August 4, 2022

Well-Life Healthcare Limited
Jenny Hsieh
6F., No.168, Lide St., Jhonghe District
New Taipei City, 23512
Taiwan

Re: K220524
Trade/Device Name: Well-Life Mini TENS Stimulator(WL-23XXC/WL-23XXE Series)
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator For Pain Relief
Regulatory Class: Class II
Product Code: NUH
Dated: April 28, 2022
Received: May 6, 2022

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Pamela Scott
Assistant Director
DHT5B: Division of Neuromodulation
and Physical Medicine Devices
OHT5: Office of Neurological
and Physical Medicine Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K220524

Device Name

Well-Life Mini TENS Stimulator (WL-23XXC/WL-23XXE Series)
Model:WL-2301C/ WL-2301E/ WL-2306C/ WL-2306E

Indications for Use *(Describe)*

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.

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Well-Life Healthcare Limited

510(K) Summary

1. Type of Submission: Traditional

2. Preparation date: 28th April, 2022

3. Submitter: Well-Life Healthcare Ltd.

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Contact: Jenny Hsieh
(jenny@welllifehealthcare.com.tw)
Registration number: 3006850006

4. Identification of the subject device:

510K No. (Applying)

Trade/Device Name: Well-Life Mini TENS Stimulator
(WL-23XXC/WL-23XXE Series)
Model: WL-2301C/WL-2301E/WL-2306C/WL-2306E

Regulation Number: 21 CFR 882.5890

Regulation Name: Transcutaneous Electrical Nerve Stimulator for Pain Relief

Regulatory Class: Class II

Product Code: NUH

5. Identification of the Predicate

Primary Predicate:

The OTC MINI PATCH K121353 (Model WL-2301A/WL-2301B) by Well-Life Healthcare Ltd. which has been cleared by Food and Drug Administration.
The Subject Device is designed based on this product, so the specifications and parameters of electrical stimulation are substantial equivalent. The following is the basic information of the product.

510K No. K121353 Trade/Device Name: OTC MINI PATCH K121353 Model: WL-2301A/WL-2301B Regulation Number: 21 CFR 882.5890 Regulation Name: Transcutaneous Electrical Nerve Stimulator for Pain Relief Regulatory Class: Class II Product Code: NUH

Secondary Predicate Device

The OTC PATCH K133723 (Model WL-2406) by Well-Life Healthcare Ltd. which has been cleared by Food and Drug Administration.
The Output Mode (Out Put Signal) of subject device WL-2306C and WL-2306E were reference from The OTC PATCH K133723 (Model WL-2406) so the output mode of electrical stimulation is substantial equivalent. The following is the basic information of the product.

510K No. K133723 Trade/Device Name: OTC PATCH Model: WL-2406 Regulation Number: 21 CFR 882.5890 Regulation Name: Transcutaneous Electrical Nerve Stimulator for Pain

Relief Regulatory Class: Class II Product Code: NUH

6. Intended Use and Indications for use of the Subject Device:

Intended for temporary relief of pain Same 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.

7. Description of the Device:

Well-Life Mini TENS Stimulator (WL-23XXC/WL-23XXE Series) provides a transcutaneous electrical nerve stimulation (TENS) for temporary relief of pain associated with sore and aching muscles due to strain from exercise, normal household chores and work-related activities. The output port transmits the output signal to the electrode, which is attached to the user's skin; with the combination of the Stimulator 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, arthritis as well as upper and lower extremities (arm and/or leg) due to strain from exercise or normal household and work activities.

The Well-Life Mini TENS Stimulator (WL-23XXC/WL-23XXE Series) is design changed from OTC MINI PATCH K121353 (Model WL-2301A/WL-2301B).

The main differences between the two are disposable battery change to reusable battery, aside from battery changes, the appearance of the devices is also different. Also, minor changes include PCBA component placement changes, frame size changes, and new accessories to improve convenience.

The definition of model name: WL is abbreviation of Well-Life Healthcare Limited. 23 is symbol of device series which are wireless, no monitor and operated by buttoning only. XX is the symbol for different program and output electrical signal in this device. The last English alphabet is the symbol of the appearance of this device, For C, it is oval shape and for E, it is round shape. The model of Stimulator device are WL-2301C, WL-2301E, WL-2306C and WL-2306E, which include operating elements, such as the ON/OFF button, intensity increase button, and intensity decrease button, and could be attached and detached to electrodes. The Stimulator device offers several different preset programs, and will switch automatically, with 21 minutes per session and will turn off automatically after each session. The Stimulator device could be operated through its buttons to manually realize its functions, such as turning on/off and increasing/decreasing intensity.

