DEC 2 0 2013

K132998

Chapter 5- 510(K) Summary

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Proprietary Name Wandy Self-adhesive Electrodes

Common Name Cutaneous electrode.

Classification Name Cutaneous electrode.

Panel Neurology

Classification

classification name	21 CFR section	Product code	Class
Cutaneous electrode	882.1320	GXY	II

Predicate Device

Wandy Self adhesive Neurostimulation electrode (K002219)
Wandy Silicon Conductive Rubber Pad (K002227)
Jiajian Self- adhesive Electrode (K090198)

Description and Indication for Use

Wandy Self-adhesive Electrode is intended to transmit electrical current to patient skin for TENS (Transcutaneous Electrical Nerve Stimulation) and EMS (Electrical Muscular Stimulation) applications, for OTC (Over-The -Counter) or Prescription use. The Electrode are used for adults only.

The Wandy Self-adhesive Electrodes transmits electrical current to patient skin, the electrical current is first transmitted via the lead wire or snap button then transmitted to the conductive gel which is adhered to patient skin.

The Wandy Self-adhesive Electrodes is used as an accessory with the TENS or EMS device units.

Substantial Equivalency

After analyzing both bench and clinical testing data, it is the conclusion of Wandy Self-adhesive Electrodes are substantial equivalent to the predicate device, Wandy Self adhesive Neurostimulation electrode (K002219), Wandy Silicon Conductive Rubber Pad (K002227) and Jiajian Self- adhesive Electrode (K090198).

Performance

The Wandy Self-adhesive Neurostimulation Electrode passed self-evaluation tests for Impedance, Wire pull and adhesiveness.

Discussion of Clinical Tests Performed:

All design specification are exactly equivalent between new devices (Wandy Self-adhesive Electrodes) and predicate devices (Wandy Self-Adhesive Neurostimulation Electrode and Wandy Silicon Conductive Rubber Pad), except claimed indication for use and proposed labeling. Two predicate devices have thousands of marketing clinical experience and didn't have adverse events occurred in the world.

Conclusions:

Wandy Self-adhesive Electrodes have the same intended use and similar technological characteristics as the above predicate devices. Moreover, information contained in this submission supplied demonstrates that any differences in their characteristics do not raise any new questions of safety or effectiveness. Thus, Wandy Self-adhesive Electrodes are substantially equivalent to the predicate devices

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

Wandy Rubber Industrial Co., Ltd.
Jack Yu
No.48, Lane 392, Fu Teh 1 Rd, Xi Zhi Dist
New Taipei City
Taiwan 221

Re: K132998
Trade/Device Name: Wandy Self-Adhesive Electrodes
Regulation Number: 21 CFR 882.1320
Regulatory Class: Class II
Product Code: GXY
Dated: September 9, 2013
Received: September 24, 2013

Dear Mr. Yu:

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): K132998

Device Name: Wandy Self-Adhesive Electrodes

Indications For Use:

Wandy Self-adhesive Electrode is intended to transmit electrical current to patient skin, for TENS (Transcutaneous Electrical Nerve Stimulation) and EMS (Electrical Muscular Stimulation) applications, for OTC (Over-The -Counter) or Prescription use. The Electrode are used for adults only.

Prescription Use ___X___ (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)

Concurrence of Center for Devices and Radiological Health (CDRH)

Joyce M. Whang -S