K041164

MAY 2 0 2004

# 10 510(k) Summary

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: _____

## 10.1 Submitter's Identification

Fuji Dynamics Ltd.
Unit 1-3, 23/F., Laws Commercial Plaza,
788 Cheung Sha Wan Road,
Kowloon, Hong Kong
Tel: (852) 2786 4218
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**Contact Person:** Anthony Ah Yin, Shum
**Date Prepared:** April 29th 2004

## 10.2 Name of Device:

**Proprietary Name:** L-TENS

**Common or Usual Name:** TENS unit

**Classification Name:** Stimulator, Nerve, Transcutaneous, for Pain Relief (21 CFR 882.5890)

**Device Classification:** Class II

## 10.3 Predicate Device Information:

The L-TENS is equivalent to the FDTENS 2010 (K994266).

## 10.4 Device Description:

The L-TENS is a handheld battery powered TENS device, which is used for pain relief. The device would generate electrical pulses and transmit it to the electrodes, which are attached to the patient's skin. Consequently, the electrical pulses would then pass through the skin to the underlying peripheral nerves to aid in the blocking of pain signals traveling to the brain.

L-TENS has one output channel and four preset programs. The program mode is displayed on a LCD. The user can adjust the output intensity by 14 steps.

**10.5 Intended Use:**

TENS is used for the symptomatic relief and management of chronic intractable pain and/or as an adjunctive treatment in the management of post-surgical and post-traumatic acute pain.

**10.6 Technological Comparison to Predicate Device:**

The L-TENS has basic technological characteristics that are substantially equivalent to the predicate device. Both devices are battery powered and have adjustable output amplitudes. On the contrary, the legally marketed predicate device has dual channels, while L-TENS is a 1-channel device. The only significant technological difference between the two devices is that L-TENS possesses an open-circuit detection feature. It means that L-TENS could check the continuity between the output terminals, and avoid increment of output in the absence of load.

All units use "shrouded patient cable connectors" to comply with the FDA's Final Rule "Medical Devices: Establishment of Performance Standards for Electrode Lead Wires and Patient Cables."

**10.7 Non-clinical Testing:**

Compliance to applicable voluntary standards includes ANSI/AAMI NS4-1986, as well as EN 60601-1, EN 60601-1-1 and EN 60601-1-2 requirements.

In addition to the compliance of voluntary standards, the software verification has been carried out according to the FDA software guidance.

**10.8 Clinical Testing**

Not Applicable as there are no new or innovative aspects that have been introduced.

**10.9 Conclusions:**

The L-TENS has the same intended use and similar technical characteristics as the FDTENS 2010 (K994266).

The information supplied in this 510(k) illustrates that the device do not pose any new questions of safety and effectiveness. Therefore, the L-TENS is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 2 0 2004

Anthony Ah Yin, Shum
R & D Department
Unit 1-3, Laws Commercial Plaza
788 Cheung Sha Wan Road
Hong Kong, China

Re: K041164
Trade/Device Name: L-TENS
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator
Regulatory Class: Class II
Product Code: GZJ
Dated: April 30, 2004
Received: May 3, 2004

Dear Mr. Shum:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# Indications for Use

510(k) Number (if known):

Device Name: L-TENS

Indications For Use:

The L-TENS is used for the symptomatic relief and management of chronic intractable pain and/or as an adjunctive treatment in the management of post-surgical and post-traumatic pain.

Prescription Use __X____ (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K 04 1169