DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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May 29, 2015

Easymed Instruments Co., Ltd
Mr. Jeffery Wu (Wu Tingjie)
General Manager
5/F – 6/F, Block A, Gupo Gongmao Building, Fengxin Road,
Fengxiang Industrial District, Daliang, 528300 Shunde, Foshan,
Guangdong, CHINA

Re: K143430
Trade/Device Name: SmartTENS
Regulation Number: 21 CFR 882.5890
Regulation Name: Stimulator, Nerve, Transcutaneous, Over-The-Counter
Regulatory Class: Class II
Product Code: NUH
Dated: April 30, 2015
Received: May 4, 2015

Dear Mr. Tingjie Wu:

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,

Felipe Aguel -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)*
K143430

Device Name
SmartTENS

Indications for Use *(Describe)*

This device is intended for the relief of pain associated with sore or aching muscles of the lower back, arms, or legs due to strain from exercise or normal household and work activities.

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.

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510(k) Summary

Date of submission prepared: October 6, 2014

Submitter: EasyMed Instruments Co., Ltd.
Address: 5/F – 6/F, Block A, Gupo Gongmao Building, Fengxin Road, Fengxiang Industrial District, Daliang, 528300 Shunde, Foshan, Guangdong, CHINA
Tel : +86 757 2809 1300
Fax : +86 757 2772 7868
E-Mail : jeffery@easymed.com.cn

Official Contact: Jeffery Wu (Wu Tingjie)

Address of the manufacturing facility: The same as above

SUBMITTED DEVICE:

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

Proprietary or Trade Name: SmartTENS

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

PREDICATE DEVICES:

Device Name: EasyStim TN28_OTC
Manufacturer: EasyMed Instruments Co., Ltd.
510(k) Number: K140168
Product Code: NUH

Add: 5/F-6/F, Gupo Gongmao Building, Fengxin Road, Fengxiang Industrial District, Da Liang, 528300 ShunDe, GuangDong, China
Tel: 86-757-28091300 Fax：86-757-27727868

Device Name: WiTouch™ Pro
Manufacturer: Hollywog, LLC
510(k) Number: K120398
Product Code: GZJ, NYN

INDICATIONS FOR USE:

This device is intended for the relief of pain associated with sore or aching muscles of the lower back, arms, or legs due to strain from exercise or normal household and work activities.

DEVICE DESCRIPTION:

SmartTENS is a portable battery powered T.E.N.S. device with a wireless remote control feature for over-the-counter use, mainly operating in home, clinic, or hospital environments.

There are three control buttons on the unit itself: ON/OFF, intensity UP and intensity DOWM. The device is also designed to be controlled wirelessly through Bluetooth 4.0 connection (Frequency: 2402.0 – 2480.0 MHz) by a matched smart phone, which is featuring a mobile application (App) developed by EasyMed Instruments Co., Ltd.

A user entered 6-digit security code ensures the access to the device can only be the user's matched smart phone, thus avoiding unauthorized controls to the device.

There are totally seven (7) modes that are intended for pain relieving treatments to the following areas: Shoulder/ Arm, Lower Back and Leg/Foot. The specifications of each mode will be described in greater details in the User Manual.

Accessories:

M-CBX-C-008	Button-affixed Electrode
P-AE-002-A	Replaceable Hydrogel Pads (gel-pads) 73mm x 62mm for external use. Pack of 2*
CBX-057-B	Charger Cradle
M-PA-004-B	Charging Adaptor

The accessories include an electrode and two hydrogel pads (gel-pads). The electrode is connected to the device by snapping the two buttons onto the device. One side of the adhesive gel-pads adheres to the electrode, and the other side adhere the device to the healthy intact skin of the user's body. Generally, the device produces either a fixed or modulated electrical signal through electrodes normally placed over the area of pain.

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A built in Li-Ion battery is the power source of the device, which can be recharged for a limited large number of times. To charge the device, remove the electrode assembly by unsnapping it off the device, place the device on the charger cradle, insert the small pin of the charging adaptor into the charge cradle, and connect the charging adaptor to the electrical power supply.

Smart Phone Hardware Requirement:

1) iPhone 4s or later models, or iPad 3 or later models, with iOS 6.0 or better system.

