DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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August 14, 2015

Andon Health Co., Ltd.
Liu Yi
President
No. 3, Jin Ping Street, Ya An Road, Nankai District
Tianjin, CN 300190

Re: K150043
Trade/Device Name: AD-2129A Transcutaneous Electrical Nerve Stimulators (TENS)
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator for Pain Relief
Regulatory Class: Class II
Product Code: NUH, NYN
Dated: July 14, 2015
Received: July 16, 2015

Dear Liu Yi:

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 -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)*
K150043

Device Name
AD-2129A Transcutaneous Electrical Nerve Stimulators (TENS)

Indications for Use *(Describe)*
The AD-2129A TENS device is intended for temporary relief of pain associated with sore and aching muscles due to strain from exercise or normal household and work activities. It is also intended for symptomatic relief and management of chronic, intractable pain and relief of pain associated with arthritis.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary

K150043

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirement of SMDA and 21 CFR 807.92.

1.0 submitter's information

Name: Andon Health Co., Ltd.
Address: No 3, Jinping Street Ya An Road, Nankai District, Tianjin, P.R. China
Phone number: 86-22-6052 6161
Fax number: 86-22-6052 6162
Contact: Liu Yi
Date of Application: 1/7/2015

2.0 Device name

Classification Name: Stimulator, Nerve, Transcutaneous, Over-The-Counter
Device name: Transcutaneous Electrical Nerve Stimulators (TENS)
Model: AD-2129A

3.0 Classification

Production code: NUH, NYN
Regulation number: 21 CFR 882.5890
Classification: II
Panel: Neurology

4.0 Predicate device information

Information	Predicate 1	Predicate 2
510(k) number:	K131159	K140168
Manufacturer	Chattem, Inc.	EasyMed Instruments

		Co., Ltd.
Trade/Proprietary Name	Smart Relief	EasyStim TN28_OTC
Classification Name	Transcutaneous Nerve Stimulator.	Transcutaneous Nerve Stimulator.
Regulation number	882.5890	21 CFR 882.5890
Classification	Class II	Class II
Product Code	NUH, NYN	NUH

5.0 Intended use

The AD-2129A TENS device is intended for temporary relief of pain associated with sore and aching muscles due to strain from exercise or normal household and work activities, It is also intended for symptomatic relief and management of chronic, intractable pain and relief of pain associated with arthritis.

6.0 Device description

The AD-2129A Transcutaneous Electrical Nerve Stimulator(TENS) is transcutaneous electrical nerve stimulator for relief of muscular pain and sold without prescription.

The device consists of a microprocessor, buttons, electrical pads, and display. Keys can control the device to choose the operation modes, adjust pulse output strength, then the channel that effectively transfers your desired choice of programmed electrical pulses directly through electrode adhesive pads to the suggested area of the body where the electrodes are placed, causing minimal muscle stimulation. The LCD display can show user the mode and strength chosen and other information like date and time

Self-adhesive electrodes are used in this devices, and they are intended for use as the disposable, conductive adhesive interface between the patient's skin and the Electrical Stimulator. The electrodes is for OTC use, and mainly consists of substrate and wire.

7.0 Performance summary

TENS conforms to the following standards:

- IEC 60601-1, Medical Electrical Equipment - Part 1: General Requirements for Safety, 2005.
- IEC 60601-2-10, Medical electrical equipment Part 2: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators
- IEC 60601-1-2, Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral standard: Electromagnetic Compatibility - Requirements and Tests, 2007.
- ISO 10993: Biological evaluation of medical devices Part 1: Evaluation and testing within a risk management process.
- ISO 10993: Biological evaluation of medical devices Part 5: Test for in vitro cytotoxicity.
- ISO 10993: Biological evaluation of medical devices Part 10: Test for irritation and skin sensitization.

8.0 Non-clinical Testing Summary

The following testing was performed on the TENS devices in accordance with the requirements of the design control regulations and established quality assurance procedures.

(1) Biocompatibility of materials

When use the TENS device, one side of the electrode will contact the user, and the materials used on this side is tested according to ISO 10993-5 and ISO 10993-10, and the result shows it meet the applicable requirements.

