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

Device 510(k) number: K111645

1. Applicant Information

Date Prepared: Oct 7, 2011

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

Model Number: FD2050
Trade Name: Slide TENS
FD TENS 2050
Common Name: Transcutaneous Electric Nerve Stimulator
Product Code: GZJ
Classification: Class II

3. Predicate Device Information:

SMART TENS [510(k) No.: K091045]

4 Device Description

General

The FD2050 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.
FD2050 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.

Software

The software is built up with different software modules. The software modules are interconnected. One software module can be activated by another software module. The hardware is the physical interface to the user. The hardware passes or receives signal to or from the controller..

Operation (refer the Functional Block)

The microcontroller (MCU) takes request from the key pad (H2). It determines the logic and the parameter setting. It displays the information to the LCD (H1). The output intensity is directly related to the output voltage. The device makes use of a boost converter (H4) such that the controller sends different numbers of pulses to the boost converter build up desired amount of charges. The charges are released through a transistor bridge circuit (H5). The controller manipulates the pulse width, timing and polarity of the pulses in different program modes.

When battery gets dry, there is signal from voltage detection chip (H3) and the controller reflects the status on the screen by turning on an icon.
The open circuit detect circuitry (H6) can sense if electrode is detached. The controller reflects the status on the screen and turn down the output intensity.

Device Safeguards
Software Malfunction – watch dog timer is used to safeguard the malfunction or dead lock of software. The watch dog timer counts down to zero in 546ms. The software in the main loop resets and restarts the timer. If the microcontroller experiences deadlock in subroutine and cannot return to the main loop within 546ms, the device will be turned off and intensity level will be down to zero.

Shock Protection – the circuitry has the open circuit detection to prevent user from getting shock. It recognizes 500 to 20k ohm as the present of load and above 200k ohm to be open load. If the electrodes are physical detached from the device, the device will turn down the level to zero.

Battery Low – a voltage detection chip is used to monitor the voltage level. If the voltage drops below a threshold, it signals the microcontroller to alert the patient by displaying an icon.

5 Intended Use:
FD2050 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:
Similarity
Engineering
FD2050 is developed on the same platform as Smart TENS.
On hardware, the schematic and the use of electronics components are the same. The software is cloned from Smart TENS so the basic mechanism, like the basic timing, key scanning and generation of pulse are the same.

Intended Use
FD2050 is intended to be a Transcutaneous Electrical Nerve Stimulator, same as Smart TENS.

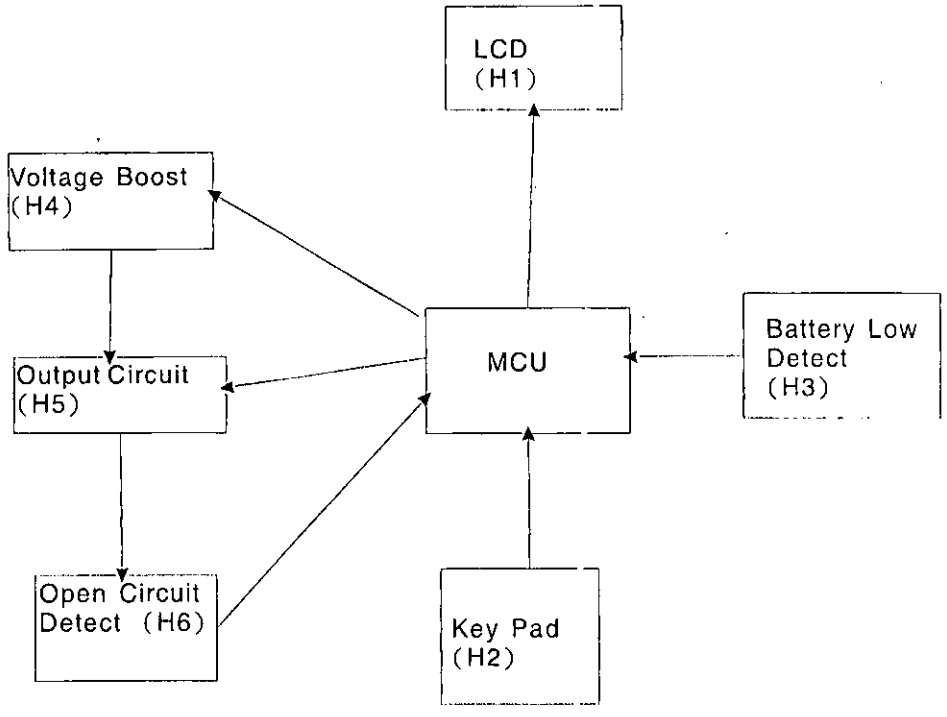
Biocompatibility
The polymer ABS of the biocompatibility test article is identical to the ABS of the final device in formulation, processing , and cleaning, and no other chemicals have been added (e.g., plasticizers, fillers, color additives, cleaning agents, mold release agents, etc.).