Or,

2) Smart phone or Tablet supporting BT 4.0 BLE feature with Android 4.3 or better system.

As above, the device is battery powered; there is no connection to AC mains supply.

ENVIRONMENT OF USE: Clinics, hospital and home environments

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SUMMARY OF SUBSTANTIAL EQUIVALENCE

Attribute	New Device	Predicate Device (1)	Predicate Device (2)
Product Name	SmartTENS	EasyStim TN28_OTC	WiTouch™ Pro
510(K) number	K143430	K140168	K120398
Product Code	NUH	NUH	GZJ, NYN
Regulation No.	21 CFR 882.5890	21 CFR 882.5890	CFR Title 21, 882.5890
Indications for Use	This device is intended for the relief of pain associated with sore or aching muscles of the lower back, arms, or legs due to strain from exercise or normal household and work activities.	This device is intended for the relief of pain associated with sore or aching muscles of the lower back, arms, or legs due to strain from exercise or normal household and work activities.	This device is used for the symptomatic relief and management of chronic intractable back pain and relief of pain of the upper and lower back associated with arthritis. It is also used for adjunctive treament fro post-surgical and post-trauma acute back pain.
Patient Population	Adult	Adult	Not specified
Prescriptive or OTC	OTC	OTC	Prescription
Wireless Control	Yes	No	Yes
Number of output modes	7	8	4
Number of output channels	1	2	1
Waveform	Biphasic rectangular Monophasic rectangular	Biphasic rectangular Monophasic rectangular	Plused biphasic rectangular
Maximum Output Voltage(max) 500 ohm 2k ohm 10k ohm	 68V @500Ω 102V @ 2 kΩ 110V @10 kΩ	 68V @500Ω 102V @ 2 kΩ 110V @10 kΩ	 35.2 V @500Ω 52V @ 2 kΩ 60.8V @10 kΩ
Maximum Output Current(max) 500 ohm 2k ohm 10k ohm	 133mA 51mA 11mA	 133mA 51mA 11mA	 70mA @500Ω 26mA @ 2 kΩ 6mA @10 kΩ
Maximum Phase	20.02μC	20.02μC	11.6μC

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charge (500 ohm)			
Maximum Average Current (500 ohm)	3.0375mA	3.0375mA	0.63mA
Maximum Current Density (500 ohm)	0.066mA/cm^2	0.188mA/cm^2	0.00149 mA/cm^2
Maximum Average Power Density (500 ohm)	2.66mW/ cm^2	7.52mW/ cm^2	0.0313mW/cm^2
Frequency (Hz)	From 1Hz to 150Hz	From 1Hz to 150Hz	From 5Hz to 120Hz
Pulse Duration (μs)	50-250μs	50-250μs	120-250μs,
Burst Mode	Yes	Yes	No
Timer range(min)	20min, 25min, 30min, 40min depending on preset program	20min, 25min, 30min, 40min depending on preset program	30min
Power Source	3.7V rechargeable lithium battery	2 Alkaline AA 1.5V (LR6) Batteries	2 Alkaline AAA 1.5V DC Batteries 1 CR2032 Lithium battery (Internal Power)
Dimensions (mm)	155.4 x 64.6 x 19.1	66×136×30.7	18 x 191 x 90
Weight	64g	146.5 grams	4.8 oz
Housing material	TPE & ABS	ABS	Silicone & ABS
Microprocessor control	Yes	Yes	Yes
Automatic Overload trip	Yes	Yes	No
Automatic no-load trip	Yes	Yes	No
Automatic shut-off	Yes	Yes	Yes
User override control	Yes	Yes	Yes
Indicator Display: - On/Off Status? - Low Battery? - Voltage/Current Level? -Output mode -Time to cut-off	 Yes Yes Yes Yes Yes	 Yes Yes Yes Yes Yes	 Yes Yes No No No
Electrode compliance with 21 CFR 898	Yes	Yes	Yes
Electrode cable	No	Yes	No

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DIFFERENCES BETWEEN NEW DEVICE AND PREDICATE DEVICES

The technical characteristics of SmartTENS are similar to those of the predicate devices in design, intended use and function. Like the predicate device EasyStim TN28_OTC (K140168) and WiTouch™ Pro (K120398), the SmartTENS is a device used to apply an electrical current to electrodes on a patient's skin to relieve pain. The stimulation parameters of new device EasyStim TN28_OTC are same as those of predicate device EasyStim TN28_OTC (K140168) and similar to those of WiTouch™ Pro (K120398).

