



Medical Device Details

Sponsor: CARSL Consulting
P O Box 480
Pukekohe
Auckland
New Zealand

WAND Reference: 080925-WAND-7JT6P7

Sponsors Own Reference: DEAL COPY - RestorativeTherapies_RT300-SL_RT300-SLSA_Class IIa

GMDN: Bicycle ergometer [10383]

Class: IIa

Intended Purpose: Restorative Therapies, Inc.'s The RT300-SL and RT300-SLSA systems are intended to allow a person with a neurological impairment to actively exercise using coordinated, electrically evoked or enhanced muscle contractions while remaining seated in their wheelchair or other chair through Functional Electrical Stimulation (FES) cycling.

Manufacturer: Restorative Therapies Inc 1434 Fleet Street
Baltimore
Maryland
UNITED STATES OF AMERICA

ARTG ID: 152657

- 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