Medical Device Application

Class IIb
Status : Approved

Application Change history

Application Progress Date	
Date received:	16/06/2005
Review Information	
Review flag:	Request to cancel ARTG entry
Auto review required:	No

ARTG & Product ID	
ARTG ID:	120154
Product ID:	201578

Application Details	
Application identifier:	DV-20050616-DA-005004-1
Submission identifier:	DV-2005-2699
Sponsor's own reference:	MERSILENE Mesh
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:	Aust L 43186 - Product No. 131117

Sponsor Details	
Sponsor name:	Johnson & Johnson Medical Pty Ltd
Contact details:	[redacted]
Contact email:	[redacted]

Class Details	
Class:	Class IIb
Intended purpose:	For the repair of hernia and other fascial deficiencies that require the addition of a reinforcing or bridging material to obtain the desired surgical result.

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:	021210-WEBE-5GNU4H : Johnson & Johnson International #3 Annex II
Manufacturer name:	Johnson & Johnson International (Belgium)[27692]
Manufacturer address as on evidence:	LENNEKE MARELAAN 6 Belgium S [150529]

GMDNS Code and Description	
GMDNS code and description:	Mesh, surgical[16048]

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

UPI (Unique product identifier):	
Total number of devices covered:	
Functional description:	

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

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

27/06/2005 3:58:40 PM Approved.

Review Completed - Accepted, 27/06/2005)

Record		Date	
Fee	670	Date Paid	20/06/2005
		Date Decision	27/06/2005

Start Dates		Finish Dates		Working Days
Application Received	16/06/2005	Payment Received	20/06/2005	2

Payment Received	20/06/2005	Application Decision	27/06/2005	7
			Total Working Days	9