DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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January 13, 2016

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

Re: K152374
Trade/Device Name: LL TENS 160A, LL TENS 160B
Regulation Number: 21 CFR 882.5890
Regulation Name: Stimulator, Nerve, Transcutaneous, Over-The-Counter
Regulatory Class: Class II
Product Code: NUH
Dated: December 8, 2015
Received: December 11, 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" (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 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,

William J. Heetderks -S

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)*
K152374

Device Name

LL TENS 160A
LL TENS 160B

Indications for Use *(Describe)*

The LL TENS 160A and LL TENS 160B are 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

Date of submission prepared: 24 December 2015

Submitter: Fuji Dynamics Ltd.

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Address of the manufacturing facility : No. A46, Gao Er South Road,
Pin Shan, Tangxia Town,
Dong Guan City,
Guang Dong Province, China

SUBMITTED DEVICE :

Generic Name: Transcutaneous Electrical Nerve Stimulator (T.E.N.S)

Proprietary or Trade Name: LL TENS 160A
LL TENS 160B

Common / Usual Name: Stimulator, nerve, transcutaneous, over-the counter

Classification Name: Stimulator, nerve, transcutaneous, over-the counter
21 CFR 882.5890

Product Code: NUH

Device Panel: Neurology

Device Classification: Class II

E. 510(k) Summary

PREDICATE DEVICES :

Device Name: Pain Buddy
Applicant: Biomedical Life Systems. Inc.
510(k) Number: K102051
Product Code: NUH

INDICATIONS FOR USE :

LL TENS 160A and LL TENS 160B are 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.

DEVICE DESCRIPTION :

LL TENS 160A and LL TENS 160B are handheld battery powered TENS devices for pain relief intended for over-the-counter use. The device would generate electrical pulses and transmit it to the electrodes, which are attached to the patient's (user'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.

LL TENS 160A and LL TENS 160B has two output channels and four preset programs. The program mode is displayed on LCD. The user can adjust the output intensity by 14 steps.

LL TENS 160A and LL TENS 160B have same hardware, software and mechanical structure. The difference is that LL TENS 160A's LCD display is placed on the bottom of keys while LL TENS 160B's LCD display is on the top of keys.

Since the device is battery powered, there is no connection to AC mains supply.

E. 510(k) Summary

SUMMARY OF SUBSTANTIAL EQUIVALENCE

Attribute	Applicant Device	Predicate Device
Product Name	LL TENS 160A LL TENS 160B	Pain Buddy
510(K) number	K152374	K102051
Product Code	NUH	NUH
Indications for use	This device 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.	Same as applicant device
Patient Population	Adult	Adult
Prescriptive or OTC	OTC	OTC
Environment of use	Clinics, hospital and home environment	Clinics, hospital and home environment
Number of output modes	4	1
Number of output channels	2	1
Waveform	Alternating Bi-phasic symmetrical Rectangular waveform	Asymmetrical Biphasic Rectangular waveform
Maximum output Voltage (max) 500 Ω 2K Ω 10K Ω	 70V 98V 108V	 30V 36.8V 38.4V
Maximum output Current (max) 500 Ω 2K Ω 10K Ω	 140 mA 49 mA 10.8 mA	 60 mA 18.4 mA 3.84 mA
Maximum Phase charge (500 Ω)	18.1 μC	13.3 μC

