



Food and Drug Administration
10903 New Hampshire Avenue
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January 17, 2017

Well-life Healthcare Limited
Chin-Chih Hsieh
Official Correspondent
1f, No. 16, Lane 454, Jungjeng Road
Yunghe District, New Taipei City, 234 TW

Re: K162663

Trade/Device Name: WELL LIFE Rx Wireless TENS/EMS Stimulator, model WR-2603/2603A, WR-2604/2604A and WR-2605/2605A

Regulation Number: 21 CFR 882.5890

Regulation Name: Transcutaneous Electrical Nerve Stimulator for Pain Relief

Regulatory Class: Class II

Product Code: GZJ, IPF

Dated: December 8, 2016

Received: December 12, 2016

Dear Chin-Chih Hsieh:

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" (21 CFR 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,

Michael J. Hoffmann -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

Indications for Use

510(k) Number (if known)

K162663

Device Name

WELL LIFE Rx Wireless TENS/EMS Stimulator, model WR-2603/2603A, WR-2604/2604A
and WR-2605/2605A

Indications for Use (Describe)

Transcutaneous Electrical Nerve Stimulator (TENS) can be used for the following applications (Available for WR-2603/2603A, and TENS function of WR-2605/ 2605A):

- For symptomatic relief of chronic intractable pain

Electrical Muscle Stimulation (EMS) can be used for the following applications (Available for WR-2604/2604A, and EMS function of WR-2605/ 2605A):

- Relax muscle spasms
- Prevent or retard disuse atrophy
- Increase local blood circulation
- Re-educate muscles
- Maintain or increase the range of motion

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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