



Medical Device Details

Sponsor: Clinical & Regulatory Services Limited
P O Box 766
Hastings
New Zealand

WAND Reference: 211101-WAND-6XVEGV

Sponsors Own Reference: Intelerad-35719-Class IIa-InteleradPACS

GMDN: Radiology picture archiving and communication system [35719]

Class: IIa

Intended Purpose: IntelPACS is a device that receives digital images and data from various sources (such as, CT scanners, MR scanners, ultrasound systems, R/F units, computer and direct radiographic devices, secondary capture devices, scanners, imaging gateways, or other imaging sources). Images and data can be communicated, processed, manipulated, enhanced, stored, and displayed within the system and/or across computer networks at distributed locations. Post-processing of the images can be performed using Multi Planar Reconstruction (MPR).

Manufacturer: Intelerad Medical Systems Incorporated 800 Boulevard De Maisonneuve Est
14th floor
Montreal
Quebec
Canada

ARTG ID:

- > 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