

## 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
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**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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