The accessories of Well-Life Mini TENS Stimulator (WL-23XXC/WL-23XXE Series) are electrode which can be patch or garment. 3 models of patches and 5 models of garments are recommended. There are CM7257, CM169100, CM13070 for electrode patch and Well-Life Garment Electrode -Arm (GM-AM-O-X00), Well-Life Garment Electrode -Elbow (GM-EB-O-X00), Well-Life Garment Electrode -Back Strech Belt (EW-BK-00lE), Well-Life Garment Electrode - Wrist (EW-WR-00lE) and Well-Life Garment-Knee (EW-KN-002E).

The electrode Pad composed of non-woven fabric, conductive layer and conductive gel, it is connected to the stimulator through buttons or wires, and is in contact with the skin through conductive gel to transmit electrical signal to the skin to achieve therapeutic effects.
The Well-Life Garment Electrode series are blending by Non-conductive textile and conductive textile, from the name of the conductive garment the user can identify the applicable body part, and the textile technology is adjusted to make the product fit on the skin. It is connected to the stimulator through buttons or wires, and is in contact with the skin through conductive textile to transmit electrical signal to the skin to achieve therapeutic effects.
The Stimulator device can connect to a specified external IEC 60601-1 compliant power supply for charging of the internal lithium-ion battery. The accessories must comply with AAMI/ ANSI/ES60601- 1, IEC 60601-1-2 and IEC 60601-2-10. The accessories include: An external power adaptor, an electrode cord I cable attached to electrodes pads and battery.

8. Statement of conformity

List of FDA-recognized voluntary consensus standards cited in this submission.

Recognition Number	Standard Designation Number and Date	Title Of Standard	Date Of Recognition
5-89	IEC 60601-1-6 Edition 3.1 2013-10	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability	06/27/2016
5-114	IEC 62366-1 Edition 1.0 2015-02	Medical devices - Part 1: Application of usability engineering to medical devices	12/23/2016
2-258	ISO 10993-1 Fifth Edition 2018-08	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process	01/14/2019
2-245	ISO 10993-5 Third Edition 2009-06-01	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity	02/23/2016
2-174	ISO 10993-10 Third Edition	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization	07/26/2016

	2010-08-01		
19-4	IEC 60601-1:2005, MOD	Medical electrical equipment- Part 1: General requirements for basic safety and essential performance	07/09/2014
19-8	IEC 60601-1-2 :2014	Medical electrical equipment -- Part 1-2: General requirements for basic safety and essential performance -- Collateral Standard: Electromagnetic disturbances -- Requirements and tests	09/17/2018
19-14	IEC 60601-1-11 Edition 2.0 2015-01	Medical electrical equipment– Part 1-11: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment	06/27/2016
17-16	IEC 60601-2-10 Edition 2.1 2016-04	Medical electrical equipment - Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators	06/27/2016
19-13	IEC 62133 Edition 2.0 2012-12	Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications [Including: Corrigendum 1 (2013)]	12/23/2019
5-125	ISO 14971 Third Edition 2019-12	Medical devices - Application of risk management to medical devices	12/23/2019
17-14	ANSIAAMI NS4:2013(R)2017	Transcutaneous Electrical Nerve Stimulators 2013(R)2017	01/14/2019
	FDA guidance,	General Principle of Software Validation; Final Guidance for Industry and FDA Staff"	January 11, 2002.

9. Clinical Testing Summary:

No clinical testing was conducted for this device.

10. Non-Clinical Testing Summary:

The following non-clinical testing was conducted in the subject devices. Those tests showed that the device met all design specifications, demonstrated safety based on current industry standards:

1) Biocompatibility Patient contacting components are in compliance with ISO 10993-1 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process, including cytotoxicity (ISO 10993-5 Third Edition 2009-06-01), sensitization (ISO 10993-10 Third Edition 2010-08-01),
2) EMC and Electrical Safety was performed to verify the electrical specifications of the proposed device and included the following:

- IEC 60601-1:2005, MOD Medical electrical equipment- Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2:2014, Medical electrical equipment -- Part 1-2: General requirements for basic safety and essential performance -- Collateral Standard: Electromagnetic disturbances -- Requirements and tests
- IEC 60601-1-11 Edition 2.0 2015-01, Medical electrical equipment- Part 1- 11: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
- IEC 62133 Edition 2.0 2012-12, Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications [Including: Corrigendum 1 (2013)]

3) Performance Testing Bench testing was performed to verify the performance to specifications of the proposed device and included the following:

