Medical Device Application

Class IIb
Status: Approved

Application Change history

E22-584746 [redacted] 27/06/2022)
As a delegate of the Secretary of the Department of Health for the purposes of section 41FDB, I have carried out the assessment of this application, including: use of the correct form for the classification of the kind of medical device, application fee, information that accompanies the application, and certification of matters in section 41FD of the TG Act.

- Class IIb, in accordance with classification rule 2.3 (1) appears correct
- Conformity assessment document(s): EC certificate HD 60146947 0001- appropriate for classification and category of device
- Other information (GMDN Code, intended purpose and device product characteristics) – consistent and appears to be correct
- Instructions For Use – is correct and appropriate

Based on the above I am satisfied that the requirements have been met and the application has passed preliminary assessment. The application has not been selected for audit under section 41FH.
Therefore, as a delegate of the Secretary for the purposes of section 41FF of the TG Act, I have made a decision to include the kind of medical device in the ARTG. [redacted], 7/07/2022)

Application Progress Date	
Date received:	07/07/2022
Review Information	
Review flag:	
Auto review required:	No

ARTG & Product ID	
ARTG ID:	391930
Product ID:	846601

Application Details	
Application identifier:	DV-2022-DA-10321-1
Submission identifier:	DA-2022-05257-1
Sponsor's own reference:	[redacted]
Application for:	Medical Device - Included
Are you applying for a medical device production system?	No
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	○ Yes ○ No

Prosthesis List?	
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:	s47G [redacted]
Contact details:	s22 [redacted]
Contact email:	s22 [redacted]@icloud.com

Class Details	
This application is to:	
Class:	Class IIb

Device Product Characteristics

Is the device, or any form of the device, supplied sterile:	Yes
Sterilisation Method:	
Is the device intended to be invasive:	No
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:	No
Is the device software:	No

Manufacturer Details	
Manufacturer evidence number:	DV-2022-MC-15523-1 :FOSHAN Manufacturer IIb
Manufacturer name:	Foshun Biosun Medical Technology Co Ltd (China)[80675]
Manufacturer address as on evidence:	1-5F Building 4 No 89 Taoyuan East Road Shishan Nanhai Foshan Guangdong 528225 China S [261517]

GMDNS Code and Description	
GMDNS code and description:	Haemoperfusion unit, absorption column[34422]

Device Category Terms	
Device category 1:	Electro mechanical medical devices
Device category 2:	Single-use devices
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

7/07/2022 9:02:00 AM Approved.

Review Completed - Accepted, 7/07/2022)

Record		Date	
Fee	1098	s47G [redacted]	
		Date Decision	07/07/2022

Start Dates		Finish Dates	Working Days
Application Received	07/07/2022	s47G [redacted]	0
		Total Working Days	40