October 18, 2024

Well-Life Healthcare Limited
Jenny Hsieh
Official Correspondent
6F., No. 168, Lide St., Jhonghe District
New Taipei City, Taiwan 235

Re: K233054
Trade/Device Name: Well-Life Pain Relief (Menstrual Plus) Electrical Stimulator; TENS/EMS WITH Menstrual Relief Stimulator; Well-Life Pain Relief Stimulator; Menstrual Plus Stimulator
Regulation Number: 21 CFR 882.5890, 21 CFR 890.5850
Regulation Name: Transcutaneous Electrical Nerve Stimulator For Pain Relief
Regulatory Class: Class II
Product Code: NUH, NGX, NYN
Dated: September 2, 2024
Received: September 18, 2024

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Robert Kang -S

for 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K233054

Device Name
Well-Life Pain Relief (Menstrual Plus) Electrical Stimulator; TENS/EMS WITH Menstrual Relief Stimulator; Well-Life Pain Relief Stimulator; Menstrual Plus Stimulator

Indications for Use *(Describe)*

For WL-2315C(M) and WL-2315E(M) models:
The WL-2315C(M) and WL-2315E(M) are designed for the symptomatic relief and management of pain. They offer temporary relief from pain associated with dysmenorrhea (menstrual cramps) when used with over-the- counter pain medication.

For WL-2405H(M) model:
The WL-2405H(M) is designed for symptomatic relief and management of chronic pain and provides temporary relief from sore and aching muscles in the shoulders, waist, back, neck, upper extremities (arms), and lower extremities (legs) due to strain from exercise or daily activities. It also offers temporary relief of pain associated with dysmenorrhea (menstrual cramps) when used with over-the-counter pain medication.
Additionally, the WL-2405H(M) features EMS functionality for stimulating healthy muscles to enhance or facilitate muscle performance (select EMS modes). It also provides symptomatic relief and management of chronic, intractable pain and relief from pain associated with arthritis (select TENS mode P8).

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.

Well-Life Healthcare Limited

510(K) Statement

1.	Type of Submission:	Traditional
2.	Preparation date:	**10/17/2024**
3.	Submitter:	Well-Life Healthcare Ltd.
	Address:	6F. No.168, Lide St., Jhonghe District, New Taipei City, 23512, Taiwan
	Phone:	+886-2-22266981
	Fax:	+886-2-22266965
	Contact:	Jenny Hsieh (Jenny@welllifehealthcare.com.tw)
	Registration number:	3006850006

1. Identification of the device:

510(K) No	K233054
Subject Device Name:	Well-Life Pain relief (Menstrual Plus) Electrical Stimulator
Common or usual name:	Electrical stimulator, Transcutaneous electrical nerve stimulator
Model:	WL-2405H (M), WL-2315C (M), WL-2315E (M)
Classification name:	stimulator, nerve, transcutaneous, over-the-counter
Classification Panel:	Neurology
Device Classification:	II
OTC/RX	OTC
Regulation Number:	21 CFR Part 882.5890
Primary Product Code	NUH
Secondary product codes	NGX, NYN

2. Identification of the Predicate Devices:

Primary Predicate Device:	
510(K) No	K172809
Device Name:	OTC Combo TENS/EMS System
Model:	WL-2405H, WL-2405(G)
Classification name:	stimulator, nerve, transcutaneous, over-the-counter
Classification Panel:	Neurology
Device Classification:	II
OTC/RX	OTC
Regulation Number:	21 CFR Part 882.5890
Product Code	NUH, NGX, NYN

Secondary Predicate Device:	
510(K) No	K183110
Device Name:	Livia
Model:	--
Classification name:	stimulator, nerve, transcutaneous, over-the-counter
Classification Panel:	Neurology
Device Classification:	II
OTC/RX	OTC
Regulation Number:	21 CFR Part 882.5890
Product Code	NUH

Reference Device 1: Accessories	
510(K) No	K082065
Device Name:	WELL LIFE SELF ADHESIVE ELECTRODE
Model:	CM, FA, PU AND SP
Classification name:	Electrode, Cutaneous
Classification Panel:	Neurology
Device Classification:	II
OTC/RX	OTC+RX
Regulation Number:	21 CFR Part 882.1320
Product Code	GXY

Reference Device 2: Reference	
510(K) No	K220524
Device Name	Well-Life Mini TENS Stimulator (WL-23XXC/WL-23XXE Series)
Model:	WL-2301E/WL-2301C
Classification name:	Stimulator, Nerve, Transcutaneous, Over-the-Counter
Classification Panel:	Neurology
Device Classification:	II
OTC/RX	OTC
Regulation Number:	882.5890
Product Code	NUH

