MAR - 1 2012

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

Device 510(k) number: K111654

1. Applicant Information

Date: Feb 8, 2012

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

Contact Person: NG, Kam Tim
Product Development Manager

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

2. General Device Information

Model No.: FD2070

Trade Name: Mini TENS

FD TENS 2070

Common Name: Transcutaneous Electric Nerve Stimulator (TENS)

Product Code: GZJ

Classification: Class II

3. Predicate Device Information:

FD2070 is substantially equivalent to FD TENS 2030 (K052813) which is also manufactured by Fuji Dynamics.

4. Device Description

As a Transcutanous Electrical Nerve Stimulator (TENS) unit, FD2070 generates 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.

5 Intended Use:

FD2070 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.

6 Comparison to Predicate Device:

Similarity

Engineering

Both FD2070 and FD TENS 2030 are developed by Fuji with the similar platform and technology.

Although the microcontrollers used are both devices are different, the software flow, the software logic and the modules are similar.

On hardware, the basic mechanisms generating the pulses are the same.

Intended Use

FD2070 is intended to be a Transcutaneous Electrical Nerve Stimulator, same as FD TENS 2030.

Biocompatibility

The polymer ABS of the biocompatibility test article is identical to the ABS of the predicate device (FD TENS 2030, K052813) 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 FD2070 is single channel but FD TENS 2030 is two channels, the electronics hardware are different. The treatment programs are also different.

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Characteristic	FD2070 / Mini TENS K111654	FD TENS 2030 K052813 (Predicate Device)
Waveform	Symmetrical Bi-Phasic	Asymmetrical Bi-Phasic
Shape	Rectangular	Rectangular
Maximum Voltage (peak voltage)	30V @500Ω 37V @2KΩ 39V @10KΩ	31V @500Ω 51V @2KΩ 85V @10KΩ
Max Output Current (peak current)	60mA @500Ω 18mA @2KΩ 4mA @10KΩ	63mA @500Ω 25 mA @2KΩ 9 mA @10KΩ
Maximum Pulse Width	333 µs	250µs
Maximum Frequency	120Hz	200Hz
Maximum Net Charge Per Pulse	* 0.5µC @500Ω	5.8µC @500Ω
Maximum Output Charge Per Phase	* 15.3µC @500Ω	15.8µC @500Ω
Maximum Output RMS Current	** 6.0 mA rms @500Ω	11.0 mA rms @500Ω
Max Current Density	** 0.074 mA/cm^2	0.1 mA / cm^2
Max Power Density	** 1.12 mW/cm^2	1.82 mW / cm^2
BURST 1	Burst 1 (Step 1) 80Hz 240pulses/burst, 1 burst/6sec 3 sec duration, 50% duty cycle Burst 1 (Step 2) 60Hz 240pulses/burst, 1 burst/8sec 4 sec duration, 50% duty cycle Burst 1 (Step 3) 100Hz 300pulses/burst, 1 burst/6sec 3 sec duration, 50% duty cycle	BURST I 80Hz Selectable pulse width between 25us and 250us 80pulses/burst, 1 burst/2sec 1 sec duration, 50% duty cycle Selectable pulse width
BURST 2	Burst 2 (Step 1) 60Hz 180pulses/burst, 1 burst/6sec 3 sec duration, 50% duty cycle Burst 2 (Step 2) 80Hz 80pulses/burst, 1 burst/2sec 1 sec duration, 50% duty cycle Burst 2 (Step 3) 100Hz 100pulses/burst, 1 burst/2sec 1 sec duration, 50% duty cycle	BURST II 28Hz Selectable pulse width between 25us and 250us 7pulses/burst, 2 burst/sec 1 sec duration, 50% duty cycle
BURST 3	Burst 3 (Step 1) 4Hz 96pulses/burst, 1 burst/28sec 24 sec duration, 85.7% duty cycle Burst 3 (Step 2) 60Hz 120pulses/burst, 1 burst/2.5sec 2 sec duration, 80% duty cycle Burst 3 (Step 3) 80Hz, 250us Amplitude Modulation 2.5Hz, 50% On 40sec, Off 4sec	

