JAN 2 8 2014

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: K133723 .

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: November 15, 2013

2. Name of the Device:

Trade/Device Name: OTC Patch, Model: WL-2406.
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous electrical nerve stimulator.
Regulatory Class: II
Product Code: NUH

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

K052785: OTC TENS For Low Back Pain Relief/ Model WL-2406.
K091757: OTC TENS For Arm & Leg Pain Relief/ Model WL-2407.

4. Device Description:

The OTC Patch, model WL-2406 is a single channel transcutaneous electrical nerve stimulator used for pain relief by applying an electrical current to electrodes, which are attached on the user's skin. The output and waveform characteristic is fixed for every operation mode, only the intensity is adjustable within specified limit.

The OTC Patch, model WL-2406, 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 user's skin so as to transmit this stimulus current for pain relief.

The stimulation modes for OTC Patch is pre-program modes with fixed pulse width, pulse rate, frequency, and fixed timer, only amplitude is adjustable. This operation way is considered the simplification from the pre-program modes of comparison clear model, OTC TENS For Low Back Pain Relief/ Model WL-2406(K052785). Every operation mode of OTC Patch, model WL-2406 has its individual stimulation operation cycle.

For the device included in this submission, we use the following of our 510(K) legally marketed predicate electrodes:K082065, "Well-Life Self Adhesive Electrode", CM Series/ model no. CM-130x70, size 130x70mm, snap type.

With the combination of the main device parts, the device can be placed on the treatment locations as recommended in the user manual for temporary relief of pain associated with sore and aching muscles in the low back as well as upper and lower extremities (arm and/or leg) due to strain from exercise or normal household and work activities.

5. Intended Use:

The OTC Patch, Model WL-2406, is intended for temporary relief of pain associated with sore and aching muscles in the low back and/or 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 IEC 60601-2-10, 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.

Discussion: The Compliance to applicable voluntary standards as above mentioned indicates that the new device in this submission used the same standards as that of predicate device. Therefore; we consider that the compliance of standards included in our submission is adequate for the determination of substantial equivalence.

7. Comparison of Significant device features

Features	510(K) Cleared Models		New Model
Model	WL-2406	WL-2407	WL-2406
510(K) No.	K052785	K091757	Unknown
Prescription or OTC	OTC	OTC	OTC
Indication for use	temporary relief of pain associated with sore and aching muscles in the low back due to strain from exercise or normal House-hold and work activities	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 House-hold and work activities	temporary relief of pain associated with sore and aching muscles in the low back as well as upper and lower extremities (arm and/ or leg) due to strain from exercise or normal House-hold and work activities
FDA product code	NUH	NUH	NUH
Electrode Used	Belt Electrode (5 X 5 cm)/K082065	Belt Electrode and/or Self Adhesive Electrode (5 X 5 cm)/K082065	Self Adhesive Electrode (13x7 cm)/K082065

8. Significant output characteristics comparison table:

Comparison feature		510(K) Cleared Model		New Model
		WL-2406(K052785)	WL-2407(K091757)	WL-2406
Net charge		0	0	0
Max. phase charge		13 uc	20.8 uc	13 uc
Max. current Density		0.0246 mA/cm^2	0.04992 mA/cm^2	0.04875 mA/cm^2
Max. Average current (RMSA)	500 Ω	50 mA	80 mA	50 mA
	2K Ω	22.5 mA	30 mA	22.5 mA
	10 Ω	7.5 mA	10 mA	7.5 mA
Max. Power Density		0.00156 Watts/ cm^2	0.00200 Watts/ cm^2	0.001219 Watts/ cm^2
Burst Mode		Yes	Yes	Yes

