Medical Device Application

ARTG No : 117686

Class IIb
Status : Approved

Application Change history

Application Progress Date	
Date received:	18/03/2005
Review Information	
Review flag:	
Auto review required:	No

Device Product Characteristics

Application Summary	
Application ID:	DV-20050317-DA-001392-2
Submission ID:	DV-2005-1100
Sponsor's own reference:	PROLIFT Pelvic Floor Repair System
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
Sponsor name:	Johnson & Johnson Medical Pty Ltd
Sponsor ID:	267
Agent name:	
Contact details :	[redacted]
Contact email:	

Manufacturer Information	
Manufacturer's evidence:	021126-WEBE-5G8UM2 : Ethicon Sarl #2 Goto
Manufacturer name:	Ethicon SARL Switzerland (Switzerland)[32135]
Assessment route:	Council Directive 93/42/EEC (MDD) Council Directive 93/42/EEC (MDD)
Assessment body:	TUV SUD Product Service GmbH [0123]
GMDN code:	Mesh kit[45034]
GMDN description:	A collection of mesh, typically pre-cut, and various instruments (e.g., guide, cannula) used to implant mesh during a surgical procedure (e.g., repair of the pelvic floor).
Intended purpose :	Total, Anterior and Posterior pelvic floor repair system for tissue reinforcement and long-lasting stabilisation of fascial structures of the pelvic floor in vaginal wall prolapse.

Device Category Terms	
Device category 1:	Single use devices

Attached Documentation

History

30/03/2005 12:26:04 PM Approved.

Review Completed - Accepted, 30/03/2005)

Record		Date	
Fee:	670	Date Paid:	23/03/2005
		Date Decision:	30/03/2005

Start Dates		Finish Dates		Working Days
Application Received	18/03/2005	Payment Received	23/03/2005	3
Payment Received	23/03/2005	Application Decision	30/03/2005	8
			Total Working Days	11

Medical Device Application

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Application Change history

Application Progress Date	
Date received:	18/03/2005
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Auto review required:	No

ARTG & Product ID	
ARTG ID	117686
Product ID	198079

Application Details	
Application identifier:	DV-20050317-DA-001392-2
Submission identifier:	DV-2005-1100
Sponsor's own reference:	PROLIFT Pelvic Floor Repair System
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:	

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

Class Details	
Class:	Class IIb
Intended purpose:	Total, Anterior and Posterior pelvic floor repair system for tissue reinforcement and long-lasting stabilisation of fascial structures of the pelvic floor in vaginal wall prolapse.

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:	Products packaged as a system
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:	021126-WEBE-5G8UM2 : Ethicon Sarl #2

Manufacturer name:	Ethicon SARL Switzerland (Switzerland)[32135]
Manufacturer address as on evidence:	RUE DU PUITS GODET 20 NEUCHATEL CH-2000 Switzerland S[91416] RUE DU PUITS GODET 20 NEUCHATEL CH-2000 Switzerland S[91416]

GMDNS Code and Description	
GMDNS code and description:	Mesh kit[45034]

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

Product Details	
UPI (Unique product identifier):	
Total number of devices covered:	
Functional decription:	

Variant List

#	Variant type	Variant range

Device system name if applicable:	

Standard Conditions

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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