510(k):

510(K) Summary

FEB - 5 2010

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: K091757 .

1. Submitter's Identifications:
   Well Life Healthcare Limited
   1F., No. 16, Lane 454, Jungjeng Road, Yunghe City, Taipei County 23455,
   Taiwan, ROC

   Contact: Jenny Hsieh

   Date of Summary Preparation: December 08, 2009

2. Name of the Device:

   OTC TENS for Arm & Leg Pain Relief / Model: WL-2407.

3. Information of the 510(k) Cleared Device (Predicate Device):
   1> The Prizm 5000-Z system (K033122)
   2> Endurance Therapeutics T1040 (K060846).

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 upper and lower extremities (arm and/or leg) due to strain from exercise or normal household and work activities. Basically the stimulation model WL-2407 is completely identical to that of model as mentioned in the Well-Life K063660- 510(K) cleared device. To change the indication for use for the treatment location as the chosen predicate devices, Well-Life change the design of electrode.

   For the device included in this submission, we use the following third party 510(K) legally marketed predicate components:
   <1>K022494, the Home Care Jelly.

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

   <1> The operation function is dual channels completely identical to the model being modified, WL-2407 for low back pain relief(K063660).
   <2> For the stimulation electrode, Well-Life uses upper arm belt as well as snap type adhesive electrode as standard accessories.
   <3> The output waveform is selectable pre-programming change among P1~P8.
   <4> The output strength is adjustable at 0~80 mA, with setting time 21 minutes counting from switching ON.
   <5> The LCD display is provided for the indication of operation status including operation mode, output program mode, output intensity, time to cut-off, and battery low warning.

5. Intended Use:

The OTC TENS for Arm & Leg Pain Relief / model WL-2407 is intended for temporary relief of pain associated with sore and aching muscles in the upper and lower extremities (arm and/or leg) 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. Power level testing comparison and acknowledge of comparison result with Prizm 5000Z system:

For the substantial equivalent comparison, the power level testing comparison with the chosen 510(K) cleared device, Prizm 5000-Z system was conducted via using 1K ohm loading resistance for the garment electrodes . Testing set up with comparison result is as the following table :

Current comparison: (Unit: mA/cm^2)

Electrode Type	Glove	Sleeve& Knee	Sock	Silicone Pad
Well-life WL-2407	0.00337	0.00386	0.00271	0.11728
Prizm 5000-Z	0.00340	0.00385	0.00274	0.11817

Power Density Comparison : (Unit: W/cm^2)

Electrode Type	Glove	Sleeve & Knee	Sock	Silicone Pad
Well-life WL-2407	0.00032	0.00036	0.00025	0.01098
Prizm 5000-Z	0.00064	0.00072	0.00051	0.02222

Based on this comparison result, we made a acknowledge that the model WL-2407 has a lower output power and power density than that of Prizm 5000-Z system while using the same electrode, and that the garment electrode for prescription use will not be packed or sold with WL-2407 model. In case the garment electrode is to be used with WL-2407 model , the effectiveness is to be determined by the physician who prescribes the use of that electrode.

7. 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.

8. Conclusions

The OTC TENS for Arm & Leg Pain Relief / model WL-2407 has the same intended use and the similar technological characteristics as the cleared device of Prizm 5000-Z system (K033122) and Endurance Therapeutics T1040 (K060846). 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

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

FEB - 5 2010

Well Life Healthcare Ltd
c/o Ms. Jenny Hsieh
Official Correspondent
1FL, No. 16, Lane 454 Jungjeng Rd.
Yunghe City, Taipei County
China (Taiwan) 234

Re: K091757
Trade/Device Name: OTC TENS For Arm & Leg 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 10, 2009
Received: December 11, 2009

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 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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/cdrh/mdr/ 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Kesia Alexander for

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications For Use

510(k) Number (if known): K091757

Device Name: OTC TENS For Arm & Leg Pain Relief / Model WL-2407.

Indications For Use:

- The OTC TENS for Arm & Leg Pain Relief / model WL-2407 are intended for temporary relief of pain associated with sore and aching muscles in the upper and lower extremities (arm and/or leg) 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 Ophthalmic, Neurological and Ear,
Nose and Throat Devices

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