MAR 2 8 2013

510(k) K122744

510(k) Summary of Safety and Effectiveness

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

I. Submitter's Information - 21 CFR §807.92(a)(1):

Prospera Corporation
405 Boulder Ct., Ste 500
Pleasanton, CA 94566
(925) 225-0888 Tel.
(925) 225-0660 Fax
Establishment Registration No. 3009049803

Contact Person: Jane Ding
Date Prepared: September 6, 2012

II. Trade Name, Common Name & Classification - 21 CFR §807.92(a)(2):

Trade Name:	Prospera OTC TENS Electronic Pulse Massager
Models:	PL009; PL009A; PL029
Common Name:	Transcutaneous electrical nerve stimulator, OTC
Regulation Number:	21 CFR 882.5890
Regulation Name:	Transcutaneous Electrical Nerve Stimulator for pain relief
Regulatory Class:	II
Product Code:	NUH, NGX
Use:	Over-The-Counter Use

III. Predicate Devices - 21 CFR §807.92(a)(3):

Prospera OTC TENS electronic pulse massager (*herein after as* "the subject matter device") is an electrically powered device intended for over the counter use and used to apply an electrical current to electrodes on a user's skin to relieve pain. The subject matter device is substantially equivalent to the following legally marketed devices in safety and effectiveness:

510(k) No.	Classification	FDA Dated	Model	Manufacturer
K102598	NUH 21 CFR §882.5890 NGX 21 CFR §882.5850 OTC	05/13/2011	JQ-5C	Hi-Dow International, Inc.
K060846	NUH 21 CFR §882.5890 NGX 21 CFR §882.5850 OTC	12/03/2007	T1040	Endurance Therapeutics
K112392	NUH 21 CFR §882.5890 OTC	03/19/2012	PP907	Hivox Biotek Inc.

The OTC predicate devices' description and indications for use:

510(k) No.	Description	Indications for Use
K102598	Portable, battery powered (3.7VDC) multi function device offering both Transcutaneous Electrical Nerve Stimulator (TENS) and Powered Muscle Stimulator (PMS) qualities in one device. Double channels that effectively transfers user's 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 contractions. There are 6 modes of operation.	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.
K060846	Pre-programmed electrical pulses are transferred directly through electrode adhesive pads to the suggested area of the body where the electrodes are placed, causing minimal muscle contractions.	Temporary relief of pain associated with sore and aching muscles in the lower back due to strain from exercise or normal household and work activities.
K112392	The stimulator can generate small pulses of electrical current. Delivered these pulses pass through the skin and activated underlying nerves.	Temporary relief of pain associated with sore and aching muscles in the lower back as well as upper and lower extremities *(arm and/or leg) due to strain from* exercise or normal household and work activities.

IV. Device Description - 21 CFR 21 CFR §807.92(a)(4):

PL009 and PL009A are electrically powered devices intended for over the counter use and used to apply an electrical current to electrodes on a user's skin to relieve pain. It provides three selectable massage pulse styles with five auto operational modes through two channels with four attachment pads and shows graphic information about massage style, intensity and time remaining on a LCD based display which is incorporated with the device body. The device uses DC 6V power supplied by 4 AAA batteries. It is approximately 0.5lbs with dimensions 8" x 2" x 1" plus attachment pads. The only difference between PL009 and PL009A is the former has a button of "Repeat" representative of the function of repeat.

PL029 is an electrically powered device intended for over the counter use and used to apply an electrical current to electrodes on a user's skin to relieve pain. It provides eight selectable massage pulse styles with five auto operational modes through two channels with four attachment pads and shows textual message about massage style, intensity and time remaining on a LCD based display which is incorporated with the device body. The device uses DC 3V power supplied by 2 AAA batteries. It is approximately 0.5lb with dimensions 8" x 2" x 1" plus attachment pads.

The differences between PL009 and PL029 include:

(1) PL009's work voltage is 6V supplied by 4 AAA batteries, while PL029's work voltage is 3V supplied by 2 AAA batteries.

