K132993

APR 2 4 2014

510(k) SUMMARY

Date of Summary Prepared: 01/24/2014

1. Submitter's Name: Counter Scientific Development (GZ) Ltd.

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2. Proposed New Device:

Trade Name: Pain Therapy Device, Model P.T.S.-IV

Classification Name: TENS Device

Regulation Number: 882.5890

Product Code: NUH

Device Class: II

3. Predicate (cleared) Device:

OMRON Electro Therapy Pain Relief, Model PM3030

510(k) Number: K110068

Manufacturer: OMRON Healthcare Co., Ltd., China.

4. Description of Proposed Device:

The Counter ***Pain Therapy Device, Model P.T.S.-IV*** features two channels and seven (7) preset programs. The output of both channels can be adjusted individually for intensity in sixteen (16) steps and the treatment time is selectable from 20, 30 or 40 minutes. All features are well indicated by large icons on a backlit LCD screen for easy reading.

The device is powered by three (3) rechargeable Lithium Batteries which are permanently built into the main unit and can be recharged with the charging unit supplied for the device.

The Pain Therapy Device consists of the handheld main unit (controller), two pairs of self-adhesive electrodes, a plug-in charging unit (adaptor 120VAC to 5VDC) and two pairs of electrode cables.

The device has been tested to and meets the requirements of the following recognized consensus standards:

IEC 60601-1:1988 + A1:1991 + A2:1995 "Medical electrical Equipment – Part 1: General requirements for basic safety and essential performance".

IEC 60601-2-10: 1987 (first Edition + amendment 1 (2001) for use in conjunction with IEC 60601-1 (1988), Amendments 1 (1991) and 2 (1995) "Medical electrical equipment – Part 2: "Particular Requirements for safety of nerve and muscle stimulators".

IEC 60601-1-2: 2001 + A1: 2004 & IEC60601-2-10: 1987 + A1: 2001 Clause 36 Medical Electrical Equipment, Part1-2: "General requirements for Basic Safety and Essential Performance" Collateral Standard: Electromagnetic Compatibility.

5. Indication for Use:

The Counter *Pain Therapy Device Model P.T.S.-IV* is intended for the relief of pain associated with sore or aching muscles of the lower back, arms, or legs due to strain from exercise or normal household work activities.

6. Environment of Use:

Clinics, Hospitals and home environments

7. Contraindications:

Do not use this device if you have a cardiac pacemaker, implanted defibrillator, or other implanted metallic or electronic device. Such use could cause electrical shock, burns, electrical interference, or death.

Do not use this device together with a life-supporting medical electronic device such as an artificial heart or lung.

Do not use this device together with a body-worn medical electronic device such as an ECG.

8. Technological Characteristics Compared to the Predicate Device

Both, the Counter *Pain Therapy Device Model P.T.S.-IV* and the predicate device the OMRON TENS Model PM3030 have the same intended use and fundamental technology. Both the Counter unit and the predicate provide electrically generated pulses applied to the skin via electrodes. The main differences between the two devices are that the Counter *Pain Therapy Device* has 7 program modes versus 3 on the OMRON unit and 2 channels versus 1 channel. However, the Counter device can be viewed as substantially equivalent to the predicate device because: The electrical stimulation provided by the Counter device is substantially equivalent to that commonly employed by TENS devices that have been cleared for marketing without prescription labeling; i.e. for OTC sale. Technological characteristics, features, specifications, materials and intended uses of the Counter device are substantially equivalent to the quoted predicate device. The differences that exist between the devices are insignificant in terms of safety or effectiveness.

9. Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence is as follows:

Counter did not conduct, nor rely upon, clinical tests to determine substantial equivalence of the *Pain Therapy Device Model P.T.S.-IV.* vs. the predicate. Non-clinical testing was performed in order to validate the design according to the company's specified design requirements, and to assure conformance with the following voluntary design standards:

IEC 60601-1:1988 + A1:1991 + A2:1995 "Medical electrical Equipment – Part 1: General requirements for basic safety and essential performance".

IEC 60601-2-10: 1987 (first Edition + amendment 1 (2001) for use in conjunction with IEC 60601-1 (1988), Amendments 1 (1991) and 2 (1995) "Medical electrical equipment – Part 2: "Particular Requirements for safety of nerve and muscle stimulators".

IEC 60601-1-2: 2001 + A1: 2004 & IEC60601-2-10: 1987 + A1: 2001 Clause 36 Medical Electrical Equipment, Part1-2: "General requirements for Basic Safety and Essential Performance" Collateral Standard: Electromagnetic Compatibility.

a. **EMC and electrical safety**

IEC 60601-1 "Medical Electrical Equipment-Part 1: General requirements for basic safety and essential performance ".
IEC 60601-1-2 "Medical Electrical Equipment - Part 1-2: General requirements for basic safety and essential performance-collateral standard: Electromagnetic compatibility-requirements and tests".

b. **Biocompatibility**

The electrodes are the only body contacting parts. They have been tested for biocompatibility as part of their separate FDA 510(k) clearance.

c. **Software**

Based upon the test results it was concluded that the software performs within specifications and is safe to the stated intended use. Since a permanent hazard analysis is implemented in the software development process, and due to the clear software architecture, it is believed that the test protocol sufficiently verifies the software's main functional operation.

d. **Cleaning**

The cleaning instructions as described the Instruction Manual have been tested to be sufficient. Testing involved validation of the manual cleaning method as per the instructions. All testing concluded that that the Pain Therapy Device can be cleaned by the use of the methods described in the Instruction Manual.

e. **EMC and Electrical Safety**

Performance testing has established that, with respect to EMC and electrical safety in its intended operational environment, the device conforms to all applicable

requirements of IEC 60601-1 and IEC 60601-1-2.

8. Conclusions:

The Counter *Pain Therapy Device, Model P.T.S.-IV* has the same intended use and technological characteristics as the predicate device. Moreover, bench testing and safety report documentation demonstrate that the submitted device could maintain the same safety and effectiveness as that of predicate device. In the other words, the differences do not affect the intended use and do not raise any new questions of safety or effectiveness or alter the fundamental scientific technology of the device. Thus, the Counter *Pain Therapy Device, Model P.T.S.-IV* 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 Center – WO66-G609
Silver Spring, MD 20993-0002

April 24, 2014

Counter Scientific Development (GZ) Ltd
c/o Guenter Ginsberg, President
Media Trade Corporation
11820 Red Hibiscus Drive
Bonita Springs, FL 34135

Re: K132993
Trade/Device Name: Counter OTC TENS Device, Model PTS-IV
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electric Nerve Stimulator for Pain Relief
Regulatory Class: Class II
Product Code: NUH
Dated: March 15, 2014
Received: March 18, 2014

Dear Mr. Ginsberg:

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

Carlos L. Peña, Ph.D., M.S.
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: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K132993

Device Name
Counter OTC TENS Device, Model PTS-IV

Indications for Use *(Describe)*
This TENS Device is to be used for temporary relief of pain associated with sore or aching muscles of lower back, arms, or legs due to strain from exercise or normal household and work activities.

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: 2014.04.24 11:58:31 -04'00'

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