K113544

JUL 27 2012

510(k) Summary

This 510(k) Summary is being submitted in accordance with the requirement of 21 CFR 807.92.

1. Contact Details

Submitter: Prospera Corporation
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Date of Submission: 11/28/2011

Address of the manufacturing facility:
Shenzhen Jingkehui Electronic Co., Ltd.
3F, Building 1, B Area, Xifa Industrial Area, Yintian Village, Xixiang Town, Baoan District, Shenzhen, China

2. Proposed Device

Trade Name: Electronic Pulse Massager, Models PL009, PL009A, and PL029
Common Name: Transcutaneous electrical nerve stimulator
Classification Name: Stimulator, Nerve, Transcutaneous, For Pain Relief
Regulation Description: Transcutaneous electrical nerve stimulator for pain relief
Regulation Medical Specialty: Neurology
Review Panel: Neurology
Product Code: GZJ
Regulation Number: 21 CFR 882.5890
Device Class: II

3. Predicate device

Predicate Device: TENS 3000 Stimulator
510(k) Number: K102014
Manufacturer: Koalaty Products, Inc.

4. Description of Proposed Device

The Electronic Pulse Massager, which includes Models PL009, PL009A, and PL029, is a Transcutaneous Electrical Nerve Stimulator (TENS) for pain relief. TENS can help to relieve the pain caused by trauma or continual strain, and is suitable to be used on the user's back, neck, shoulders, legs, arms, and feet. The proposed Electronic Pulse Massager, which is compact, portable, and microprocessor-controlled, delivers a gentle electrical pulse to the underlying nerve through the wires and electrode pads placed on the skin of users. According to the need of users, the pulse intensity can be adjustable on the front control panel of the massager. Both Models PL009 and PL009A have five automatic stimulation programs and three manual programs, while Massager PL029 contains five automatic stimulation programs and eight selectable programs. The only difference between Models PL009 and PL009A is the former has a "REPEAT" program function and the latter does not. All these programs as well as the pulse intensity and time remaining can be displayed on the liquid crystal display screen of both massagers.

PL009, PL009A, and PL029 Electronic Pulse Massagers consist of the following:

1. Stimulation unit with the microprocessor-controlled integrated circuit, liquid crystal display, and ABS plastic shell included
2. Four AAA batteries for PL009 and PL009A; two AAA batteries for PL029
3. Two wires
4. Four pieces electrode pads (FDA-cleared under 510(k) #K100117, manufactured by SHENZHEN DONGDIXIN TECHNOLOGY CO, LTD.)

5. Intended Use Statement of Proposed Device

The proposed Electronic Pulse Massager, Models PL009, PL009A, and PL029, is intended for symptomatic relief of acute post traumatic pain, acute post surgical pain, and chronic intractable pain.

The proposed Electronic Pulse Massager, Models PL009, PL009A, and PL029, is intended for prescription use only.

6. Technological Characteristics

Both the proposed and predicate devices have the same intended use and fundamental technology. A side-by-side comparison of these two devices is included in the 510(k) submission, showing the proposed Electronic Pulse Massager, Models PL009, PL009A, and PL029, is substantially equivalent to the predicate device (Table 1, below).

Table 1. Technological characteristic comparison between the proposed device and predicate device

		Proposed Device	Predicate Device
1	510(k) Number		K102014
2	Device Name	Electronic Pulse Massager Models PL009, PL009A, and PL029	TENS 3000 Stimulator
3	Intended Use	Symptomatic relief of acute post traumatic pain, acute post surgical pain, and chronic intractable pain	Symptomatic relief of chronic intractable pain, acute post traumatic pain or acute post surgical pain
4	Power Source	6V Battery for PL009 and PL009A; 3V Battery for PL029	9V Battery
5	Method of Line Current Isolation	Battery Supply N/A	Battery Supply N/A
6	Number of Output Channels	2	2
7	Method of Channel Isolation	By Enclosure	By Enclosure
8	Software/Firmware /Microprocessor Control	Yes	Yes
9	Automatic Overload Trip	No	No
10	Automatic Over Current Trip	No	No
11	Automatic No-Load Trip	No	No

12	Automatic Shut Off	No	No
13	Patient Override Control	No	No
14	Indicator Display	Yes	Yes
15	Timer Range	15 min, continue	15 min, continue
16	Waveform	Biphasic or Monophasic Rectangular Pulse	Biphasic or Monophasic Rectangular Pulse
17	Frequency	2-60 Hz	2-150 Hz
18	Compliance with Voluntary Standards	EN55014-1, EN55014-2, EN60335-1, EN60335-2, EN62233, IEC60601-1, IEC60601-1-2, IEC60601-2-10	IEC60601-1, IEC60601-1-2, IEC60601-2-10
19	Compliance with 21 CFR 898	Yes	Yes
20	Weight	150 grams for PL009 and PL009A; 125 grams for PL029	115 grams
21	Dimensions (HxWxT)	200x55x33mm for PL009 and PL009A 203x63x13mm for PL029	95x65x23.5mm
22	Housing Materials & Construction	Enclosure: ABS Plastic	Enclosure: ABS Plastic

7. Non-Clinical Tests Performed for Determination of Substantial Equivalence

The Electronic Pulse Massager, Models PL009, PL009A, and PL029 do not conduct, nor rely upon, clinical tests to determine substantial equivalence. Non-clinical testing was performed in order to validate the design and to assure conformance with the following voluntary design standards:

(a) EN55014-1: Electromagnetic compatibility—Requirements for household appliances, electric tools, and similar apparatus—Part 1: Emission—Product family standard

(b) EN55014-2: Electromagnetic compatibility—Requirements for household appliances, electric tools, and similar apparatus—Part 2: Immunity—Product family standard

(c) EN60335-1: Household and similar electrical appliances - Safety - Part 1: General requirements

(d) EN60335-2: Safety of household and similar electrical appliances—Part 2: Particular requirements for massage appliances

(e) EN62233: Measurement methods for electromagnetic fields of household appliances and similar apparatus with regard to human exposure

(f) IEC 60601-1 "Medical electrical equipment - Part 1: General requirements for safety".

(g) IEC 60601-1-2 "Medical electrical equipment - Part 1-2: General requirements for safety - Collateral Standard"

(h) IEC 60601-2-10 "Medical electrical equipment - Part 2: Particular requirements for the safety of nerve and muscle stimulators"

8. Conclusion

The Electronic Pulse Massager, Models PL009, PL009A, and PL029, has the same intended use and technological characteristics as the predicate device. The comparison of these devices

demonstrates that the submitted models are as safe, as effective, and perform as well as the predicate device. Therefore, the Electronic Pulse Massager, Models PL009, PL009A, and PL029, is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

JUL 27 2012

Alcon Research, Ltd.
% Ms. Jane Ding
Chief Executive Officer
405 Boulder Court, Suite 500
Pleasanton, CA 94566

Re: K113544
Trade/Device Name: Electronic Pulse Massager, Models PL009, PL009A and PL029
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous electrical nerve stimulator for pain relief
Regulatory Class: II
Product Codes: GZJ
Dated: June 21, 2012
Received: June 22, 2012

Dear Ms. Ding:

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

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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,

Deborah Falls

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K113544

Device Name: Electronic Pulse Massager, Models PL009, PL009A, and PL029

Indications for Use: Symptomatic relief of acute post traumatic pain, acute post surgical pain, and chronic intractable pain.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

For DXS

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

510(k) Number K113544