(2) PL009 provides three operational modes, i.e., massage, beat and knead, which can be combined into six stimulation programs for WAIST, SHOULDER, JOINT, HAND-FOOT, REPEAT and SOLE, while PL029 provides eight operational, i.e., massage, beat, knead, slim, acupuncture, scraping, cupping and immune.

(3) PL009 uses mechanical potentiometer to control power and intensity, while PL029 uses electronic switches to control power and intensity.

(4) PL009's LCD display shows body parts in graphics when the device is in operation, while PL029's LCD display shows working modes in text only when the device is in operation.

V. Indication for Use - 21 CFR §807.92(a)(5):

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.

VI. Technical Characteristics - 21 CFR §807.92(a)(6):

The operational principle of the above listed OTC predicate devices is to generate small pulses of electrical current and deliver the pulses to an ordinary user's skin through electrode adhesive pads such that the underlying nerves are activated and the pain associated with sore and aching muscles is temporarily relieved.

Similarly, the operational principle of the subject matter device manufactured by the submitter is to generate small pulses of electrical current and deliver the pulses to an ordinary user's skin through electrode adhesive pads such that the underlying nerves are activated and the pain associated with sore and aching muscles is temporarily relieved.

Table 1, attached hereto, illustrates PL009's and PL009A's comparison with the OTC predicate devices.

Table 2, attached hereto, illustrates PL029's comparison with the OTC predicate devices.

The data in Table 1 and Table 2 indicates that the technical characteristics, features, specifications and intended use of the subject matter device are substantially equivalent to those of the OTC predicate devices.

The design differences between the subject matter device and the OTC predicate devices are insignificant and do neither affect the intended use, nor alter the operational principle of the subject matter device.

VII. Non-Clinical Tests Performed - 21 CFR §807.92(b)(1):

Compliance to applicable voluntary standards includes IEC 60601-1 and IEC 60601-1-2.

Non-clinical tests were performed on the subject matter device in order to validate the design and to assure conformance with the following voluntary design standards in connection with medical device electrical safety, electromagnetic compatibility, and particular requirements for the safety of nerve and muscle stimulators:

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

In addition to the compliance of voluntary standards, the software verification has been carries out according to the FDA Guidance for the Content of Premarket Submission for Software Contained in Medical Devices.

Electrodes, as accessories of the subject matter device, are also meet safety requirement.

VIII. Conclusion - 21 CFR §807.92(b)(3):

The product description, the non-clinical tests performed and the comparison of technical characteristics demonstrate that the subject matter device is as safe, as effective, and performs as well as or better than the foregoing identified OTC predicate devices which are legally marketed in the United States.

K122744, 510(K) SUMMARY, TABLE A: Comparisons of PL009/PL009A/PL029 Basic Unit Characteristics with Predicate Devices:

