



**Australian Government**  
**Department of Health and Aged Care**  
Therapeutic Goods Administration

**Public Summary**

**Summary for ARTG Entry:** 314229 Connexion Surgical Pty Ltd - Orthopaedic prosthesis implantation instrument, single-use

**ARTG entry for** Medical Device Included Class IIa

**Sponsor** Connexion Surgical Pty Ltd

**Postal Address** 12 Finch Avenue, Concord, NSW, 2137  
Australia

**ARTG Start Date** 14/02/2019

**Product Category** Medical Device Class IIa

**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**

<b>Name</b>	<b>Address</b>
Mighty Oak Medical	750 W Hampden Ave Suite 120 Englewood, Colorado, 80110 United States Of America

**Products**

**1 . Orthopaedic prosthesis implantation instrument, single-use**

<b>Product Type</b>	<b>Effective Date</b>
Single Device Product	14/02/2019

**GMDN** 58927 Orthopaedic prosthesis implantation instrument, single-use

**Intended Purpose** Pedicle screw navigation guide. Orthopaedic prosthesis implantation instrument, single-use.

**Specific Conditions**

No Specific Conditions included on Record

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