
Review flag:	
Auto review required:	No

ARTG & Product ID	
ARTG ID:	372170
Product ID:	800330

Application Details	
Application identifier:	DV-2021-DA-13747-1
Submission identifier:	DA-2021-06410-1
Sponsor's own reference:	CARDIOVASCULAR SYSTEMS, 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	
Sponsor name:	Bio-Excel Australia Pty Ltd

Contact details:	s22 [redacted]
Contact email:	s22 [redacted]

Class Details

This application is to:	
Class:	Class IIa

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:	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:	
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:	No

Manufacturer Details

Manufacturer evidence number:	DV-2021-MC-11077-1 :CARDIOVASCULAR SYSTEMS, INC. WIRION Embolic Protection System
Manufacturer name:	Cardiovascular Systems Inc (United States Of America)[55172]
Manufacturer address as on evidence:	1225 Old Highway 8 NW Saint Paul MN 55112 United States Of America S [236319]

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):	
Total number of devices covered:	
Functional description:	

Variant List

#	Variant type	Variant range

Standard Conditions

- The inclusion of the kind of device in the ARTG is subject to compliance with all conditions placed or imposed on the ARTG entry. Refer Part 4-5, Division 2 (Conditions) of the Therapeutic Goods Act 1989 and Part 5, Division 5.2 (Conditions) of the Therapeutic Goods (Medical Devices) Regulations 2002 for relevant information.
- Breaching conditions of the inclusion related to the device of the kind may lead to suspension or cancellation of the ARTG entry; may be a criminal offence; and civil penalties may apply.

Non Standard Conditions

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

To remove, enter item #

Declaration

41FD Matters to be certified:

The applicant must certify that:
(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 subsection 41BD(2); 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) the applicant:
(i) has available sufficient information to substantiate that compliance with the essential principles; or
(ii) has procedures in place, including a written agreement with the manufacturer of the kind of devices setting out the matters required by the regulations, to ensure that such information can be obtained from the manufacturer within the period specified in the regulations; and
(f) either:
(i) an appropriate conformity assessment procedure has been applied to devices of that kind; or
(ii) requirements, comparable to the conformity assessment procedures, have been applied to devices of that kind; and
(g) the applicant:
(i) has available sufficient information to substantiate the application of the procedures referred to in subparagraph (f)(i) or the requirements referred to in subparagraph (f) (ii); or
(ii) has procedures in place, including a written agreement with the manufacturer of the kind of devices setting out the matters required by the regulations, to ensure that such information can be obtained from the manufacturer within the period specified in the regulations; and
(h) both of the following are complied with in relation to devices of that kind:
(i) the applicable provisions of the Therapeutic Goods Advertising Code;
(ii) the other requirements (if any) relating to advertising applicable under Part 5-1 or 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.

Note: See section 41BH for when a medical device complies with the essential principles, section 41BI for when conformity assessment procedures are taken not to have been applied to a medical device and section 41BIA for when requirements comparable to those procedures are taken not to have been applied to a medical device.

41FDA Basis of certification of conformity assessment procedures

When certifying the matter referred to in paragraph 41FD(f), the applicant must also state that the certification of the matter is based:
(a) on a conformity assessment certificate that is in force; or
(b) on an Australian conformity assessment body certificate that is in force; or
(c) on an overseas regulator conformity assessment document that is in force.

This is in accordance with Therapeutic Goods (Medical Devices—Information that Must Accompany Application for Inclusion in the Register) Determination.

IMPORTANT - It is taken that the person, who is stated in this application as the contact person, has authorised and electronically signed the declaration under section 41FD of the Act, as provided above, on behalf of the sponsor.

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

4/08/2021 12:01:26 PM Approved.
Payment notification mail has been sent to PDC on 16/07/2021
Review Completed - Accepted, 4/08/2021)

Record	Date	
Fee	Date Paid	15/07/2021
	Date Decision	04/08/2021

Start Dates		Finish Dates		Working Days
Application Received	13/07/2021	Payment Received	15/07/2021	2
			Total Working Days	2