K131921

NOV 15 2013

510(k) Summary

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

1. Submitter's Information

Submitter: Shenzhen Jingkehui Electronic Co., Ltd.
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Date of Preparation: 06/22/2013

2. Proposed Device

Trade Name: Electronic Pulse Stimulator
Common Name: Transcutaneous electrical nerve stimulator
Classification Name: Stimulator, Nerve, Transcutaneous, Over-The-Counter (OTC)
Regulation Description: Transcutaneous electrical nerve stimulator for pain relief
Regulation Medical Specialty: Neurology
Review Panel: Neurology
Product Code: NUH, NGX
Regulation Number: 21 CFR 882.5890
Device Class: II
Use: Over-The-Counter

3. Predicate device

Predicate Device: Prospera OTC TENS Electronic Pulse Massager
510(k) Number: K122744
Use: Over-The-Counter
Submitter: Prospera Corporation

4. Description of Proposed Device

The Electronic Pulse Stimulator is a Transcutaneous Electrical Nerve Stimulator (TENS), intended for the over-the-counter use to relieve pain in different body areas (waist, back, neck, shoulders, legs, and arms). The proposed Electronic Pulse Stimulator, which is compact, portable, and microprocessor-controlled, delivers a gentle electrical pulse through the connecting wires and electrode pads to the user's skin for pain relief. According to the need of users, the pulse intensity can be adjustable on the front control panel of the device.

5. Intended Use Statement of Proposed Device

To be used for temporary relief of pain associated with sore and aching muscles in the shoulder, waist, neck, back, arm, and leg, due to strain from exercise or normal household and work activities.

6. Substantial Equivalence

The operational principle of the above predicate device is to generate small pulses of electrical current and delivers the pulses to the user's skin through adhesive electrode pads such that the underlying

nerves are activated and the pain associated with sore and aching muscles is temporarily relieved.

Identically, the proposed device generates small pulses of electrical current and delivers the pulses to the user's skin through adhesive electrode pads such that the underlying nerves are activated and the pain associated with sore and aching muscles is temporarily relieved.

Table 1 below summarizes the comparison between the proposed device and predicate device, indicating the technical characteristics, specifications, and intended use of the proposed device are substantially equivalent to those of the predicate device.

Table 1. Comparison between the proposed device and predicate device

	Proposed Device	Predicate Device
510(k) Number	K131921	K122744
Device Name	Electronic Pulse Stimulator	Prospera OTC TENS Electronic Pulse Massager
Intended Use	To be used for temporary relief of pain associated with sore and aching muscles in the shoulder, waist, neck, back, arm, and leg, due to strain from exercise or normal household and work activities.	To be used for temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back, neck, upper extremities (arm), and lower extremities (leg) due to strain from exercise or normal household work activities.
Power Source	Battery	Battery
Number of Output Channels	2	2
Automatic Overload Trip	No	No
Automatic No-Load Trip	No	No
Automatic Shut Off	Yes	Yes
User Override Control	Yes	Yes
Indicator	Yes	Yes
Waveform	Pulsed	Pulsed
Shape	Rectangular	Rectangular
Frequency (Hz)	100	100
Maximum charge (μC) at 500Ω	23	23
Maximum current density (mA/cm^2) at 500Ω	1.4	1.4
Compliance with Voluntary Standards	IEC60601-1, IEC60601-1-2	IEC60601-1, IEC60601-1-2
Compliance with 21 CFR 898	Yes	Yes

7. Non-Clinical Tests Performed

The Electronic Pulse Stimulator does not conduct, nor rely upon, clinical tests to determine substantial equivalence. Non-clinical tests were performed on the proposed device in order to validate the design and to assure conformance with the following voluntary design standards in connection with medical device electrical safety, and electromagnetic compatibility.

(a) IEC 60601-1 "Medical Electrical Equipment - Part 1: General requirements for basic safety and essential performance".
(b) IEC 60601-1-2 "Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral standard: Electromagnetic Compatibility - Requirements and Tests".

In addition to the compliance of voluntary standards, the verification of software used in the proposed device has been carried out according to the FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices. The electrodes, as the accessory of the proposed device, also meet the requirement of safety.

8. Conclusion

The tests performed and the comparison of technical characteristics, specifications, and intended use demonstrate the proposed device is substantially equivalent to the predicate device. Therefore, the proposed device is as safe, as effective, and performs as well as the foregoing identified OTC predicate devices that have been legally marketed in the United States.

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

November 15, 2013

Shenzhen Jingkehui Electronic Co., Ltd.
c/o Qaunqin (Bill) Dai
Sunovo, LLC
513 Piazza Drive, Unit B
Mountain View, CA 94043

Re: K131921
Trade Name: Electronic Pulse Stimulator
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous electrical nerve stimulator for pain relief
Regulatory Class: Class II
Product Code: NUH, NGX
Dated: October 28, 2013
Received: October 30, 2013

Dear Dr. Dai:

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 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. 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,

Joyce M. Whang -S

for Victor Krauthamer, Ph.D.
Acting Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K131921

Device Name: Electronic Pulse Stimulator

Indications For Use:

To be used for temporary relief of pain associated with sore and aching muscles in the shoulder, waist, neck, back, arm, and leg, due to strain from exercise or normal household and work activities.

Prescription Use _____ (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use ___X___ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of Center for Devices and Radiological Health (CDRH)

Joyce M. Whang -S