E. 510(k) Summary (per 21 CFR 807.92)

Device 510(k) number: K092780

1. Applicant Information

Date Prepared: Aug 20, 2009 JAN - 7 2010

Submitter: Fuji Dynamics Ltd.
Unit 1-3, 23/F., Laws Commercial Plaza
788 Cheung Sha Wan Road, Kowloon
Hong Kong

Contact Person: LEE, Ching Kong Felix

Tel: (852) 2786 4218
Fax: (852) 2744 6775

2. General Device Information

Trade Name: INF 4160 PLUS
Model Code: D-FJ31F

Common Name: Interferential Stimulator

Product Code: LIH

Classification: unclassified

3. Predicate Device Information:

IF-4000 [510(k) No.: K952683]

4 Device Description

INF 4160 PLUS is an Interferential Current Therapy Device. It generates a set of symmetric sinusoidal electrical signals which are delivered to the user or patient through lead cables to the electrode pads placed on the skin. The electric signals stimulate the nerves underneath. The symptomatic relief from chronic intractable pain can be obtained from this electrical stimulation.

K092780

E. 510(k) Summary (per 21 CFR 807.92)

5 Intended Use:

INF4160 PLUS is intended to use as

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

6 Comparison to Predicate Device:

INF4160 PLUS has the following similarities when compared to the predicate device.

- The operating principle is the same.
- The intended use is the same.
- The power sourcing method is the same; both can operate with battery or AC adaptor.

7 Non-clinical Testing:

INF4160 PLUS complies with the following standard.

EN60601-1	Safety requirement
EN60601-1-2	EMC requirements

The design control follows the FDA quality system requirement and the software verification has been carried out according to the FDA software guidance.

8 Clinical Testing

None

9 Conclusions:

INF 4160 PLUS has the same intended use and the same technical characteristics as the predicate device, IF-4000 [510(k) No.: K952683].

INF4160 PLUS is as safe and as effective as the predicate device.

Therefore, the INF4160 PLUS is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Fuji Dynamics Limited
c/o Mr. Ching Kong Lee
Product Development Manager
Unit 1-3, 23/F, Laws Commercial Plaza
788 Cheung Sha Wan Road
Kowloon, Hong Kong
China

JAN - 7 2010

Re: K092780
Trade/Device Name: INF 4160 PLUS
Regulation Number: Unclassified
Regulation Name: Interferential Current Therapy
Regulatory Class: Unclassified
Product Code: LIH
Dated: November 26, 2009
Received: November 30, 2009

Dear Mr. Lee:

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 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Kesia Alexander for

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

D. Indication For Use

510(k) Number (if known):

Device Name: **INF 4160 PLUS**

Indications For Use:

The INF 4160 PLUS 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)

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

510(k) Number K092780