DEC 2 0 2013

K131933

**Exhibit 013_Revised 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: Gurin Products, LLC
Address: 2522 Chambers Road, Suite 100, Tustin, CA 92780
Contact Person: Sanjay Gupta
Tel: 888-666-1557
Email: iroams@earthlink.net
Date of Preparation: 06/24/2013

**2. Proposed Device**

Trade Name: Santamedical 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
Use: Over-The-Counter
Device Class: II

**3. Predicate device**

Prospera OTC TENS Electronic Pulse Massager
510(k) Number: K122744
Submitter: Prospera Corporation

**4. Description of Proposed Device**

The Santamedical Pulse Stimulator, a Transcutaneous Electrical Nerve Stimulator (TENS), is for over-the-counter use and for home use, which is intended to relieve 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. The portable and microprocessor-controlled Santamedical Pulse Stimulator delivers a gentle electrical pulse through two channels with four attachment pads and shows graphic information about mode style, intensity and time remaining on a LCD based display which is incorporated within the device body.

**5. 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.

**6. Technological Characteristics**

Both the proposed and predicate devices have the identical technological characteristics, as shown in Table 1 below.

**Table 1. Characteristic comparison between the proposed device and predicate device**

| | Proposed Device | Predicate Device |
|---|---|---|
| 510(k) Number | K131933 | K122744 |
| Device Name | Santamedical 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, back, neck, upper extremities (arm), and lower extremities (leg) due to strain from exercise or normal household 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 Over Current Trip | No | No |
| Automatic No-Load Trip | No | No |
| Automatic Shut Off | Yes | Yes |
| User Override Control | Yes | Yes |
| Indicator Display | Yes | Yes |
| Waveform | Monophasic, pulsed | Monophasic, pulsed |
| Frequency | 1-100 Hz | 1-100 Hz |
| Compliance with Voluntary Standards | IEC60601-1, IEC60601-1-2 | IEC60601-1, IEC60601-1-2 |
| Compliance with 21 CFR 898 | Yes | Yes |
| Housing Materials & Construction | ABS Plastic | ABS Plastic |

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

Compliance to applicable voluntary standards includes IEC 60601-1 and IEC 60601-1-2. Non-clinical tests were performed on the proposed Santamedical Pulse Stimulator 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) 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 electrodes also meet the safety requirement, and the software verification has been carried out according to the FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices.

**8. Conclusion**

The proposed device is substantially equivalent to the predicate device. Therefore, the proposed Santamedical Pulse Stimulator is as safe, as effective, and performs as well as the foregoing identified OTC predicate devices which 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

December 20, 2013

Gurin Products, LLC
Sanjay Gupta
President
2522 Chambers Road, Suite 100
Tustin, CA 92780

Re: K131933
Trade/Device Name: Santamedical 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: November 25, 2013
Received: December 3, 2013

Dear Mr. Gupta:

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 Carlos L. Peña, PhD
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): K131933

Device Name: Santamedical Pulse Stimulator

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 IF NEEDED)

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Concurrence of Center for Devices and Radiological Health (CDRH)

Joyce M. Whang -S