DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

January 22, 2016

Fuji Dynamics Ltd.
Man Man Chung
Product Development Manager
1-3, 23/F., Laws Commerical Plaza
788 Cheung Sha Wan Road
Hong Kong, China

Re: K152676
Trade/Device Name: FD TENS 2090 and FD TENS 2095
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator for Pain Relief
Regulatory Class: Class II
Product Code: GZJ, IPF
Dated: December 16, 2015
Received: December 21, 2015

Dear Man Man Chung:

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 contact the Division of Industry and Consumer Education 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. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Industry and Consumer Education 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,

Michael J. Hoffmann -A

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K152676

Device Name
FD TENS 2090 and FD TENS 2095

Indications for Use *(Describe)*
As a TENS device, FD TENS 2090 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.

As a EMS device, FD TENS 2090 is an electrically powered device intended for medical purposes that repeatedly contracts muscles by passing electrical currents through electrodes on the affected body area. It is intended for:
- Prevention or retardation of muscle disuse atrophy.
- Relaxation of muscle spasm.
- Muscle re-education.
- Maintaining or increasing range of motion.
- Increasing local blood circulation.
- Immediate post-surgical of calf muscle to prevent venous thrombosis.

FD TENS 2095 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.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

510(k) Summary
[As required by 21 CFR 807.92]

Device 510(k) number: K152676

1. Applicant Information

Date prepared: Aug 3, 2015
Submitter: Fuji Dynamics Ltd.
Unit 1-3, 23/F., Laws Commercial Plaza
788 Cheung Sha Wan Road, Kowloon
Hong Kong
Contact Person: Man Man Chung
Tel: (852) 2786 4218
Fax: (852) 2744 6775

2. General Device Information/Trade name

Model No: FD TENS 2090
FD TENS 2095

Common Name: Transcutaneous Electrical Nerve Stimulator and Powered Muscle Stimulator
Product code: GZJ, IPF
Classification: Class II

3. Predicate Device Information

510k number	Device Name	Manufacturer	Date cleared
K052813	FD TENS 2030	Fuji Dynamics	2006
K063642	FD EMS	Fuji Dynamics	2007

4. Device Description

FD TENS 2090

FD TENS 2090 can provide both TENS treatments and EMS treatments. During TENS treatments, the FD TENS 2090 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.

During EMS treatments, FD TENS 2090 generates electrical pulses and transmit it to the electrodes attached to the patient skin, causing the muscle to expand and contract. It is used to relax muscle spasms, prevent or retard atrophy, maintain or increase range of motion, increase local blood circulation, re-educate muscle and provide immediate post-surgical stimulation of calf muscle to prevent venous thrombosis.

FD TENS 2095

FD TENS 2095 can provide TENS treatments. During treatment, the FD TENS 2095 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:

FD TENS 2090

As a TENS device, FD TENS 2090 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.

As a EMS device, FD TENS 2090 is an electrically powered device intended for medical purposes that repeatedly contracts muscles by passing electrical currents through electrodes on the affected body area. It is intended for:

- Prevention or retardation of muscle disuse atrophy.
- Relaxation of muscle spasm.
- Muscle re-education.
- Maintaining or increasing range of motion.
- Increasing local blood circulation.
- Immediate post-surgical of calf muscle to prevent venous thrombosis.

FD TENS 2095

FD TENS 2095 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:

TENS Program comparison between FD TENS 2090, FD TENS 2095 and FD TENS 2030

Characteristic	**Subject device K152676**	**Predicate device K052813**
Device	FD TENS 2090 and FD TENS 2095	FD TENS 2030
Waveform	Symmetrical Bi-Phasic	Symmetrical Bi-Phasic
Shape	Rectangular	Rectangular
Maximum Voltage **Load: 0.50 kohm** **02 kohm** **10 kohm**	(0-peak voltage) 48.8V 70.4V 88.8V	(0-peak voltage) 31.3V 50.7V 85.0V
Maximum Current **Load: 0.50 kohm** **02 kohm** **10 kohm**	 97.6 mA 35.2 mA 8.88 mA	 62.6 mA 25.35 mA 8.5 mA
Maximum pulse width	250µs	250µs
Maximum frequency	150 Hz	200 Hz
Maximum Output **Net charge per phase** **Load: 500 ohm**	 10.41 µC	 5.83µC
Maximum output **Charge per phase** **Load: 500 ohm** **1kohm**	 22.13µC 16.33µC	 15.77µC 13.60µC
Maximum output **RMS Current** **Load: 500 ohm** **1kohm**	 11.55 mA rms 8.49 mA rms	 10.99 mA rms 8.95 mA rms
Max Current Density	0.15	0.1

(mA/cm^2)		
Max Power Density (W/cm^2)	.00525	.00182
Burst Mode **a. Pulses per burst** **b. Burst per second** **c. Burst duration** **d. Duty cycle** **a. Pulses per burst** **b. Burst per second** **c. Burst duration** **d. Duty cycle**	Burst 1 7 2 bursts per second 250 ms 50% Burst 2 80 1 burst per 2 seconds 1 second 50%	Burst II 7 2 250ms 50% Burst I 80 1 burst per 2 seconds 1 second 50%
Continuous Mode a. Pulse width b. Pulse frequency 	P1 CONST 59µs default Adjustable from 50µs to 250µs 120 Hz default Adjustable from 1 to 150 Hz	CONSTANT 50µs default Adjustable from 25 to 250µs 120 Hz default Adjustable from 1 to 200 Hz
Pulse width modulation a. Pulse width b. Pulse frequency 	P4 MODUL 1 50µs to 250µs in 5s 120Hz default Adjustable from 1 to 150 Hz	W. MODUL 25µs to 250µs in 8s 120 Hz default Adjustable from 1 to 200 Hz
Frequency modulation a. Pulse frequency b. Pulse width 	P5 MODUL 2 20 to 100 Hz in 5s 150µs default Adjustable from 50 to 250µs	F. MODUL 20 to 100Hz in 8s 50µs default Adjustable from 25 to 250µs