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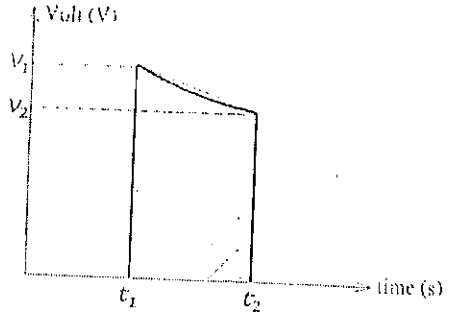
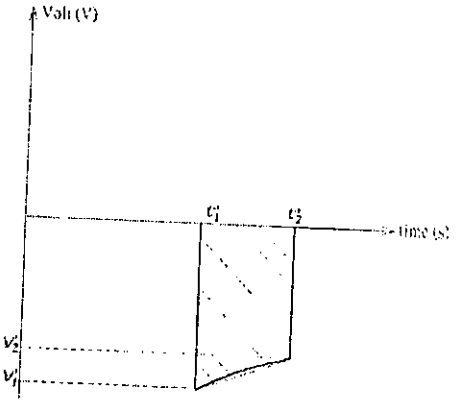
Continuous Mode	Not available	Selectable 1Hz to 200Hz Selectable 25us to 100us
Pulse Width Modulation	Not available	Selectable 1Hz to 200 Hz 25µs to 250µs in 8 sec 250us to 15us in 8sec, repeat
Frequency Modulation	Not available	Selectable 25us to 250us 100Hz to 20 Hz in 8 sec, 20Hz to 100Hz in 8sec, repeat
MODUL 1 **(Modulation 1)**	Modulation 1 (Step 1) 100Hz, 200µs 0.5Hz, 50% On 42sec, Off 6sec Modulation 1 (Step 2) 80Hz, 250µs 2Hz, 30% On 4sec, Off 4sec Modulation 1 (Step 3) 60Hz, 333µs 1.25Hz, 30% On 4sec, Off4sec	
MODUL 2 **(Modulation 2)**	Modulation 2 (Step 1) 100Hz, 200µs 0.5Hz, 50% On 38sec, Off 4sec Modulation 2 (Step 2) 80Hz, 250µs 1.25Hz, 40% On 8sec, Off 4sec Modulation 2 (Step 3) 120Hz, 167µs 1.25Hz, 40% On 8sec, Off 4sec	
MODUL 3 **(Modulation 3)**	Modulation 3 (Step 1) 120Hz, 167µs 0.5Hz, 50% On 40sec, Off 4sec Modulation 3 (Step 2) 100Hz, 120µs 0.25Hz, 50% On 36sec, Off 4sec Modulation 3 (Step 3) 80Hz, 250µs 0.125Hz, 50% On 56sec, Off 8sec	

*** Sample Calculation – using Burst 3 (Step 1)**

Positive Pulse



Negative Pulse



$$V_{(t)} = V_1 e^{-(t-t_1)/\tau}$$

$$\therefore \tau = \frac{-(t_2 - t_1)}{\ln\left(\frac{V_2}{V_1}\right)} \quad \text{..... (3)}$$

$$Q = \int_{t_1}^{t_2} i(t) \cdot dt = \frac{V_1}{R_L} \int_{t_1}^{t_2} e^{(t_1 - t)/\tau} dt = \frac{V_1 \tau}{R_L} \left[1 - e^{-(t_2 - t_1)/\tau}\right] \text{....(4)}$$

$$\tau_+ = \frac{-354\,\mu s}{\ln\left(\frac{2.4V}{30.8V}\right)} = 139\,\mu s \qquad \tau_- = 142\,\mu s$$

$$Q_+ = \frac{30.8V \cdot 139us}{500\Omega}\left[1 - e^{-354\mu s/139\mu s}\right] = 7.88\,\mu C \qquad Q_- = 7.41\,\mu C$$

The maximum charge per phase: $Q_+ + Q_- = 7.88 + 7.41 = \underline{15.3\,\mu C}$

The maximum net charge per phase: $Q_+ - Q_- = 7.88 - 7.41 = \underline{0.5\,\mu C}$

**** Sample Calculation – using Burst 1 (Step 3)**

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

From equation (3), (4) and (iii) above

	Positive Pulse	Negative Pulse
Equation (3)	$\tau_+ = \frac{-202\,\mu s}{\ln\left(\frac{6.0V}{31.2V}\right)} = 123\mu s$	$\tau_- = 120\mu s$
Equation (4)	$Q_+ = \frac{31.2V \cdot 123us}{500\Omega}\left[1 - e^{-202\mu s/123\mu s}\right] = 6.18\mu C$	$Q_- = 5.66\mu C$
Equation (iii)	$I_{rms}^2 = \frac{123\mu s}{2(1/100Hz)}\left(\frac{31.2V}{500\Omega}\right)^2\left(1 - e^{-202\mu s/123\mu s}\right)$ $= 0.0193mA^2$	$I_{rms}^2 = 0.0165mA^2$

$$I_{rms} = \sqrt{0.0193mA^2 + 0.0165mA^2} = \underline{6.0mA}$$

$$CurrentDensity = \frac{Q_+ + Q_-}{period \cdot area} = \frac{11.8\mu C}{(1/100Hz)\cdot(4cm \times 4cm)} = \underline{0.074mA/cm^2}$$

$$\frac{Effective\ Power}{Area\ of\ Electrode} = \frac{\sum (I_{rms}^2 \cdot R_L)}{A} = \frac{(0.0193 + 0.0165)mA^2 \cdot 500\Omega}{4cm \cdot 4cm} = \underline{1.12\,mW/cm^2}$$

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7 Non-clinical Testing:

FD2070 is compliance 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:

FD2070 has the same intended use and the same technical characteristics as the predicate device FD TENS 2030 (K052813).
FD2070 is as safe and as effective as 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. Tim Ng
Product Development Manager
Unit 1-3, 23/F., Laws Commercial Plaza
788 Cheung Sha Wan Road
Hong Kong, China

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Re: K111654
Trade/Device Name: FD TENS 2070
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator for Pain Relief
Regulatory Class: Class II
Product Code: GZJ
Dated: February 8, 2012
Received: February 23, 2012

Dear Mr. Ng:

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) : K111654

Model No.: FD2070
Device Name: Mini TENS
FD TENS 2070

Indications For Use:

FD2070 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)

Daryl L. Kaufman, Ph.D.

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

510(k) Number K111654