JAN 2 4 2014

K131910

5. 510(k) Summary

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

Marc Pro, Inc.
5702 Bolsa Ave.
Huntington Beach, CA 92649

Phone: (855) 627-2776
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Contact Person: Ryan P. Heaney

Date Prepared: December 11, 2013

Name of Device

MPP

Common or Usual Name/Classification Name

Transcutaneous Electrical Nerve Stimulator for Pain Relief - OTC
21 C.F.R. § 882.5890 (Product Code NUH)
Powered Muscle Stimulator for Muscle Conditioning – OTC
21 C.F.R. § 890.5850 (Product Code NGX)

Predicate Devices

(K081998)
(K121757)
(K112485)

Intended Use / Indications for Use

The MPP is 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 and normal household and work activities.

The MPP is intended for muscle conditioning by stimulating muscle in order to improve or facilitate muscle performance.

Technological Characteristics

The MPP consists of a portable battery operated electrical stimulation device with two channels, two sets of lead wires, six packages of self-adhesive electrodes, and a battery charger. Each channel has a pair of buttons to select the desired frequency and a dial to control the intensity of the signal. The stimulator also is supplied with an output jack for each channel, a charging jack, timer buttons, and an LCD display. The device creates stimulation at frequencies of 1–70 Hz depending on the desired effects.

Performance Data

The MPP conforms to the following recognized consensus standards:

- IEC 60601-2-10 1987/Amendment 1 2001, Medical electrical equipment - Part 2-10: Particular requirements for the safety of nerve and muscle stimulators.
- IEC 60601-1 Medical Electrical Equipment - Part 1: General Requirements for Safety, 1988; Amendment 1, 1991-11, Amendment 2, 1995 subclause 56.3(c).
- IEC 60601-1-2: Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral Standard: Electromagnetic Compatibility - Requirements and Tests (2001).

Software

The software was validated for a moderate level of concern device.

Substantial Equivalence

The MPP has the same intended uses and/or substantially similar output parameters as the predicate devices.

The MPP has the same intended uses and substantially similar output parameters as the legally marketed electrical nerve stimulator K121757. This demonstrates the safety of these for over the counter indications.

The muscle conditioning indication of the proposed MPP device is identical to the indication of the legally marketed OTC stimulator K081998. The two devices have identical output parameters other than the fact that the MPP can deliver a larger frequency range to allow for the additional 'temporary pain' indication for use. This demonstrates that the technology is effective for over the counter muscle conditioning and safe for over the counter use.

The MPP is technologically identical to the predicate K112485, which is cleared for pain relief including temporary pain. The only difference is that the MPP

indication is for over the counter temporary relief of pain. This demonstrates that the technology is effective for temporary pain relief.

The identical technology has already been cleared for OTC muscle conditioning and for temporary pain relief with a prescription; in addition the K121757 has the same two OTC indications for use and substantially similar technology. Therefore the proposed device does not raise new questions of safety or effectiveness.

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

January 24, 2014

Marc Pro, Inc.
c/o Gregory Holland
Regulatory Specialists, Inc.
3722 Sausalito Ave.
Irvine, CA 92606 US

Re: K131910
Trade/Device Name: MPP
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator for Pain Relief
Regulatory Class: Class II
Product Code: NUH, NGX
Dated: December 20, 2013
Received: December 26, 2013

Dear Mr. Holland:

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, 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 on last page.

510(k) Number *(if known)*
K131910

Device Name
MPP

Indications for Use *(Describe)*
The MPP is 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 and normal household and work activities.

The MPP is intended for muscle conditioning by stimulating muscle in order to improve or facilitate muscle performance.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Joyce M. Whang -S

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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