SEP 7 2012

# 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: K121353

1. Submitter's Identifications:

Well Life Healthcare Limited
1F., No. 16, Lane 454, Jungjeng Road, Yunghe City, Taipei County 234, Taiwan, ROC

Contact: Jenny Hsieh
Telephone: + 886 2 2928 2112

Date of Summary Preparation: August 17, 2012

2. Name of the Device:

Trade/Device Name: Mini Patch, model : WL-2301A & WL-2301B.
Regulation Number: 21 CFR 882.5890
Regulation Name: Stimulator, Nerve, Transcutaneous For Pain Relief.
Regulatory Class: II
Product Code: NUH

3. Information of the 510(k) Cleared Device (Predicate Device):
Well-Life OTC TENS for Arm & Leg Pain Relief. (K091757)

4. Device Description:

The Mini Patch, models WL-2301A & WL-2301B are transcutaneous electrical nerve stimulator used for pain relief by applying an electrical current to electrodes, which are attached on the skin. The output and waveform characteristic is fixed for every model, only the intensity is adjustable.

The Mini Patch, models WL-2301A & WL-2301AB, consist mainly of two parts: the stimulus generator, electrode. The stimulus generator generates the output current specified as the input of controller. The output port transmits the output current to the electrode, which is attached to the patient's skin so as to transmit this stimulus current to the patient for pain relief.

The stimulation mode for Mini Patch is burst mode with fixed pulse width, pulse rate, frequency, and fixed timer, only amplitude is adjustable. This operation way is considered the simplification from the burst mode of comparison clear model, WL-2302(K020020). Every model of Mini-TENS has its individual stimulation operation cycle.

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5. Intended Use:

The Mini Patch, model: WL-2301A & WL-2301B Transcutaneous Electrical Nerve Stimulators 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.

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 IEC 60601-1, and IEC 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. Comparison of Significant device features

| Comparison Features | Models to be Compared | |
|---|---|---|
| | OTC TENS for Arm & Leg | Mini Patch |
| Model | WL-2407 | WL-2301A & WL-2301B |
| 510(K) No. | K091757 | K121353 |
| Prescription or OTC | OTC | Same |
| Indication for use | 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 | Same |
| FDA product code | NUH | Same |
| Electrode Used | K082065, Snap Type self adhesive electrode( 5 X 5 cm) | K082065, Snap Type self adhesive electrode ( 2.925 x 5.6 cm) |
| Manufacturer | Well-Life | Same |

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## 8. Comparison of Unit Characteristics & Output Specification

| Parameter | | Predicate Device | New Device | |
|---|---|---|---|---|
| 510(K) Number | | K091757 | K121353 | K121353 |
| Device Name and Model | | WL-2407 | WL-2301A | WL-2301B |
| Manufacturer | | Well-Life | Same | Same |
| Power Source(s) | | 1.5Vx3 (AAA Size) | 3Vx1 | 3Vx1 |
| - Method of Line current Isolation | | Type BF | Same | Same |
| - Patient Leakage Current | | --- | --- | --- |
| - Normal condition (uA) | | Under 0.1 | Same | Same |
| - single Fault condition (uA) | | Under 0.5 | Same | Same |
| Average DC current through electrodes when device is on but no pulses are being applied (uA) | | Not applicable | Same | Same |
| Number of Output Modes | | 8 | 3 | 3 |
| Number of Output Channels: | Synchronous or Alternating? | Synchronous | Same | Same |
| | Method of Channel Isolation | Output Coil | Same | Same |
| Regulated Current or Regulated Voltage? | | Voltage | Same | Same |
| Software/Firmware/Microprocessor control? | | Yes | Same | Same |
| Automatic Overload Trip? | | No | Same | Same |
| Automatic No-Load Trip? | | Yes | Same | Same |
| Automatic Shut Off? | | Yes | Same | Same |
| User Override control? | | No | Same | Same |
| Indicator Display: | On/Off Status? | Yes | Same | Same |
| | Low Battery? | Yes | Same | Same |
| | Voltage/Current Level? | Yes | Same | Same |
| Timer Range (Minutes) | | 5~60 | 20 | 20 |
| Compliance with Voluntary Standards? | | ANSI/AAMI NS4, IEC 60601-1 & IEC 60601-1-2. | Same | Same |
| Compliance with 21 CFR 898? | | Yes | Same | Same |
| Weight (g) | | 43 | 20 | 20 |
| Dimensions (mm.) [W x H x D] | | 90×52.5×19.4 | 59×30×12.15 | 60.2×31.9×14.4 |
| Housing Materials and construction | | ABS | Same | Same |

