



Australian Government
Department of Health
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 147761 Enlightened Therapies Pty Ltd - Stimulator, electrical, analgesic, peripheral nerve, transcutaneous

ARTG entry for Medical Device Included Class IIa
Sponsor Enlightened Therapies Pty Ltd
Postal Address PO Box 191, CONCORD, NSW, 2137
 Australia
ARTG Start Date 28/11/2007
Product category Medical Device Class IIa
Status Active
Approval area Medical Devices

Conditions

- The inclusion of the kind of device in the ARTG is subject to compliance with all conditions placed or imposed on the ARTG entry. Refer Part 4-5, Division 2 (Conditions) of the Therapeutic Goods Act 1989 and Part 5, Division 5.2 (Conditions) of the Therapeutic Goods (Medical Devices) Regulations 2002 for relevant information.
- Breaching conditions of the inclusion related to the device of the kind may lead to suspension or cancellation of the ARTG entry; may be a criminal offence; and civil penalties may apply.

Manufacturers

Name	Address
Fuji Dynamics Mfg Ltd	Unit 1-3 23F / 788 Cheung Sha Wan Road Laws Commercial Plaza Kowloon, , Hong Kong - SAR of China

Products

1. Stimulator, electrical, analgesic, peripheral nerve, transcutaneous

Product Type	Single Device Product	Effective date	28/11/2007
GMDN	35372 Analgesic TENS system		
Intended purpose	The interactive electro neuroadaptive electrostimulation device is for the purpose of relief of pain, rehabilitation of disability by applying electrical stimulation onto the skin and the mucous membranes.		

Specific Conditions

No Specific Conditions included on Record

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