Parameter		Your Device			Predicate	Predicate	Predicate
510(k) Number		K122744	K122744	K122744	K102598	K112392	K060846
Device Name and Model		PL009	PL009	PL029	JQ-5C	PP907	T1040
Manufacturer		Prospera	Prospera	Prospera	Hi-Dow international Inc	HIVOX BIOTEK INC	Endurance Therapeutics
Power Source(s)		6V Battery	6V Battery	3V Battery	3.7V Lithium	3V Battery	4.5V Battery
- Method of Line Current Isolation		Battery Supply N/A	Battery Supply N/A	Battery Supply N/A	Battery Supply N/A	Battery Supply	Battery Supply
- Patient Leakage Current							
- Normal Condition (µA)		1.8µA	1.8µA	2.0µA	2.0µA	NA	NA
- Single Fault Condition (µA)		3.3µA	3.3µA	3.0µA	4.2µA	NA	NA
Average DC current through electrodes when device is on but no pulses are being applied		0µA	0µA	0µA	0µA	0µA	0µA
Number of Output Modes		3	3	8	6	1	10
Number of Output Channels:	Synchronous/Alternating?	Synchronous	Synchronous	Alternating	Synchronous	Synchronous	Synchronous
	Method of Channel Isolation	ON/OFF switch	ON/OFF switch	By software	ON/OFF switch	ON/OFF switch	ON/OFF switch
Regulated Current or Regulated Voltage?		Voltage control	Voltage control	Voltage control	Voltage control	Voltage control	Voltage control
Software/Firmware/Microprocessor Control?		Yes	Yes	Yes	Yes	Yes	Yes
Automatic Overload Trip?		No	No	No	No	No	No
Automatic No-Load Trip?		No	No	No	No	No	No
Automatic Shut Off?		Yes	Yes	Yes	Yes	Yes	No
User Override Control?		Yes	Yes	Yes	Yes	Yes	Yes
Indicator Display:	On/Off Status?	Yes	Yes	Yes	Yes	No	Yes
	Low Battery?	No	No	No	No	No	No
	Voltage/Current	No	No	No	No	No	No
Timer Range (minutes)		15 min	15 min	5 min, 10min,		20min	
Compliance with Voluntary Standards?		Yes	yes	Yes.	Yes	Yes	Yes
Compliance with 21 CFR 898?		Yes	yes	Yes	Yes	Yes	Yes
Weight (lbs., oz.)		0 lb., 8.21 oz.	0 lb., 8.21 oz.	0 lb., 6.40 oz		0 lb.,0.53 oz.	0lbs, 14.4 oz
Dimensions (in.) [W x H x D]		2.24 x 7.80 x 0.91	2.24 x 7.80 x 0.91	2.32 x 7.87 x 0.83	4.45 x 2.76 x 0..38	3.55 x	6 x 1 x 2.8
Housing Materials and Construction		Enclosure: ABS	Enclosure: ABS	Enclosure: ABS	ABS	silicone	ABS

K122744, 510(K) SUMMARY, TABLE B: PL009 & PL 009A'S COMPARISON WITH PREDICATE DEVICES

Parameter		PL009 K122744	PL009A K122744	JQ-5C K102598	PP909 K112392	PP907 K112392	PP904 K112392	T1040 K060846
Waveform		Monophasic	Monophasic	Monophasic	Symmetrical biphasic	Symmetrical biphasic	Symmetrical biphasic	Biphasic
Shape		Rectangular	Rectangular	Rectangular	Rectangular	Rectangular	Rectangular	Rectangular
Maximum output voltage (Volts +/- 20%) at 500Ω		12.8	12.8	62.4	40.0	68.8	57.6	40.7
Maximum output voltage (Volts +/- 20%) at 2KΩ		51	51	79.2	84.0	88.0	89.6	105.1
Maximum output voltage (Volts +/- 20%) at 10kΩ		368	368	84	92.0	95.2	96.0	154.1
Maximum output current (mA +/- 20%) at 500Ω		15 mA	15 mA	124.8	80.0	137.6mA	115.2	81.4
Maximum output current (mA +/- 20%) at 2KΩ		3.2 mA	3.2 mA	39.6	42.0	44.0mA	44.8	47.8
Maximum output current (mA +/- 20%) at 10KΩ		0.6 mA	0.6 mA	8.4	9.2	9.52mA	9.6	15.4
Duration of primary (depolarizing phase (μSec)		40 nsec	40 nsec	N/A	N/A	N/A	N/A	N/A
Pulse Duration (μSec)		120-6800 μSec	120-6800 μSec	16.3-781mS	200 μSec (fixed)	200 μSec (fixed)	200 μSec (fixed)	4.1~500mS
Frequency (Hz)		1-100	1-100	61.3	35	2 and 40	2, 5, and 40	245Hz
Net Charge per pulse (μC) at 500Ω		18000 μC	18000 μC		0.3200	1.1008	0.2304	4.07
Maximum charge (μC) at 500Ω		23 μC	23 μC	17.92	16.0	27.52	23.04	16.9
Maximum current density (mA/cm^2) at 500Ω		1.4 mA/cm^2	1.4 mA/cm^2	9.92	1.964	3.378	2.828	2.71
Maximum average power density (W/cm^2) at 500Ω		0.23W/cm^2	0.23W/cm^2	2.72	0.078	0.232	0.163	5.35 (mW/ cm^2)
Burst Mode	(a) Pulse per burst	1	1	N/A	1	N/A	N/A	N/A
	(b) Burst per second	0-25	0-25	N/A	4	N/A	N/A	N/A
	(c) Burst-duration (sec)	1	1	N/A	2	N/A	N/A	N/A
	(d) Duty Cycle	5	5	N/A	8	N/A	N/A	N/A
ON time (sec)		Potentiometer switch	Potentiometer switch	N/A	120	120	120	N/A
OFF time (sec)		Potentiometer switch	Potentiometer switch	N/A	0	0	0	N/A
Additional features		N/A	N/A	N/A	N/A	N/A	N/A	N/A