3. Indications for use of the Subject Device:

Well-Life Healthcare Limited

Indications for use

Well-Life Pain Relief (Menstrual Plus) Electrical Stimulator
The Well-Life Pain Relief (Menstrual Plus) Electrical Stimulator includes three models: WL-2315C(M), WL-2315E(M), and WL-2405H(M). The indications for use are as follows:

For WL-2315C(M) and WL-2315E(M)

The WL-2315C(M) and WL-2315E(M) are designed for the symptomatic relief and management of pain. They offer temporary relief from pain associated with dysmenorrhea (menstrual cramps) when used with over-the- counter pain medication.

For WL-2405H(M)

The WL-2405H(M) is designed for symptomatic relief and management of chronic pain and provides temporary relief from sore and aching muscles in the shoulders, waist, back, neck, upper extremities (arms), and lower extremities (legs) due to strain from exercise or daily activities. It also offers temporary relief of pain associated with dysmenorrhea (menstrual cramps) when used with over-the-counter pain medication.
Additionally, the WL-2405H(M) features EMS functionality for stimulating healthy muscles to enhance or facilitate muscle performance (select EMS modes). It also provides symptomatic relief and management of chronic, intractable pain and relief from pain associated with arthritis (select TENS mode P8).

4. Description of the Device:

The Well-Life Pain relief (Menstrual Plus) Electrical Stimulator is designed for symptomatic relief and management of chronic pain, and for temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back, neck, upper extremities (arm) and lower (extremities) leg due to strain from exercise or normal household work activities. It also provides symptomatic relief and management of chronic, intractable pain and relief from pain associated with arthritis
This stimulator should be applied to the normal, healthy, dry, and clean skin of adult patients with the aim of stimulating healthy muscles and enhancing muscle performance.
There are three available models: WL-2405H(M), WL-2315E(M), and WL-2315C(M).
WL-2405H(M) is derived from the WL-2405H (FDA 510K no. K172809) with modifications. It includes the original TENS modes P1-P8 and EMS modes P1-P6, along with two additional TENS modes (P9, P10). TENS P9 is used for Pain Relief/Menstrual pain relief, while TENS P10 is suitable for Pain Relief. The WL-2405H(M) model offers 16 preset modes, with 10 modes for TENS (Transcutaneous Electrical Nerve Stimulation) and 6 modes for EMS (Electrical Muscle Stimulation). It features an LCD/LED display and a user-friendly interface that allows for adjustments to preset modes, output signal intensity, and treatment duration. It also includes two output channels.
The WL-2315E(M)/WL-2315C(M) model is a distinct version that exclusively focuses on the TENS P9 mode for dysmenorrhea pain relief, derived from the WL-2405H(M) model. This series of products is an adaptation of the mini-TENS stimulator.
(wl-23xxc/wl-23xxe series) family (FDA 510K no. K220524), with identical external design and internal components, software, etc., with the only modification being the Output Signal. This model has three buttons for power on/off and intensity adjustment and is intended for use with the specified preset mode, providing relief for chronic pain and sore muscles in various body areas. It is for alleviating pain associated with dysmenorrhea (menstrual cramps).

The Well-Life Pain Relief (Menstrual Plus) Electrical Stimulator must be used with 510K cleared Electrode pads (K082065) and Garment electrodes (K200942). These accessories are available for purchase along with the device or separately as supplementary packs.

5. **Non-Clinical Performance Testing**:

Non-clinical testing was conducted to verify that the subject devices met all design specifications, demonstrated safety based on current industry standards, and to demonstrate substantial equivalence to the predicate. The following tests were performed:

1) Sterilization and Shelf Life
   To demonstrate the adequacy of the shelf life, the recommended study process for the similar product released on guidance document FDA-2020-D-0957 "Shelf Life of Medical Devices" and ASTM F1980-16 "Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices "is followed. After test and study, the shelf life for electrodes to be used with the device is 2 years.

2) Biocompatibility
   No biocompatibility testing performed for this submission because the electrodes to be used with the device have already been cleared in K082065 and K200942.

3) Software Validation
   The FDA guidance document titled "General Principles of Software Validation: Final Guidance for Industry and FDA Staff"issued on 11/05/2005" was used to validate software used in the device. Required documentation was provided in accordance with this guidance document.