Difference
Since the shape of FD2050 is different from Smart TENS, the PC boards are different between two devices. The software basically the same while the parameters for treatment programs are changed so they have different treatment programs.

K111645

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

Functional Block



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

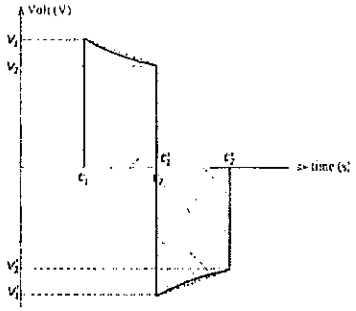
Output Specification Comparison

Parameter	FD2050 / Slide TENS K111645	SMART TENS K091045 (Predicate Device)
Waveform	Asymmetrical Bi-Phasic Rectangular Waveform	Asymmetrical Bi-Phasic Rectangular Waveform
Maximum Voltage (0 to peak voltage)	60V @500Ω 75V @2KΩ 83V @10KΩ	61V @500Ω 76V @2KΩ 90V @10KΩ
Max Output Current	120 mA @500Ω 37 mA @2KΩ 8 mA @10KΩ	122 mA @500Ω 38 mA @2KΩ 9 mA @10KΩ
Maximum Pulse Width	250 µs	250 µs
Maximum Frequency	150Hz	100Hz
Maximum Output Charge Per Phase	* 23.0µC @500Ω 17.1µC @1KΩ 11.9µC @2KΩ 3.4µC @10KΩ	28.4µC @500Ω 21.3µC @1KΩ 13.9µC @2KΩ 3.9µC @10KΩ
Maximum Output Net Charge Per Phase	* 11.9µC @500Ω 6.2µC @1KΩ 2.9µC @2KΩ 0.4µC @10KΩ	14.4µC @500Ω 6.5µC @1KΩ 2.9µC @2KΩ 0.4µC @10KΩ
Maximum Output RMS Current	* 13.1mA_{rms} @500Ω 8.4 mA_{rms} @1KΩ 5.3 mA_{rms} @2KΩ 1.4 mA_{rms} @10KΩ	14.4 mA_{rms} @500Ω 10.0 mA_{rms} @1KΩ 6.3 mA_{rms} @2KΩ 1.7 mA_{rms} @10KΩ
Max Current Density	* 0.22mA/cm^2 @500Ω	0.11 mA/cm^2 @500Ω
Max Power Density	* 5.3mW/cm^2 @500Ω	4.2 mW/cm^2 @500Ω
Treatment Timer	5 selectable timer Continuous 15 minutes 30 minutes 45 minutes 60 minutes	5 selectable timer Continuous 15 minutes 30 minutes 45 minutes 60 minutes
Continuous Stimulation (CONTS)	150us Selectable 1Hz to 150Hz	100Hz Selectable 20µs to 250µs
Burst (BURST 1 BURST 2)	Burst 1 28Hz, 150µs, 2 bursts/sec, 7 pulses/burst Burst 2 80Hz, 150µs,1 burst/2sec, 80 pulses/burst	32Hz, selectable 20µs to 250µs 2 burst/sec, 7 pulses/burst
Pulse Width Modulation (MODUL 1)	50µs -> 250µs in 6sec 250us -> 50us in 6sec repeat 42 selectable pulse rate between 1Hz and 150Hz	20us -> max pulse width in 5 sec max pulse width ->20us in 5sec repeat 23 selectable max pulse width between 20µs and 250µs
Frequency Modulation (MODUL 2)	Pulse width 150us 20Hz -> 100Hz in 6sec 100Hz -> 20Hz in 6sec Then repeat	Not Available