- Particular requirements for the basic safety and essential performance of nerve and muscle stimulators (IEC 60601-2-10 Edition 2.1 2016-04)
- Transcutaneous Electrical Nerve Stimulators 2013(R)2017 (ANSI AAMI NS4:2013(R)2017)
- Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability (IEC 60601- 1-6 Edition 3.1 2013-10) and Medical devices - Part 1: Application of usability engineering to medical devices (IEC 62366-1 Edition 1.0 2015-02)

10. Substantial Equivalence Determination:

10.1 Substantial Equivalence Comparison to Predicate/ Original Device (Regular Specification)

		Primary Predicate Device	Subject Device	
Device Name		OTC MINI PATCH Model: WL-2301A	Well-Life Mini TENS Model: WL-23XXC/WL-23XXE Series	--
510(K) Number		K121353	Applying	--
Regulation Number		882.5890	882.5890	Same
Product Code		NUH	NUH	Same
OTC/Rx		OTC	OTC	Same
Indication for use		Intended for temporary relief of pain Same 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.	Intended for temporary relief of pain Same 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
Power Source(s)		3V (CR2032)	Rechargeable Li-Battery	Note1
-Method of Line current Isolation		Type BF	Type BF	Same
-Patient Leakage Current		---	---	--
-Normal condition(μA)		Under 0.1	Under 0.1	Same
-single Fault condition(μA)		Under 0.5	Under 0.5	Same
Average DC current through electrodes when device is on but no pulses are being applied(μA)		Not applicable	Not applicable	Same
Number of Output channels:	Synchronous or alternating?	Synchronous	Synchronous	Same

Well-Life Healthcare Limited

	Method of Channel Isolation	Output Coil	Output Coil	Same
Regulated Current or Regulated Voltage?		Voltage	Voltage	Same
Software/Firmware/Microprocessor control?		Yes	Yes	Same
Automatic Overload Trip?		No	No	Same
Automatic No-Load Trip?		Yes	Yes	Same
Automatic Shut Off?		Yes	Yes	Same
User Override control?		No	No	Same
Indicator Display:	On/Off Status?	Yes	Yes	Same
	Low Battery?	Yes	Yes	Same
	Voltage/Current Level?	Yes	Yes	Same
Timer Range (Minutes)		20	20	Same
Compliance with Voluntary Standards?		**ES60601-1, IEC60601-1-2, IEC60601-2-10, IEC 60601-1-11**	**ES60601-1, IEC60601-1-2, IEC60601-2-10, IEC 60601-1-11**	Same
Compliance with 21 CFR 898?		Yes	Yes	Same
Weight(g) including battery		14.2g	23.8g	--
Dimensions (mm.) [L x W x H]		59*30*13.0 mm (L*W*H)	WL-2301C/2306C: 64*41*16.7 mm (L*W*H) WL-2301/2306E: 56*49*15.9 mm (L*W*H)	--
Housing Materials and construction		ABS	ABS	Same

10.2 Substantial Equivalence Comparison to Predicate/ Original Device (Output Signal Specification)

	Primary **K121353**	**Subject Device**		**Second Predicate** **K133723**	
Model Number	WL-2301A	WL-2301C/E, WL-2306C/E		WL-2406	
Waveform (e.g., pulsed monophasic, biphasic)	Bia-phasic				Same as primary
Number of Output Modes	WL-2301A: 3	WL-2301C/E:3		WL-2406:8	Same as primary
		WL-2306C/E:8			See 2.3 Note.2 Same as Ref.
Shape	Rectangular (With deformation on the top of each pulse)				Same as primary
Maximum Output Voltage(volts) (+/-_20%)	30V@500Ω 50V@2KΩ 80V@10KΩ	**WL-2301C/E** 30V@500Ω 50V@2KΩ 80V@10KΩ	**WL-2306C/E** 30V@500Ω 50V@2KΩ 80V@10KΩ	25V@500Ω 45V@2KΩ 75V@10KΩ	Same as primary
Maximum Output Current(mA) (+/-_20%)	60mA@500Ω 25mA@2KΩ 8mA@10KΩ	**WL-2301C/E** 60mA@500Ω 25mA@2KΩ 8mA@10KΩ	**WL-2306C/E** 60mA@500Ω 25mA@2KΩ 8mA@10KΩ	50mA@500Ω 22.5mA@2KΩ 7.5mA@10KΩ	Same as primary
Pulse Duration(μsec)	WL-2301A: 250MAX	WL-2301C/E:250		WL-2406: 260MAX	Same as primary
		WL-2306C/E:260			See 2.3