4) Electromagnetic compatibility and electrical safety
   Testing was performed to verify the electromagnetic compatibility and electrical safety of the subject device using the following standards:
   (1) IEC60601-1: General requirements for basic safety and essential performance
   (2) IEC-60601-1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
   (3) IEC-60601-1-11: 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
   (4) IEC-60601-2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators
   (5) Bench testing was performed to verify the output parameter specifications of the device using the AAMI NS4(2013) standard for Transcutaneous Electrical Nerve Stimulators

5) Clinical Testing Performance Testing

No clinical performance testing was conducted or necessary for this device and indications for use.

7. Substantial Equivalence Discussion:

7.1 Substantial Equivalence Comparison to Predicate Device

Attribute	Subject Device	Primary Predicate Device:	Secondary Predicate Device:	Comparison
Product Name	The Well-Life Pain relief (Menstrual Plus) Electrical Stimulator	OTC Combo TENS/EMS System	Livia	
Model	WL-2405H(M), WL-2315E(M), WL-2315C(M)	WL-2405H, WL-2405G	---	
Manufacture	Well-life Healthcare	Well-life Healthcare	Life-Care Ltd.	
510(K) number	Applying	K172809	K183110	
Product Code	NUH, NGX, NYN	NUH, NGX, NYN	NUH	**Identical**
Regulation No.	882.5890	882.5890	882.5890	**Identical**
Main function	1. TENS General Pain/ Menstrual pain relief/for WL-2405H(M) 2. EMS	1. TENS (General Pain/) 2. EMS	TENS (General Pain/ Menstrual pain relief)	**Note. 1**
Indications for Use	The Well-Life Pain Relief (Menstrual Plus) Electrical Stimulator includes three models: WL- 2315C(M), WL-2315E(M), and WL-2405H(M). The indications for use are as follows: For WL-2315C(M) and WL-2315E(M)	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. (Choose TENS Modes P1 through P7) 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	The Livia is designed for symptomatic relief and management of chronic pain, and for temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back, neck, upper extremities (arm) and lower (extremities) leg due to strain from exercise or normal household work activities and for temporary relief of pain associated with dysmenorrhea (menstrual cramps) when used with OTC pain medication	--

	The WL-2315C(M) and WL-2315E(M) are designed for the symptomatic relief and management of pain. They offer temporary relief from pain associated with dysmenorrhea (menstrual cramps) when used with over-the- counter pain medication. For WL-2405H(M) The WL-2405H(M) is designed for symptomatic relief and management of chronic pain and provides temporary relief from sore and aching muscles in the shoulders, waist, back, neck, upper extremities (arms), and lower extremities (legs) due to strain from exercise or daily activities. It also offers temporary relief of pain associated with dysmenorrhea (menstrual cramps) when used with over-the-counter pain medication. Additionally, the WL-2405H(M) features EMS functionality for stimulating healthy muscles to enhance or facilitate muscle performance (select EMS modes). It also provides symptomatic relief and			

	management of chronic, intractable pain and relief from pain associated with arthritis (select TENS mode P8).			

Attribute	Subject Device	Primary Predicate Device:	Secondary Predicate Device:	Comparison
		activities. (Choose TENS Modes P1 through P7) For symptomatic relief and management of chronic, intractable pain and relief of pain associated with arthritis. (Choose TENS Mode P8) For use by healthy adults for the stimulation of healthy muscles in order to improve or facilitate muscle performance. (Choose EMS Modes P1 through P6		
Prescriptive or OTC	OTC	OTC	OTC	**Identical**
Number of output modes	WL-2315E(M), WL-2315C(M) 1 mode for TENS WL-2405H(M) TENS: 10+EMS: 6	TENS: 8 EMS: 6	1	**Note. 2**
Power Source(s)	3.7V Lithium-Ion Battery	3.7V Lithium-Ion Battery	3.7V Lithium-Ion Battery	**Identical**
Method of Line Current Isolation	Output is electrically disabled when connect to charger, by Output is electrically disabled when connect to charger, by Identical 4-6 means of microprocessor charging circuit	Output is electrically disabled when connect to charger, by Output is electrically disabled when connect to charger, by Identical 4-6 means of microprocessor charging circuit	Output is electrically disabled when connect to charger, by Output is electrically disabled when connect to charger, by Identical 4-6 means of microprocessor charging circuit	**Identical**
Patient Leakage Current - Normal Condition (μA)	Battery powered (< 10μA)	Battery powered (< 10μA)	Battery powered (< 10μA)	**Identical**
Patient Leakage Current	Battery powered (< 50μA)	Battery powered (< 50μA)	Battery powered (< 50μA)	**Identical**