9. Comparison of Unit Characteristics & Output Specification

		Predicate Device		New Device
Mode or Program Name		WL-2406	WL-2407	WL-2406 OTC Patch
Waveform (e.g., pulsed monophasic, biphasic)		Biphasic	Biphasic	Biphasic
Shape (e.g., rectangular, spike, rectified sinusoidal)		Rectangular	Rectangular	Rectangular
Maximum Output Voltage (volts) (+/-_20 %)		25V @500Ω 45V @2KΩ 75V @10KΩ	40V @500Ω 60V @2KΩ 100V @10KΩ	25V @500Ω 45V @2KΩ 75V @10KΩ
Maximum Output Current (mA) (+/-_20 %)		50mA @500Ω 22.5mA @2KΩ 7.5mA @10KΩ	80mA @500Ω 30mA @2KΩ 10mA @10KΩ	50mA @500Ω 22.5mA @2KΩ 7.5mA @10KΩ
Duration of primary phase (usec)		260 max	260 max	260 max
Pulse Duration (usec)		8700 max	650 max	8700 max
Frequency (Hz) [or Rate (pps)]		120 max	60 max	120 max
For multiphasic waveforms only:	Symmetrical phases?	Yes	Yes	Yes
	Phase Duration (include units),(Stage range, if applicable),(both phases, if asymmetrical)	Not applicable	Not applicable	Not applicable
510(K) Number		K052785	K091757	Unknown
Device Name and Model		WL-2406	WL-2407	WL-2406 OTC Patch
Manufacturer		Well-Life	Well-Life	Well-Life
Power Source(s)		1.5Vx2 (AAA Size)	1.5Vx3 (AAA Size)	1.5Vx2 (AAA Size)
- Method of Line current Isolation		Type BF	Type BF	Type BF
- Patient Leakage Current		---	---	---
- Normal condition (uA)		Under 0.1	Under 0.1	Under 0.1
- single Fault condition (uA)		Under 0.5	Under 0.5	Under 0.5
Average DC current through electrodes when device is on but no pulses are being applied (uA)		Not applicable	Not applicable	Not applicable
Number of Output Modes		8	8	8
Number of Output Channels:	Synchronous or Alternating?	Synchronous	Synchronous	Synchronous
	Method of Channel Isolation	Output Coil	Output Coil	Output Coil
Regulated Current or Regulated Voltage?		Voltage	Voltage	Voltage
Software/Firmware/Microprocessor control?		Yes	Yes	Yes
Automatic Overload Trip?		No	No	No
Automatic No-Load Trip?		Yes	Yes	Yes
Automatic Shut Off?		Yes	Yes	Yes
User Override control?		No	No	No
Indicator Display:	On/Off Status?	Yes	Yes	Yes
	Low Battery?	Yes	Yes	Yes
	Voltage/Current Level?	Yes	Yes	Yes
Timer Range (Minutes)		10-60	5-60	10-60
Compliance with Voluntary Standards?		IEC 60601-2-10	IEC 60601-2-10	IEC 60601-2-10
Compliance with 21 CFR 898?		Yes	Yes	Yes
Weight (g) including battery		51.6	125.5	51.6
Dimensions (mm.) [W x H x D]		68×60×17.5	90×50.8×12.7	68×60×17.5
Housing Materials and construction		ABS	ABS	ABS
Pulse per burst		Same for each program	Same for each program	Same for each program
Burst per second		Same for each program	Same for each program	Same for each program
Bust duration		Same for each program	Same for each program	Same for each program
Duty Cycle		Same for each program	Same for each program	Same for each program
Method of achieving zero net charge for net charge/pulse		Biphasic symmetric wave for each pulse	Biphasic symmetric wave for each pulse	Biphasic symmetric wave for each pulse

10. Summary for the technology comparison.

Basically the OTC Patch, Model WL-2406 has the similar technological characteristics with the predicate device in the product design, material, energy source type, main program mode and the main output waveform...etc. There exists some difference in the detailed output parameters (mainly in the pulse duration and electrode sizes). Through the detailed calculation comparison of stimulation output energy for each operation mode(in particular the output current density and power density), we found the output level in each operation mode for our OTC Patch, model WL-2406 and predicate device are very close and within the acceptable range as specified in FDA guidance. So we believe the difference in detailed output parameters does not affect the determination of substantial equivalence.

11. Conclusions

The OTC Patch, Model: WL-2406 have the same intended use and the similar technological characteristics as the cleared devices. Moreover, verification and validation tests contained in this submission 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 Center – WO66-G609
Silver Spring, MD 20993-0002

January 28, 2014

Well-Life Healthcare Limited
c/o Jenny Hsieh
1FL., No.16, Lane 454, Jungjeng Rd.
Yunghe City, Taipei County 234, Taiwan, R.O.C.

Re: K133723
Trade/Device Name: Well-Life OTC Patch, model: WL-2406
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator
Regulatory Class: Class II
Product Code: NUH
Dated: December 4, 2013
Received: December 6, 2013

Dear Jenny 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 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. 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,

Carlos L. Pena -S

Carlos L. Peña, Ph.D., M.S.
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K133723

Device Name
Well-Life OTC Patch, model: WL-2406

Indications for Use *(Describe)*
The OTC Patch, Model WL-2406, is intended for temporary relief of pain associated with sore and aching muscles in the low back as well as upper and lower extremities (arm and/or leg) due to strain from exercise or normal household and work activities

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Carlos L. Pena -S

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