



Medical Device Details

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

WAND Reference: 161208-WAND-6N7UFT

Sponsors Own Reference: XCITE CLINICAL STATION

GMDN: Stimulator, neuromuscular, [35370]

Class: IIa

Intended Purpose: Xcite is intended to be used for: 1. relaxation of muscle spasms; 2. prevention or retardation of disuse atrophy; 3. increasing local blood circulation; 4. muscle re-education; 5. immediate post-surgical stimulation of calf muscles to prevent venous thrombosis; 6. maintaining or increasing range of motion.

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

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: System
 - ☒ Components:
 - Component: Cart, optional cart
 - Component: Database, RTILink.com online database
 - Component: Electrodes, Adhesive electrodes
 - Component: Xcite Stimulator, Xcite Stimulator with: - one or two 6 channel stimulators - an easy-to-use touch interface - backup battery power - AC/DC power adapter
- 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

