



## Medical Device Details

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

WAND Reference: 240905-WAND-741W5R

Sponsors Own Reference: College Park Industries Single Axis Stabilizing Knee

GMDN: Mechanical-resistance external knee prosthesis [64718]

Class: I

Intended Purpose: The device is intended for transfemoral amputees and is designed to restore some function of an anatomical knee.  
College Park Industries Inc 17505 Helro Drive

Manufacturer: 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 not 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