

Medical Device Details

Sponsor: Chris Mander
40B Howe Street
Howick
Auckland
New Zealand

WAND Reference: 190930-WAND-6TBVD8

Sponsors Own Reference: Straxcorp Radiology DICOM image processing application software

GMDN: Radiology DICOM image processing application software [57812]

Class: IIa

Intended Purpose: The software uses data from computed tomography scans of the Distal Radius to produce an analysis report on the bone microarchitecture and its fragility. This information can be used as an aid in the clinical assessment by healthcare professionals of general bone health disorders, specifically it can aid in the assessment of fracture risk and in monitoring the effects of treatment over time of bone disorders such as osteoporosis & osteomalacia

Manufacturer: StraxCorp Pty Ltd Suite 5, Level 10
470 Collins Street
Melbourne
Victoria
Australia

ARTG ID: 244571

- > The device is supplied unsterilised.
- > The device is not intended to be invasive.
- > The device is not intended for single use.
- > The device is an active device.
- > The device does not contain material or ingredients of microbial origin.
- > The device does not contain material or ingredients of recombinant origin.
- > The device does not contain material or ingredients manufactured or formulated using a genetically modified organism.
- > The device does not contain material or ingredients of human origin.
- > The device does not contain human blood or its components.
- > The device consists of: Single product
- > The device does not contain material or ingredients of animal origin.
- > The device is not medicated.
- > The device is not formulated.
- > The product does not contain a medicine that has consent for marketing in New Zealand.
- > The product does not contain a medical device which incorporates a medicine as an integral part and that has an action ancillary to the device.

Status: Active