Attribute	Subject Device	Primary Predicate Device:	Secondary Predicate Device:	Comparison
- Single Fault Condition (μA)				
Average DC current through Electrodes when device is on but no pulses are being applied (μA)	0 μA	0 μA	0 μA	**Identical**
Regulated Current or Regulated Voltage	Current	Current	Current	**Identical**
Software/Firmware/Micro processor Control	Yes	Yes	Yes	**Identical**
Automatic Overload Trip	Yes	Yes	Yes	**Identical**
Automatic No-Load Trip	Yes	Yes	Yes	**Identical**
Automatic Shut Off	Yes	Yes	Yes	**Identical**
User Override Control	Yes	Yes	Yes	**Identical**
Indicator Display: On/Off Status/Low Battery/Voltage/Current Level	Yes	Yes	Yes	**Identical**
Number of output channels	WL-2405H(M): 2 WL-2315E(M)/WL-2315C(M): 1	2	1	**Identical**
Automatic no-load trip	Yes	Yes	Yes	**Identical**

Well-Life Healthcare Limited

Attribute	Subject Device	Primary Predicate Device:	Secondary Predicate Device:	Comparison
Patient override control method	Yes	Yes	Yes	**Identical**
Maximum output voltage	WL-2405H(M): 40V @500 ohm WL-2315E(M): 30V @500 ohm	40V@500 ohm	65.6 V @500 ohm 121V @2K ohm 130.4V @10K ohm	**Similar** **Note. 3**
Maximum output current	WL-2405H(M): 80mA @500 ohm WL-2315E(M): 60mA@500 ohm	80mA@500 ohm	130.4 mA @500 ohm	**Similar** **Note. 3**
Pulse width	TENS 2-245 us EMS 4-99 us	TENS 2-245 us EMS 4-99 us	100 us	**Similar** **Note. 3**
Frequency	TENS 100-260 Hz EMS 200-300 Hz	TENS 156-260 Hz EMS 200-300 Hz	100 Hz	**Similar** **Note. 3**
Accessories	Default accessories Electrode Pads (K082065) Optional accessories Garment electrodes (K200942)	Electrode Pads (K082065)	Electrode Pads	**Similar** **Note. 4**
Compliance with voluntary standard	60601-1 60601-1-2 60601-1-11 60601-2-10	60601-1 60601-1-2 60601-1-11 60601-2-10	60601-1 60601-1-2 60601-1-11 60601-2-10	**Identical**

7.2 Intra Comparison

	WL-2405H / K172809 (**Primary Predicate Device)**	WL-2405H(M) (Applying)	**Comparison**
Channel	2	2	**Identical**
Level	0-25 Digital	0-25 Digital	**Identical**
Max Voltage	40 (Vpp @ 500 ohm)	40 (Vpp @ 500 ohm)	**Identical**
Max current	80mA Max	80mA Max	**Identical**
Power indicator	LCD+LED Backlight	LCD+LED Backlight	**Identical**
Timer	5-60 min	5-60 min	**Identical**
Power source	3.7V Li-Rechargeable battery	3.7V Li-Rechargeable battery	**Identical**
Waveform	Asymmetrical square pulse	Asymmetrical square pulse	**Identical**
Frequency range	TENS 2-245 EMS 4-99	TENS 2-245 EMS 4-99	**Identical**
Pulse Width range	TENS 156-260 EMS 200-300	TENS 100-260 EMS 200-300	**Similar** **Note.3**
Preset Mode	TENS:8Modes EMS:6Modes	TENS:10Modes EMS:6Modes	**Similar** **Note.3**

