JUN 20 2008

510(K) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K080304

1. Submitter's Identifications:

Well-Life Healthcare Limited
1FL., No. 16, Lane 454, Jungjeng Rd., Yunghe City, Taipei County, Taiwan, R.O.C.

Contact: Jenny Hsieh
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Date of Summary Preparation: February 05, 2008

2. Name of the Device:

i. Pro TENS / Model: WL-2407Rx.

3. Information of the 510(k) Cleared Device (Predicate Device):

WL-2402 (K020020)

4. Device Description:

The Well Life TENS devices, WL-2407Rx is the model of prescription TENS intended for symptomatic relief of chronic intractable pain.

WL-2407Rx is a selectable dual channel, 4.5V (3xAAA/Alkaline battery) operated TENS device with the following features:

<1> The operation of device is via the connection of wire and electrode through the dual operation channels.
<2> The stimulation electrode includes adhesive electrode and garment electrode. It may be chosen depending upon the prescription of physician.
<3> The output waveform is selectable pre-programming change among P1~P6.
<4> The output strength is adjustable at 0~80 mA, with setting time 5~60 minutes counting from switching ON.
<5> The LCD display is provided for the indication of operation status including operation mode, output wave form, output strength, time to cut-off, and battery low warning.

5. Intended Use:

The model WL-2407Rx TENS is a portable, battery-powered, transcutaneous electrical nerve stimulator (TENS device) that is intended for symptomatic relief of chronic intractable pain.

The standard format for the statement of indications and contraindication for use are provided hereafter.

6. Discussion of Non-Clinical Tests Performed Determination of Substantial Equivalence are as follows:

Compliance to applicable voluntary standards includes ANSI/AAMI, NS4-1985, as well as EN 60601-1, and EN 60601-1-2 requirement.

In addition to the compliance of voluntary standards, the software verification has been carried out according to the FDA software guidance.

7. Conclusions

The i. Pro TENS/ model WL-2407Rx has the same intended use and the similar technological characteristics as the cleared device of WL-2402 (K020020). Moreover, verification and validation tests contained in this submission demonstrate that the difference in the submitted demonstrate that the difference in the submitted models could maintain the same safety and effectiveness as that of cleared device.

In the other words, those engineering difference do not: (1) affect the intended use or (2) alter the fundamental scientific technology of the device.

Therefore; i. Pro TENS model WL-2407Rx is considered substantial equivalent to the 510(K) cleared model WK-2402(K020020).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 20 2008

Well-Life Healthcare Limited
% Ms. Jenny Hsieh
1FL., No. 16, Lane 454
Jungjeng Rd.
Yunghe City, Taipei County, Taiwan, R.O.C.

Re: K080304
Trade/Device Name: Pro TENS, Model WL-2407 Rx
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous electrical nerve stimulator for pain relief
Regulatory Class: Class II
Product Code: GZJ
Dated: May 21, 2008
Received: June 4, 2008

Dear Ms. 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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.
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If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications For Use

510(k) Number (if known):

Device Name: i. Pro TENS / Model WL-2407Rx.

Indications For Use:

- The i. Pro TENS; model WL-2407Rx is a portable, battery-powered, transcutaneous electrical nerve stimulator (TENS device) that is intended for symptomatic relief of chronic intractable pain.

Prescription Use √ OR Over-The-Counter Use ___
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

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