



Australian Government

Department of Health and Aged Care
Therapeutic Goods Administration

Australian Register of Therapeutic Goods Certificate

Issued to

Evolution Surgical Pty Ltd

for approval to supply

**Evolution Surgical Pty Ltd - Navient - Stereotactic surgery system,
neurological**

| | |
|-------------------------|---|
| ARTG Identifier | 437272 |
| ARTG Start Date | 24/01/2024 |
| Product Category | Medical Device Included Class IIb |
| GMDN | 32568 |
| GMDN Term | Stereotactic surgery system, neurological |
| Intended Purpose | Navient is an image-guided navigation system. It detects multimodal fiducials for automatic registration as well as allowing anatomic landmarks for manual registration for precisely positioning probes, other instruments, or implantable devices during image-guided neurosurgery, and is used in conjunction with navigation instruments and ancillaries. |

| Manufacturer Details | Address | Certificate number(s) |
|----------------------|---|-----------------------|
| ClaroNav Kolahi Inc | 1140 Sheppard Avenue West Unit 10 , Toronto , Canada | DV-2023-MC-31702-1 |

ARTG Standard Conditions

The above Medical Device Included Class IIb has been entered on the Register subject to the following 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.

Products Covered by This Entry

1. Navient - Stereotactic surgery system, neurological

Product Specific Conditions

No specific conditions have been recorded against this entry.

Therapeutic Goods Administration
PO Box 100, Woden ACT 2606 Australia
Phone: 1800 020 653
Email: info@tga.gov.au

ARTG Identifier: 437272
ARTG Start Date: 24/01/2024



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Evolution Surgical Pty Ltd - Stereotactic surgery system, orthopaedic

| | |
|-------------------------|---|
| ARTG Identifier | 433676 |
| ARTG Start Date | 12/01/2024 |
| Product Category | Medical Device Included Class 1 |
| GMDN | 45200 |
| GMDN Term | Stereotactic surgery system, orthopaedic |
| Intended Purpose | ClaroNav surgical instruments are manually operated devices for use during surgical procedures. These devices typically include positioning and alignment components and other instruments that may be used for spinal, cranial, biopsy and ENT image-guided surgery. |

| Manufacturer Details | Address | Certificate number(s) |
|----------------------|---|-----------------------|
| ClaroNav Kolahi Inc | 1140 Sheppard Avenue West Unit 10 , Toronto , Canada | |

ARTG Standard Conditions

The above Medical Device Included Class 1 has been entered on the Register subject to the following 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.

Products Covered by This Entry

1. Stereotactic surgery system, orthopaedic

Product Specific Conditions

No specific conditions have been recorded against this entry.

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ARTG Identifier: 433676
ARTG Start Date: 12/01/2024