MAY 30 2014

510(k) SUMMARY

(per 21 CFR 807.92)

Date: December 11, 2013

Premarket Notification: K133779

Trade Name: CP Relief Wand® Model CP-1000

Sponsor:

Mid-America Medical Innovations, LLC
1709 Honey Creek Road
Jefferson City, MO 65101

Contact Person:

Norm Schroeder
Mid-America Medical Innovations, LLC
2704 Industrial Drive
Jefferson City, MO 65109
Phone: 573-496-3213
Fax: 573-496-4015

Common Name: Transcutaneous Electrical Nerve Stimulator

Classification Name: Stimulator, Nerve, Transcutaneous. For pain relief

Device Classification: Class II

Regulation: 21 CFR 882.5890

Device Product Code: GZJ

Device Description: The CP Relief Wand® Model CP-1000 is a portable hand held TENS device with self-contained electrodes. The device is powered by a standard 9 volt alkaline battery. In operation, the electrode end of the CP-1000 is covered by a gel pad and positioned to touch the skin over the pain center. The electrical pulses travel from one electrode, through the skin, through the underlying nerve tissue, and back through the skin to the other electrode to desensitize the underlying nerves within the current path. Convenient controls on the unit are provided for power, intensity, pulse width, and pulse polarity. The materials comprising the gel pad and CP1000 electrodes are comparable to the materials comprising Axelgaard's PALS® Neurostimulation Electrodes cleared per K132422.

Intended Use: The CP Relief Wand® CP-1000 is a TENS Device and is intended for use as an adjunctive therapy for pain management for medical purposes such as symptomatic relief of chronic

intractable pain and relief of acute post-surgical and post-traumatic pain.

Predicate Devices: TENS 3000 Stimulator (K102014)
InterX5000 (K042912)

Technological Characteristics: The CP Relief Wand® Model CP-1000 possesses similar technological characteristics as the predicate device, including intended use, basic design, use of materials established as safe, and performance. The primary differences are in the use of fewer modes, fewer channels, and slight differences in performance parameters. These differences between the CP Relief Wand® Model CP-1000 and the predicates do not affect the safety and effectiveness of the device. The differences in design result in a less complex device than the predicates and do not affect safety and effectiveness of the device. The slight differences in performance parameters are negligible and do not affect safety and effectiveness of the device. Performance testing was conducted to compare the waveforms and to establish conformance with IEC 60601-1, IEC 60601-1-2, and IEC 60601-2-10.

Performance Data: Performance testing of the CP-1000 has been conducted for functional and design verification and validation. Side by side testing was also performed for comparison with the predicate device. The testing indicates the device is substantially equivalent to the predicate device and is in compliance with the following recognized consensus standards:

- IEC60601-1 Edition 2:1988 (A1:1991 + A2:1995) Medical Electrical Equipment; Part 1: General Requirements for Safety and Essential Performance
- IEC60601-1-2:2007 Third Edition, Medical electrical equipment – Section 1.2 Collateral standard: Electromagnetic compatibility – Requirements and tests
- IEC60601-2-10 (1987) and Amendment 1 (2001) Medical Electrical Equipment – Part 2-10: Particular requirement for the basic safety and essential performance of nerve and muscle stimulators

Conclusion: The CP Relief Wand® is substantially equivalent to the TENS 3000 Stimulator and InterX5000

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

May 30, 2014

Mid-American Medical Innovations, LLC
Norm Schroeder
Co-Manager
2704 Industrial Drive
Jefferson City, MO 65109

Re: K133779
Trade/Device Name: CP Relief Wand ® Model CP-1000
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator
Regulatory Class: Class II
Product Code: GZJ
Dated: April 28, 2014
Received: April 29, 2014

Dear Mr. Schroeder:

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 Industry and Consumer Education 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 Industry and Consumer Education 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,

Felipe Aguel -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 below.

510(k) Number *(if known)*
K133779

Device Name
CP Relief Wand ® Model CP-1000

Indications for Use *(Describe)*
The CP Relief Wand® CP-1000 is a TENS Device and is intended for use as an adjunctive therapy for pain management for medical purposes such as symptomatic relief of chronic intractable pain and relief of acute post-surgical and post-traumatic pain.

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)*

Felipe Aguel -S Date: 2014.05.30 16:11:40 -04'00'

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