



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 289017 Connexion Surgical Pty Ltd - Fixation device, internal, spine, construct

ARTG entry for Medical Device Included Class IIb
Sponsor Connexion Surgical Pty Ltd
Postal Address 12 Finch Avenue, Concord, NSW, 2137
Australia
ARTG Start Date 16/05/2017
Product Category Medical Device Class IIb
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
Neo Medical SA	Route de Lausanne 157 A 1096 Villette , Lavaux, Switzerland

Products

1 . Fixation device, internal, spine, construct

Product Type	Single Device Product	Effective Date	16/05/2017
GMDN	37272 Fixation device, internal, spine, construct		
Intended Purpose	A device that consists of rods/hooks/screws (including pedicle)/wires intended to help provide immobilization, correction and stabilization of spinal segments as an adjunct to fusion of the thoracic, lumbar, and/or sacral spine. It may be made of stainless steel, titanium or other materials. It may contain single use instruments.		
Product names	Neo Pedicle Screw System		

Specific Conditions

No Specific Conditions included on Record

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