



Medical Device Details

Sponsor: Ossur New Zealand Limited
6/80 Westpoint Drive
Hobsonville
Auckland
New Zealand

WAND Reference: 211223-WAND-6Y6IPE

Sponsors Own Reference: Single-axis stabilizing knee prosthesis

GMDN: Single-axis stabilizing knee prosthesis [58962]

Class: IIa

Intended Purpose: The device is intended as a part of a prosthetic system that replaces knee function of a missing lower limb

Manufacturer: Ossur HF Grjothals 5
Reykjavik
Iceland

ARTG ID: 324606

- > 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