



Australian Government

Department of Health and Aged Care
Therapeutic Goods Administration

Australian Register of Therapeutic Goods Certificate

Issued to

Emergo Asia Pacific Pty Ltd T/a Emergo Australia

for approval to supply

Emergo Asia Pacific Pty Ltd T/a Emergo Australia - Surgical planning/navigation-enhancement system

ARTG Identifier	275800
ARTG Start Date	25/05/2016
Product Category	Medical Device Included Class IIa
GMDN	61496
GMDN Term	Surgical planning/navigation-enhancement system
Intended Purpose	Navident is a dental navigation system intended to assist preoperative planning and real-time positioning of tools during dental procedures, when a pre-acquired CT scan of the jaw is available. In particular, it provides visual real-time feedback on the location of the active tip of a dental handpiece and its direction relative to a volumetric CT image of the patient's jaw anatomy registered to that anatomy, and, when a path has been planned, relative to a path planned on that image. It is intended to be used by a qualified dental surgeon as an optional aid.

Manufacturer Details	Address	Certificate number(s)
ClaroNav Inc	1140 Sheppard Ave West - Unit 10 Toronto , Ontario , M 3K 2A2 Canada	DV-2016-MC-06361-1

ARTG Standard Conditions

The above Medical Device Included Class IIa 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. Surgical planning/navigation-enhancement system

Product Specific Conditions

- No specific conditions have been recorded against this entry.

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ARTG Start Date: 25/05/2016