JAN 2 5 2006

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: K052813

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
Fax: (852) 2744 6775

Contact Person: Anthony Ah Yin, Shum
Date Prepared: September 9th 2005

10.2 Name of Device:

Proprietary Name: FD TENS 2030

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 FD TENS 2030 is equivalent to the FDTENS 2010 (K994266).

10.4 Device Description:

The FD TENS 2030 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.

FD TENS 2030 has two output channels and five preset programs. The program mode is displayed on a LCD. The user can adjust the output intensity by 20 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 FD TENS 2030 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 only significant technological difference between the two devices is that FD TENS 2030 possesses an open-circuit detection feature. It means that FD TENS 2030 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 the 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 FD TENS 2030 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 FD TENS 2030 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

JAN 25 2006

Mr. Anthony Ah Yin Shum
Fuji Dynamics Ltd.
Unit 1-3, 23/F.
Laws Commercial Plaza
788 Cheung Sha Wan Road
Kowloon
HONG KONG

Re: K052813
Trade/Device Name: FD TENS 2030
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous electrical nerve stimulator for pain relief
Regulatory Class: II
Product Code: GZJ
Dated: January 11, 2006
Received: January 11, 2006

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.

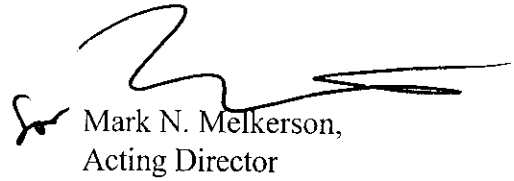
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act 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/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson,
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Appendix A—Indication For Use

510(k) Number (if known): K052813

Device Name: FD TENS 2030

Indications For Use:

The FD TENS 2030 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.

Prescription Use _X_ AND/OR Over-The-Counter Use ____
(Part 21 CFR 801 Subpart D)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K052813