E. 510(k) Summary

Maximum Average Current (500 Ω)	0.9 mA	0.2 mA
Maximum Current density (500 Ω)	0.062 mA/cm^2	0.066 mA
Maximum Power Density (500 Ω)	2.25 mW/cm^2	2.28 mW / cm^2
Frequency (Hz)	90 Hz	80 Hz
Pulse Duration (μs)	208 μs	160 μs
Burst Mode	Yes	No
Timer range (min)	Continuous, 15 min, 30 min, 45 min and 60 min selectable.	Continuous
Indication display -On/Off status -Low Battery -Voltage/Current level -Output mode -Time to cut-off	 Yes Yes Yes Yes No	 Yes Yes Yes Yes No
Power Source	2 AAA Batteries	2 AAA Batteries
Dimensions (mm)	38 (W) x 127 (L) x 20 (H) mm	35 (W) x 125(L) x 16(H) mm
Weight	70 g	60 g
Housing material	ABS	ABS
Microprocessor control	Yes	Yes
Automatic Overload trip	No	No
Automatic no-load trip	Yes	Yes
Automatic shut-off	Yes	Yes
Electrode compliance with 21 CFR 898	Yes	Yes
Electrode cable	Yes	Yes

E. 510(k) Summary

DIFFERENCES BETWEEN NEW DEVICE AND PREDICATE DEVICE:

The technical characteristics of LL TENS 160A / LL TENS 160B are similar to those of the predicate devices in design, energy source, intended use and function. Like the predicate device Pain Buddy, the LL TENS 160A / LL TENS 160B is a device used to apply an electrical current to electrodes on a patient's skin to relieve pain.

LL TENS 160A and LL TENS 160B are developed on the similar platform as the predicate device Pain Buddy. On hardware, the schematic and the use of electronics components are similar. The software uses same mechanism as Pain Buddy. Therefore the basic timing, key scanning and generation of pulse are the same.

Some output parameters, including maximum output voltage, maximum output current, phase charge, maximum average current, maximum frequency and pulse duration are different from those of Pain Buddy. However, the maximum phase charge of LL TENS is 18.1uC, which is less than the limit of the safety standard. The Maximum average current is 0.9mA, which is also below the 10mA limit. The maximum average power density is 0.0025 W/cm^2, which is also less than 0.25W/cm^2. The maximum frequency of LL TENS is 90Hz. It is slightly higher than those of predicate device and thus does not raise question of safety and effectiveness. Finally, the maximum pulse duration is 208us and higher than those than of predicate device. Nevertheless, the maximum phase charge of LL TENS is still less than safety limit in this pulse duration. In conclusion, these differences between LL TENS and predicate device do not raise a question in safety and effectiveness.

The LL TENS 160A and LL TENS 160B are views as substantially equivalent to the predicate devices because the electrical stimulation provided by the LL TENS 160A and LL TENS 160B is substantially equivalent to that commonly employed by TENS devices that have been cleared for marketing without prescription labeling, i.e. for OTC use.

The differences between LL TENS and the predicate device do not raise questions on safety and effectiveness. In other word, LL TENS 160A and LL TENS 160B are as safe as the predicate device.

PERFORMANCE TESTS:

The relevant standards including :

IEC 60601-1:2005 + CORR. 1:2006 + CORR. 2:2007 + AM1:2012 Medical Electrical Equipment – Part 1: General requirements for basic safety and essential performance.

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IEC 60601-1-2:2007 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance. Collateral Standard: Electromagnetic Compatibility. (Edition 3).

IEC 60601-1-11:2010 Medical electrical equipment – Part 1-11 General requirement for basic safety and essential performance – Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment.

IEC 60601-1-6:2010 Medical electrical equipment – Part 1-6 General requirements for basic safety and essential performance – Collateral standard: Usability.

USABILITY STUDY:

A usability study has been performed and showed that users were able to use the device correctly and safety.

CONCLUSION:

The electrical stimulation provided by the LL TENS 160A and LL TENS 160B is similar to that commonly employed by TENS devices that have been cleared for marketing without prescription labeling (i.e. OTC).

LL TENS 160A and LL TENS 160B have the same intended use and the same technical characteristics as the OTC cleared predicate device, Pain Buddy [510(k) No.: K102051].

The differences between LL TENS and the predicate device do not raise questions on safety and effectiveness. In other words, LL TENS 160A and LL TENS 160B are as safe as the predicate device.

Thus, the new device LL TENS 160A and LL TENS 160B are substantially equivalent to the predicate device.