K111645

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

*** Sample Calculation**



$$V_{(t)} = V_1 e^{-(t-t_1)/\tau} \qquad \tau = \frac{-(t_2 - t_1)}{\ln\left(\frac{V_2}{V_1}\right)}$$

$$Q = \int_{t_1}^{t_2} i(t) \cdot dt = \frac{V_1}{R_L} \int_{t_1}^{t_2} e^{(t_1 - t)/\tau} dt = \frac{V_1 \tau}{R_L}\left[1 - e^{-(t_2 - t_1)/\tau}\right]$$

$$\tau_+ = \frac{-250\,\mu s}{\ln\left(\frac{18.0V}{60.0V}\right)} = 208\mu s \qquad Q_+ = \frac{60V \cdot 208us}{500\Omega}\left[1 - e^{-250\mu s/208\mu s}\right] = 17.44\mu C$$

$$\tau_- = \frac{-250\,\mu s}{\ln\left(\frac{7.2V}{16.0V}\right)} = 313\mu s \qquad Q_- = \frac{16V \cdot 313us}{500\Omega}\left[1 - e^{-250\mu s/313\mu s}\right] = 5.51\mu C$$

$$MaxCharge = Q_+ + Q_- = 17.44 + 5.51 = \underline{23.0\mu C}$$

$$NetCharge = Q_+ - Q_- = 17.44 - 5.51 = \underline{11.9\mu C}$$

$$CurrentDensity = \frac{Q_+ + Q_-}{period \cdot area} = \frac{(17.44 + 5.51)\mu C}{(1/150Hz) \cdot (4cm \times 4cm)} = \underline{0.22mA/cm^2}$$

$$I_{rms}^2 = \frac{1}{T}\int_{t_1}^{t_2}\left(\frac{V_1}{R_L} e^{-(t-t_1)/\tau}\right)^2 dt = \frac{\tau}{2T}\left(\frac{V_1}{R_L}\right)^2\left(1 - e^{-t_p/\tau}\right)$$

Positive pulse $$I_{rms}^2 = \frac{208\mu s}{2(1/150Hz)}\left(\frac{60V}{500\Omega}\right)^2\left(1 - e^{-250\mu s/208\mu s}\right) = 0.1571mA^2$$

+ve Pulse I_{rms}^2 = 0.1571mA^2

-ve Pulse I_{rms}^2 = 0.0132mA^2

$$I_{rms} = \sqrt{0.1571mA^2 + 0.0132mA^2} = \underline{13.1mA}$$

$$MaxPowerDensity = \frac{Effective\ Power}{Area\ of\ Electrode} = \frac{\sum (I_{rms}^2 \cdot R_L)}{A}$$

$$= \frac{(0.1571 + 0.0132)mA^2 \cdot 500\Omega}{4cm \cdot 4cm} = \underline{5.3\ mW/cm^2}$$

K111645

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7 Non-clinical Testing:

FD2050 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:

FD2050 has the same intended use and the same technical characteristics as the predicate device, SMART TENS [510(k) No.: K091045].

FD2050 is as safe and as effective as the predicate device.

Therefore, the FD2050 is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

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

NOV - 9 2011

Re: K111645
Trade/Device Name: Slide TENS FD TENS 2050
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous electrical nerve stimulator for pain relief
Regulatory Class: Class II
Product Code: GZJ
Dated: October 11, 2011
Received: October 12, 2011

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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/MedicalDevices/Safety/ReportaProblem/default.htm 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 (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

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): K111645

Model No.: FD2050
Device Name: FD TENS 2050
Slide TENS

Indications For Use:

The FD2050 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)

Daniel L. Kaufman -S

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

510(k) Number K111645