



Medical Device Details

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

WAND Reference: 240904-WAND-741W2Q

Sponsors Own Reference: College Park Industries Mecatroic Knee

GMDN: Lower-limb orthosis knee component, mechanical-resistance [66445]

Class: I

Intended Purpose: The product is intended for transfemoral amputees as a prosthetic medical device designed to restore some function of an anatomical knee joint

Manufacturer: College Park Industries Inc 17505 Helro Drive
Fraser
Michigan
United States

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