FEB 1 1 2005

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: K043407

10.1 Submitter's Identification

Fuji Dynamics Ltd.
Unit 1-3, 23/F., Laws Commercial Plaza,
788 Cheung Sha Wan Road,
Kowloon, Hong Kong
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Contact Person: Anthony Ah Yin, Shum
Date Prepared: December 6th 2004

10.2 Name of Device:

Proprietary Name: INF 4160

Model Number: D-FJ27F

Common or Usual Name: Interferential Stimulator

Product Code: LIH

Device Classification: unclassified

10.3 Predicate Device Information:

The INF 4160 is equivalent to the IF-4000 (510(k) No.: K952683).

10.4 Device Description:

The INF 4160 is a rechargeable battery operated Interferential Current Therapy Device. Its internal circuitry can generate symmetrical sinusoidal waveforms. The associated outputs are delivered through lead cables to electrodes placed on the user/patient skin. The output passes through the skin and activates the underlying nerves. The symptomatic relief from chronic intractable pain can be obtained from this electrical stimulation.

10.5 Intended Use:

The intended uses of the INF 4160 are:

- Symptomatic relief of chronic intractable pain
- Adjunctive treatment for the management of post-traumatic or post-surgical pain.

10.6 Technological Comparison to Predicate Device:

The INF 4160 has basic technological characteristics that are substantially equivalent to the predicate device. The major significant technological difference between the two devices is that INF 4160 uses a pack of rechargeable batteries as the power source. The INF 4160 will cutoff the power source if the battery voltage drops below a preset value. In addition, it cannot be operated while the batteries are recharging. Therefore, this difference will not affect the safety and effectiveness of the device.

Both 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 items 3.1-3.1.2.1, 3.1.3-3.2.5, 4.1-4.2.3.2, as well as 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 INF 4160 has the same intended use and similar technical characteristics as the IF-4000 (510(k) No.: K952683).

The information supplied in this 510(k) illustrates that the device do not pose any new questions of safety and effectiveness. Therefore, the INF4160 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

FEB 11 2005

Anthony Shum
R&D Manager
Fuji Dynamics Ltd.
Liyatong Industrial District
Lin Chun, Tang Xia
Dong Guan, Guangdong, China

Re: K043407
Trade/Device Name: INF 4160
Regulation Number: Unclassified
Regulatory Class: Interferential Current Therapy Device
Product Code: LIH
Dated: January 18, 2005
Received: January 18, 2005

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" (21CFR 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,

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

FOR QUESTION 8

Appendix A—Indication For Use

510(k) Number (if known): K043407

Device Name: INF 4160

Indications For Use:

The INF 4160 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) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhern

(Division Sign-Off)

Division of General, Restorative, and Neurological Devices

510(k) Number K043407