K122744, 510(K) SUMMARY, TABLE C: PL029'S COMPARISON WITH PREDICATE DEVICES

Parameters		**PL029 K122744**	**JQ-5C K102598**	**PP909 K112392**	**PP907 K112392**	**PP904 K112392**	**T1040 K060846**
Waveform		Monophasic	Monophasic	Symmetrical biphasic	Symmetrical biphasic	Symmetrical biphasic	Biphasic
Shape		Rectangular	Rectangular	Rectangular	Rectangular	Rectangular	Rectangular
Maximum output voltage (Volts +/- 20%) at 500Ω		49.6	62.4	40.0	68.8	57.6	40.7
Maximum output voltage (Volts +/- 20%) at 2KΩ		99.2	79.2	84.0	88.0	89.6	105.1
Maximum output voltage (Volts +/- 20%) at 10kΩ		114	84	92.0	95.2	96.0	154.1
Maximum output current (mA +/- 20%) at 500Ω		18 mA	124.8	80.0	137.6mA	115.2	81.4
Maximum output current (mA +/- 20%) at 2KΩ		3.2 mA	39.6	42.0	44.0mA	44.8	47.8
Maximum output current (mA +/- 20%) at 10KΩ		0.6 mA	8.4	9.2	9.52mA	9.6	15.4
Duration of primary (depolarizing phase (μSec)		40 msec	N/A	N/A	N/A	N/A	N/A
Pulse Duration (μSec)		100-200 μSec	16.3-781mS	200 μSec (fixed)	200 μSec (fixed)	200 μSec (fixed)	4.1~500mS
Frequency (Hz)		0.5-86Hz	61.3	35	2 and 40	2, 5, and 40	245Hz
Net Charge per pulse (μC) at 500Ω		18000 μC		0.3200	1.1008	0.2304	4.07
Maximum charge (μC) at 500Ω		23	17.92	16.0	27.52	23.04	16.9
Maximum current density (mA/cm^2) at 500Ω		1.4 mA/cm^2	9.92	1.964	3.378	2.828	2.71
Maximum average power density (W/cm^2) at 500Ω		0.23 W/cm^2	2.72	0.078	0.232	0.163	5.35 (mW/cm^2)
Burst Mode	A. Pulse per burst	1	N/A	1	N/A	N/A	N/A
	B.Burst per second	0-7	N/A	4	N/A	N/A	N/A
	C.Burst-duration (sec)	1	N/A	2	N/A	N/A	N/A
	D.Duty Cycle	7	N/A	8	N/A	N/A	N/A
ON time (sec)		40 ms	N/A	120	120	120	N/A
OFF time (sec)		18 ms	N/A	0	0	0	N/A
Additional features		N/A	N/A	N/A	N/A	N/A	N/A

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

March 28, 2013

Prospera Corporation
% Mr. Leon E. Jew
Attorney at Law
Dayhee Law Group
5776 Stoneridge Mall Rd., Suite 288
Pleasanton, CA 94588

Re: K122744
Trade/Device Name: OTC TENS Electronic Pulse Massager
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous electrical nerve stimulator for pain relief
Regulatory Class: II
Product Codes: NUH, NGX
Dated: March 15, 2013
Received: March 18, 2013

Dear Mr. Jew:

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 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,

Victor Krauthamer -S

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): K122744

Device Name: PROSPERA OTC TENS Electronic Pulse Massager

Models: PL009; PL009A; PL029

Indications for Use:

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.

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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Victor Krauthamer -S
2013.03.28 17:12:31 -04'00'

Division of Neurological and
Physical Medicine Devices
510(k) Number: K122744