(2) Electromagnetic Compatibility

Electromagnetic Compatibility test has been performed on the TENS devices according to the identical standard of IEC 60601-1-2, and the test result show that, the device meet all the applicable requirements.

(3) Electrical Safety Testing

Electrical Safety Test has been performed according to IEC 60601-1, and the test result shows that, the device meet all the applicable requirements. Also,

particular safety test has been performed according to IEC 60601-2-10.

9.0 Comparison to the predicate device and the conclusion

The applicant device TENS is substantially equivalent to Smart Relief (K131159) and EasyStim TN28_OTC(K140168).

Similarities and differences comparison			
Characteristics	**Subject device**	**Predicate device(1)**	**Predicate device(2)**
Product name	AD-2129A TENS device	Smart Relief	EasyStim TN28_OTC
510(K)number	To be assigned	K131159	K140168
Product code	NUH, NYN	NUH, NYN	NUH
Regulation No.	21 CFR 882.5890	21 CFR 882.5890	21 CFR 882.5890
Intended use	The device is intended for temporary relief of pain associated with sore and aching muscles due to strain from exercise or normal household and work activities, It is also intended for symptomatic relief and management of chronic, intractable pain and relief of pain associated with arthritis.	To be used for temporary relief of pain associated with sore and aching muscles due to strain from exercise or normal household and work activities. To be used for symptomatic relief and management of chronic, intractable pain and relief of pain associated with arthritis.	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.
Presentation or OTC	OTC	OTC	OTC
Environment of use	Home use	Not specified	Clinics, hospital and home environments
Number of Outputs mode	8	1	8
Number of Outputs	2	1	2
Waveform	Monophasic rectangular	Asymmetrical Biphasic rectangular	Biphasic rectangular Monophasic rectangular
Maximum output voltage(max) 500 Ω, 2 kΩ, and 10 kΩ	500 Ω: 48V 2KΩ: 91.2V 10 kΩ: 46V	Not specified	500 Ω: 68V 2KΩ: 102V 10 kΩ: 110V
Maximum	500 Ω: 96mA		500 Ω: 133mA

Output Current 500 Ω, 2 kΩ, and 10 kΩ	2KΩ: 4.33mA 10 kΩ:0.44 mA	Not specified	2KΩ: 51mA 10 kΩ:11 mA
Maximum Phase Charge, (μC) @ 500 Ω	11.92uC	Not specified	20.02uC
Maximum Average Current(500ohm)	8.64mA	Not specified	3.0375mA
Maximum Current Density, (mA/cm² @ 500 Ω)	0.38mA/cm^2	Not specified	0.188mA/cm^2
Maximum Average Power Density, (W/cm² @ 500 Ω	1.62mW/cm^2	Not specified	7.52mW/cm^2
Frequency (Hz)	2-125HZ	1-100 Hz	1-150Hz
Pulse Duration(us)	60-125	Not specified	10-250us, in steps of 50us
Burst Mode	None	None	Yes
Timer range(min)	15 minutes for all programs	Not specified	20min, 25min, 30min, 40min depending on preset program
Indication display:	-On/Off status -Output strength -Output mode -Time to cut-off	Not specified	-On/Off status -Low battery -Voltage/Current level -Output mode -Time to cut-off
Power Source	4×1.5 size AAA ⎓	3 V lithium battery	2 Alkaline AA 1.5V (LR6) Batteries
Dimension	140mm×63mm×30mm	64mmX38mmX13mm	66mm×136mm×30.7mm
Weight	88g (exclude battery)	20g	146.5 grams
Housing Materials	ABS	ABS	ABS
Microprocessor control	Yes	Yes	Yes
Automatic Overload trip	No	Not specified	Yes
Automatic no-load trip	Yes	Not specified	Yes

Automatic shut-off	Yes	Not specified	Yes
User override control	No	Not specified	Yes
Electrode compliance with 21 CFR 898	Yes	Yes	Yes
Electrode cable	Yes	No	Yes

The new device AD-2129A TENS has the same intended use, design, technological characteristics as the predicate device K131159 and K140168. Only pulse frequency, pulse strength and the appearance are different, but the Electrical Safety test and the EMC test in this submission provides demonstrated that these small differences do not raise any new questions of safety and effectiveness to the new devices.