K063660

510(K) Summary

FEB 7 2007

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: _____.

1. Submitter's Identifications:
   Well Life Healthcare Limited
   5Fl., Ste 504, Empire Centre, 68 Mody Road, Tsimshatsuim, Kowloon, Hong Kong

   Contact: Jenny Hsieh

   Date of Summary Preparation: January 31, 2007.

2. Name of the Device:

   OTC TENS for Low Back Pain Relief / Model: WL-2407.

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

   WL-2402 (K040512), and WL-2406 (K052785).

4. Device Description:

   The Well Life TENS devices, WL-2407 is the model of OTC TENS intended for temporary relief of pain associated with sore and aching muscles in the lower back due to strain from exercise or normal household and work activities.

   WL-2407 is a selectable dual channel, 4.5V (3xAAA/Alkaline battery) operated TENS device with the following features:
   <1> The stimulation electrode is dual channels electrode.
   <2> The output waveform is selectable pre-programming change among P1~P8.
   <3> The output strength is adjustable at 0~80 mA, with setting time 21 minutes counting from switching ON.
   <4> 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-2407 TENS is intended for temporary relief of pain associated with sore and aching muscles in the lower back due to strain from exercise or normal household and work activities

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 OTC TENS for low back pain relief/ model WL-2407 has the same intended use and the similar technological characteristics as the cleared device of WL-2402 (K040512), and WL-2406 (K052785). 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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Well-Life Healthcare Limited
% Ms. Jenny Hsieh
68 Mody Road, Empire Centre, Suite 504
Tsimshatsuim, Kowloon
Hong Kong

FEB 7 2007

Re: K063660
Trade/Device Name: OTC TENS for Low Back Pain Relief/Model WL-2407
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous electrical nerve stimulator for pain relief
Regulatory Class: II
Product Code: NUH
Dated: December 6, 2006
Received: December 8, 2006

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120 Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (240) 276-3150 or at its 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: OTC TENS For Low Back Pain Relief / Model WL-2407.

Indications For Use:

- The model WL-2407 are intended for temporary relief of pain associated with sore and aching muscles in the lower back due to strain from exercise or normal household and work activities.

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

510(k) Number k063660