| Parameter | | Predicate Device | New Device | |
|---|---|---|---|---|
| Mode or Program Name | | WL-2407 | WL-2301A | WL-2301B |
| Waveform (e.g., pulsed monophasic, biphasic) | | Biphasic | Same | Same |
| Shape (e.g., rectangular, spike, rectified sinusoidal) | | Rectangular (with deformation on the top of each pulse) | Same | Same |
| Maximum Output Voltage (volts) (+/- 20 %) | | 40V @500Ω | 30V @500Ω | 30V @500Ω |
| | | 62V @2kΩ | 50V @2kΩ | 50V @2kΩ |
| | | 104V @10kΩ | 80V @10kΩ | 80V @10kΩ |
| Maximum Output Current (specify units) (+/- 20 %) | | 80mA @500Ω | 60mA @500Ω | 60mA @500Ω |
| | | 31mA @2kΩ | 25mA @2kΩ | 25mA @2kΩ |
| | | 10.4mA @10kΩ | 8.0mA @10kΩ | 8.0mA @10kΩ |
| Duration of primary (desplarizing) phase (usec) | | 260 Max | 250 Max | 250 Max |
| Pulse Duration (usec) | | 500.26 ms/Max. | 33.58 ms/Max. | 33.58 ms/Max. |
| Frequency (Hz) [or Rate (pps)] | | 60 Max | 60 Max | 60 Max |
| For multiphasic waveforms only: | Symmetrical phases? | No | Same | Same |
| | Phase Duration (include units), (Stage range, if applicable), (both phases, if asymmetrical) | Not applicable | Same | Same |

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9. Significant output characteristics comparison table:

| Comparison feature | | Model | | Remarks |
|---|---|---|---|---|
| | | WL-2407 | WL-2301/2301B | |
| Net charge | | 0 | 0 | Note 1 |
| Max. phase charge | | 20.8 uc | 15uc | |
| Max. current Density | | 0.050 mA/cm$^2$ | 0.055 mA/cm$^2$ | |
| Max. Average current (RMSA) | 500 Ω | 38.43mA | 29.394 mA | |
| | 2K Ω | 14.892mA | 12.248 mA | |
| | 10 Ω | 4.996mA | 3.9192 mA | |
| Max. Power Density | | 0.0020Watts/ cm$^2$ | 0.0017Watts/ cm$^2$ | |
| Burst Mode | | No | 6Sec/On & 1Sec/Off | |

Note: Net Charge is Zero for the symmetrical stimulation biphasic wave

10. Conclusions

The Well-Life Mini Patch, model: WL-2301A & WL-2301B Transcutaneous Electrical Nerve Stimulators has the same intended use and the similar technological characteristics as the cleared device- Well-Life OTC TENS for Arm & Leg Pain Relief. (K091757) . 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
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

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Well Life Healthcare, Ltd
% Ms. Jenny Hsieh
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Taiwan, R.O.C.

Re: K121353
Trade/Device Name: Mini Patch, Model WL-2301A & WL-2301B
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator for Pain Relief
Regulatory Class: II
Product Code: NUH
Dated: August 17, 2012
Received: August 21, 2012

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. 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 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/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,

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): K121353

Device Name: Mini Patch, model : WL-2301A & WL-2301B

Indications For Use:

The Mini Patch, model: WL-2301A & WL-2301B Transcutaneous Electrical Nerve Stimulators 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)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

510(k) Number K121353