Medical Device Application

Class IIb
Status : Approved

Application Change history

Application Progress Date	
Date received:	22/12/2009

Review Information	
Review flag:	
Auto review required:	No

ARTG & Product ID	
ARTG ID	168581
Product ID	282699

Application Details	
Application identifier:	DV-2009-DA-14567-3
Submission identifier:	DA-2010-00047-7
Sponsor's own reference:	Lima Orthopaedics - SMR System glenoid components
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:	

Sponsor Details	
Agent name:	[redacted]
Sponsor name:	Lima Orthopaedics Australia Pty Ltd
Contact details:	[redacted]

Contact email:	[redacted]

Class Details	
Class:	Class IIb
Intended purpose:	A component of a shoulder joint prosthesis that is affixed to the glenoid cavity bone to replace or repair the articulating surface. The device may be designed to be used with or without bone cement.

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:	DV-2009-MC-13143-3 :Lima Ortho Aust - Lima Lto Italy

Manufacturer name:	Lima Lto SPA (Italy)[28937]
Manufacturer address as on evidence:	Via Nazionale 52 Villanova di San Daniele UDINE 33030 Italy S [103905]

GMDNS Code and Description

GMDNS code and description:	Prosthesis, internal, joint, shoulder, glenoid component[36259]

Device Category Terms

Device category 1:	Non-active implantable 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

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

(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

2/02/2010 1:00:29 PM Approved.

Review Completed - Accepted, 2/02/2010)

Record		Date	
Fee	790	Date Paid	04/01/2010
		Date Decision	02/02/2010

Start Dates		Finish Dates		Working Days
Application Received	22/12/2009	Payment Received	04/01/2010	9
Payment Received	04/01/2010	Application Decision	02/02/2010	30
			Total Working Days	39