



## Medical Device Details

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

WAND Reference: 250521-WAND-75LD2V

Sponsors Own Reference: College Park Industries Passive Shoulder Prosthesis

GMDN: Passive shoulder prosthesis [41102]

Class: I

Intended Purpose: The device is a prosthetic shoulder joint intended to replace one or more functions of the biological human shoulder.

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

ARTG ID: 474973

- › 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