EMS Program comparison between FD TENS 2090 and FD EMS

Characteristic	**Subject device K152676**	**Predicate device K063642**
Trade name	FD TENS 2090	FD EMS
Waveform	Symmetrical Bi-Phasic	Symmetrical Bi-Phasic
Shape	Rectangular	Rectangular
Maximum Voltage **Load: 500 ohm** **2 kohm** **10 kohm**	(0 to peak voltage) 48.4 V 67.2 V 87.2 V	(0 to peak voltage) 48.7 V 60.0 V 64.7 V
Max Output current **Load: 500 ohm**	96.8 mA	97.40 mA

2 kohm **10 kohm**	33.6 mA 8.72 mA	30.0 mA 6.47 mA
Max pulse width	300µs	300µs
Max frequency	40 Hz	60 Hz
Biphasic waveform - **Symmetrical phases** - **Phase Duration**	Symmetrical Bi-Phasic Rectangular Waveform Fixed Pulse width, max 300 us	Symmetrical Bi-Phasic Rectangular Waveform Fixed Pulse width, max 300 us
Maximum Output Net Charge Per Phase **Load: 500 ohm**	13.05uC	3.57 uC
Maximum Output Charge Per Phase **Load: 500 ohm** **1 kohm**	 24.11 uC 17.77 uC	 48.61 uC 28.77 uC
Maximum Output RMS Current **Load: 500 ohm** **1 kohm**	 6.62 mA rms 4.91 mA rms	 12.5 mA rms 7.40 mA rms
Max Current Density (mA/cm2)	0.046	0.1966
Max Power Density (W/cm2)	0.00152	0.00614
On Time	5 or 10 sec fixed	1 to 9 sec adjustable
Off Time	10 or 30 sec fixed	1 to 9 sec adjustable
Output pattern - EMS Cycle Mode	Fixed pulse frequency, ramp up/down and work/rest time. Only pulse width is user selectable. (P6,P8,P9)	Fixed pulse widthandwork/rest time. Selectable frequency and ramp up/down time.
EMS Reciprocal Mode	Fixed pulse frequency, ramp up/down and work/rest time. Only pulse width is user selectable (P7).	Fixed pulse width andwork/rest time. Selectable pulse frequency and ramp up/down time.
Preset Program,P6 of subject device	Program Name P6 EMS Mode Cycle mode Pules Freq: 35Hz Pulse width:300µs Ramp up : 2sec On time : 10sec Ramp down : 2sec Off time : 30sec	Program Name CYCLE 2 EMS Mode Cycle mode Pules Freq: 50Hz* Pulse width:300µs Ramp up : 3sec On time : 9sec Ramp down : 3sec Off time : 15sec
Preset Program,P7of subject device	Program Name P7 EMS Mode Reciprocal mode Pules Freq: 40Hz Pulse width:300µs	Program Name RECIPROCAL 3 EMS Mode Reciprocalmode Pules Freq: 50Hz* Pulse width:300µs

	Ramp up : 4sec On time : 10sec Ramp down : 4sec Off time : 10sec	Ramp up : 4sec On time : 8sec Ramp down :4sec Off time : 14sec
Preset Program, P8	Program Name P8 EMS Mode Cyclemode Pules Freq: 40Hz Pulse width:300µs Ramp up : 4sec On time : 10sec Ramp down : 4sec Off time : 10sec	Program Name CYCLE 2 EMS Mode Cycle mode Pules Freq: 50Hz* Pulse width:300µs Ramp up : 3sec On time : 9sec Ramp down : 3sec Off time : 15sec
Preset program P9	Program Name P9 EMS Mode Cyclemode Pules Freq: 20Hz Pulse width:200µs Ramp up : 2sec On time : 5sec Ramp down : 2sec Off time : 10sec	Program Name CYCLE 1 EMS Mode Cycle mode Pules Freq: 50Hz* Pulse width:300µs Ramp up : 2sec On time : 6sec Ramp down : 2sec Off time : 10sec
Preset Program, P1	Program Name P1 Pulse width: 120µs default Adjustable from 50µs to 250µs Pulse freq: 120Hz default adjustable from 1 to 150Hz	Program Name CONSTANT 1 Pulse width: 50 µs fixed Pulse freq: 30Hz fixed ---------- Program Name CONSTANT 2 Pulse width 200µs fixed Pulse freq: 50Hz

7. Non clinical Testing

IEC 60601-1:2005 + CORR. 1 (2006) + CORR. 2 (2007) Safety requirement
IEC 60601-1-2:2007 (Edition 3) EMC requirement

8. Clinical testing

None

9. Conclusion

FD TENS 2090 and FD TENS 2095 have the same intended use and the same technical characteristics as the predicate device(s), FD TENS 2030 (K052813) and FD EMS (K063642). FD TENS 2090, FD TENS 2095 are as safe and as effective as the predicate device. Therefore, FD TENS 2090 and FD TENS 2095 are substantially equivalent to the predicate device.