



Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration

Record Summary	181919	Orthotech Pty Ltd - Lumbar total disc replacement prosthesis
Sponsor	Orthotech Pty Ltd	
Therapeutic Type	Medical Device	
Product Category	Included Class IIb	
ARTG Start Date	5/04/2011 11:00:00 PM	
Postal Address	PO Box 203, ALBION, QLD, 4010 Australia	
Billing Address	PO Box 203, ALBION, QLD, 4010 Australia	
Product Type	Medical Device - Class IIb - Included	
Status	Active	
Approval Area	Medical Devices	

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.

Manufacturers

Name	Address	Certificate number(s)
FH Industrie	6 Rue Nobel Z.I. de Kernevez , QUIMPER , 29000 France	DV-2011-MC-02920-3

Products

1 . Lumbar total disc replacement prosthesis

Product Type	Single Device Product	Status	Current
		Effective Date	6/04/2011
GMDN	48165 Lumbar total disc replacement prosthesis		
Functional Description	Not included on record		
Intended Purpose	The device is an artificial disc that can be implanted into the lumbar spine, replacing the damaged disc to permit normal load bearing and motion of the spine. The artificial disc is also called a disc replacement.		

Variant Information

Device Information

07 Non-active implantable devices

Specific Conditions

No Specific Conditions included on Record

Record Summary