					Note.2
Frequency (Hz) [or Rate (pps)]		WL-2301A: 60 MAX	WL-2301C/E:60	WL-2406:120 MAX	Same as primary
			WL-2306C/E:120		See 2.3 Note.2
For multiphasic waveforms only:	Symmetrical phases?	No	No	No	Same as primary
	Phase Duration (include units), (Stage range, if applicable), (both phases if asymmetrical)	N/A	N/A	N/A	Same as primary
Accessories or consumables		K082065/ CM7257 K082065/ CM169100	K082065/ CM7257 K082065/ CM169100 K082065/ CM13070 K200942/Garment Electrode EB K200942/Garment Electrode AM Exclusive accessories Back Belt Exclusive accessories Knee Belt Exclusive accessories Wrist Belt	K082065/ CM7257 K082065/ CM169100	Note3

		Predicate/ Original Device (WL-2301A)	Subject device (WL-2301C / WL-2301E)	Subject device (WL-2306C / WL-2306E)
Maximum output charge per pulse (uC)		15		15.6
Maximum average current (mA)		0.9		1.87
Maximum output power (W)		0.027		0.056
K082065/ CM7257	Max Current Density (mA/cm^2)	0.0549		0.1140
	Max Power Density (W/cm^2)	0.0016		0.0003
K082065/ CM169100	Max Current Density (mA/cm^2)	0.0281		0.0584
	Max Power Density (W/cm^2)	0.0008		0.0002
K082065/ CM13070	Max Current Density (mA/cm^2)	not applicable	0.0281	0.0584
	Max Power Density (W/cm^2)	not applicable	0.0008	0.0002
K200942/Garment Electrode EB	Max Current Density (mA/cm^2)	not applicable	0.0353	0.0733
	Max Power Density (W/cm^2)	not applicable	0.0011	0.0002
K200942/Garment Electrode AM	Max Current Density (mA/cm^2)	not applicable	0.0231	0.0479
	Max Power Density (W/cm^2)	not applicable	0.0007	0.0001
Exclusive accessories Back Belt	Max Current Density (mA/cm^2)	not applicable	0.0360	0.0748
	Max Power Density (W/cm^2)	not applicable	0.0011	0.0002
Exclusive accessories Knee Belt	Max Current Density (mA/cm^2)	not applicable	0.0231	0.0479
	Max Power Density (W/cm^2)	not applicable	0.0007	0.0001
Exclusive accessories Wrist Belt	Max Current Density (mA/cm^2)	not applicable	0.0600	0.1247
	Max Power Density (W/cm^2)	not applicable	0.0018	0.0004

The device and accessories are developed base on "IEC60601-2-10" and "ANSI AAMI NS4:2013(R)2017 Transcutaneous Electrical Nerve Stimulators". The standard of "Maximum Average Current Density < 2 mA/cm^2" refers to "IEC60601-2-10 Clause 201.4.2" and the standard of "Maximum Peak Power Density < 0.25W/cm^2" refer to "ANSI AAMI NS4:2013(R)2017 Transcutaneous Electrical Nerve Stimulators".

3. Comparison in Detail(s):

Note 1

The Power Source of Subject Device is changed into Rechargeable. By the study data from the section 14, 15, 17, 18, 21 and 22, it can be identified to be substantial equivalent to the Predicated Device.

Note 2

The Output Signal Specification of Model no. WL-2301C/E of Subject device is identical to Predicated device.
The Output Signal Specification of Model no. WL-2306C/E of Subject device is minor different from Predicated device but same as Reference Device (K133723, WL-2406).
Thus, based on the above conclusions, we believe that the slight modification of the Subject device is not impact safety and effectiveness.

For comparison of related safety specifications, Annex of NS4 table is stated. The difference of Output Signal Specification is minor and can be adjusted. Therefore, the Output Signal Specification of Model no. WL-2306C/E of Subject device can be identified to be substantial equivalent to the Predicated Device.

Note 3

With regard to Accessories or consumables, 2 items are recommended to use with the predicated device and 8 items are with the subject device. The additional 6 contain 3 FDA approval (K082065/ CM13070, K200942/Garment Electrode EB, K200942/Garment Electrode AM and 3 Non-FDA approval (Exclusive accessories Back Belt, Exclusive accessories Knee Belt and Exclusive accessories Wrist Belt. Those 3 Non-FDA approval garment electrodes are extensive model of K200942/Garment Electrode and necessary tests are conducted and no concern in the safety and effectiveness.

4. Conclusion:

After Comparison and Evaluation, the subject device Well-Life Mini TENS Stimulator (WL-23XXC/WL-23XXE Series) has all same feature as predicate devices. No matter with impact of the safety or effectiveness is considered and studied.

The minor differences are explained and no matter with impact of the safety and effectiveness. Thus, the subject device is substantially equivalent with the Predicate Device: OTC MINI PATCH Model: WL-2301A (K121353).