The predicate device EasyStim TN28_OTC (K140168) utilizes flexible wires between the electrodes and the electical stimulus generator. However, the new device SmartTENS utilize wireless remote controls for the considerations of a more user friendly design, which is similar to WiTouch™ Pro (K120398).

The intended design of SmartTENS limits the application for use to sites of lower back, arms and legs. The design includes Thermal Plastic Elastomer (TPE) electrodes that are intended for reuse and are button-affixed to the electrical stimulus generator. The unique connection makes the electrodes integral to the generator. The connection and shape of the electrodes limit application of the device. These unique characteristics of the integral electrodes are similar to those of WiTouch™ Pro (K120398) and insignificant as it relates to safety and effectiveness, which is not critical to the intended use between the device and the referenced predicate devices.

The predicate device EasyStim TN28_OTC (K140168) utilizes affixed buttons as the sole method to control the electrical stimulus generator. The new device SmartTENS utilizes an additional method of a wireless remote control which similar to the predicate device WiTouch™ Pro (K120398). The difference is WiTouch™ Pro (K120398) utilizes radio frequency transveiver to control the electrical stimulus generator, while the SmartTENS ultilzes Bluetooth 4.0 as the wireless connecting technology to control the electrical stimulus generator. Furthermore, the remote controller is the Mobile Medical Application that need to be installed in the smart phone. This uniqueness of controlling the electrical stimulus generator by utilizing a Bluetooth wireless connecting technology is insignificant as it relates to safety and effectiveness, and is not critical to the intended use between the device and the referenced predicate devices.

Technological characteristics, features, specifications and intended uses of the new device SmartTENS are substantially equivalent to the referenced predicate devices. The differences that exist between SmartTENS and predicate devices are insignificant in the terms of safety or effectiveness.

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PERFORMANCE TESTS

FDA recognition No.	Standard Title
19-5	AAMI/ANSI ES60601-1:2005/(R)2012 And A1:2012,, C1:2009/(R)2012 And A2:2010/(R)2012 (Consolidated Text) Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance (IEC 60601-1:2005, Mod). (General I (QS/RM))
19-2	AAMI / ANSI / IEC 60601-1-2:2007/(R)2012, Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements And Tests (Edition 3). (General II (ES/EMC))
19-6	IEC 60601-1-11 Edition 1.0 2010-04, Medical Electrical Equipment - Part 1-11: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Requirements For Medical Electrical Equipment And Medical Electrical Systems Used In The Home Healthcare Environment [Including: Technical Corrigendum 1 (2011)]. (General II (ES/EMC))
17-11	IEC 60601-2-10 Edition 2.0 2012-06, Medical Electrical Equipment -- Part 2-10: Particular Requirements For The Basic Safety And Essential Performance Of Nerve And Muscle Stimulators. (Neurology)
5-40	ISO 14971: Second Edition 2007-03-01 Medical devices- Application of Risk Management To Medical Devices. (General I (QS/RM))
5-85	IEC 60601-1-6 Edition 3.0 2010-01, Medical Electrical Equipment-Part 1-6: General Requirements For Basic Safety and Essential Performance- Collateral Standard: Usability(General I (QS/RM))
13-8	IEC 62304 First Edition 2006-05, Medical devices software- Software life cycle processes (Software/ Informatics)

USABILITY STUDY:

A usability study was conducted and showed that users were able to use the device correctly and safety.

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CONCLUSION:

The new device SmartTENS has the same indications for use and similar technological characteristics to the predicate device EasyStim TN28_OTC (K140168) and WiTouch™ Pro (K120398). The stimulation parameters of new device SmartTENS are all in the same range of those of predicate devices. Thus, the new device SmartTENS is substantially equivalent to the predicate devices and any differences between the devices do not pose any new questions of safety and effectiveness.

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