

## **Medical Device Details**

**CARSL Consulting** 

Sponsor: P O Box 766
Hastings

New Zealand

WAND Reference: 161208-WAND-6N7UFT

Sponsors Own Reference: XCITE CLINICAL STATION

GMDN: Stimulator, neuromuscular - specify [35370]

Class: IIa

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.

Restorative Therapies Inc 8098 Sandpiper Circle, Suite M

Manufacturer: Nottingham Maryland

United States

## ARTG ID:

Intended Purpose:

> 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 a
- > 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