Well-Life Healthcare Limited

	WL-2306E / K220524 (Reference Device 2)	WL-2315E(M) (Applying)	WL-2306C / K220524 (Reference Device 2)	WL-2315C(M) (Applying)	**Comparison**
Channel	1	1	1	1	**Identical**
Level	0~10 Digital	0~10 Digital	0~10 Digital	0~10 Digital	**Identical**
Max Voltage	30V (Vpp @ 500 ohm)	30V (Vpp @ 500 ohm)	30V (Vpp @ 500 ohm)	30V (Vpp @ 500 ohm)	**Identical**
Max current	60mA Max	60mA Max	60mA Max	60mA Max	**Identical**
Power indicator	LED indicator	LED indicator	LED indicator	LED indicator	**Identical**
Timer	20 min	20 min	20 min	20 min	**Identical**
Power source	3.7V Li-Rechargeable battery	3.7V Li-Rechargeable battery	3.7V Li-Rechargeable battery	3.7V Li-Rechargeable battery	**Identical**
Waveform	Asymmetrical square pulse	Asymmetrical square pulse	Asymmetrical square pulse	Asymmetrical square pulse	**Identical**
Frequency range (Hz)	15-120	100	15-120	100	**Similar Note.3**
Pulse Width range (uSec)	150-260	100	150-260	100	**Similar Note.3**
Preset Mode	1 mode for TENS	1 mode for TENS	1 mode for TENS	1 mode for TENS	**Identical**

7.3 Output Parameter Specifications by Mode

WL-2405H(M)				
Mode	**Pulse width**	**Frequency**	**Duty Time Up-Hold-Down-OFF**	**Suggested Uses**
TENS P1	**260**	**15**	**Continual**	**Pain Relief**
TENS P2	**260**	**60**	**Continual**	**Pain Relief**
TENS P3	**260**	**60**	**Continual**	**Pain Relief**
TENS P4	**260-156**	**2-60**	**Continual**	**Pain Relief**
TENS P5	**260-156**	**60**	**Continual**	**Pain Relief**
TENS P6	**260**	**7-60**	**Continual**	**Pain Relief**
TENS P7	**260-156**	**60**	**Continual**	**Pain Relief**
TENS P8	**210**	**2.45-245**	**Continual**	**Pain Relief /Arthritis**
TENS P9	**100**	**100**	**Continual**	**Pain Relief /Menstrual pain relief**
TENS P10	**100**	**80/8**	**Continual**	**Pain Relief**
EMS P1	**300**	**40-99**	**x-2-x-1**	**Warm up**
EMS P2	**200**	**4**	**Continual**	**Recovery**
EMS P3	**300**	**5**	**Continual**	**Recovery**
EMS P4	**200**	**99**	**x-2-x-1**	**Recovery**
EMS P5	**200**	**4-20**	**2-6-2-1**	**Endurance**
EMS P6	**300**	**50**	**2-5-3-10**	**Performance**

Well-Life Healthcare Limited

WL-2315E(M)/WL-2315C(M)				
Mode	**Pulse width**	**Frequency**	**Duty Time Up-Hold-Down-OFF**	**Indications**
Default (TENS P9)	**100**	**100**	**Continual**	**Pain Relief /Menstrual pain relief**

Subject	Model	Max Freq (Hz)	Max Pulse-Width (us)	Max Voltage (V)	Max avg. current (A)	Max charge per pulse (uC)	Electrode Area (cm^2)	Max. Average Current Density (mA/cm^2)	Maximum Average Power Density (mW/cm^2)
WL-2405H									
K172809	CM-5050	210	245	40	0.08	19.6	25.0	0.16	0.007
WL-2405H(M)									
Applying	CM-5050	210	245	40	0.08	19.6	25.0	0.16	0.007
WL-2306E and WL-2306C									
K220524	CM-7257	120	260	30	0.06	15.60	16.80	0.11	0.0033
WL-2315E(M) and WL-2315C(M)									
Applying	CM-7257	100	100	30	0.06	6.00	16.80	0.04	0.0011

Comparison to Livia

Due to the fact that TENS/EMS electrical stimulator products deliver higher output energy at lower impedance levels, and skin resistance only reaches 500Ω under extreme or unusual conditions, evaluations are conducted under standards such as IEC 60601-2-10 and NS4. These standards assess the safety of electrical stimulator devices under the most hazardous conditions when output signals are delivered to the skin. In general, skin impedance is around 2000 to 2700Ω.

For the subject device, although the voltage (current) at 500Ω load shows slight differences compared to the secondary predicate device, most skin resistance falls within the 2000 to 2700Ω range. After testing, we found the differences to be minimal, and the specifications are close to those of Livia (K183110), therefore it is considered substantially equivalent.

The following is a comparison of the values.

Livia K183110:
- At 500 ohms, the voltage is 50V
- At 2000 ohms, the voltage is 64V
- At 2700 ohms, the voltage is 64V

WL-2315C(M):
- At 500 ohms, the voltage is 30V, with a difference of -66.7% compared to the Livia.
- At 2000 ohms, the voltage is 61V, with a difference of -4.9% compared to the Livia.
- At 2700 ohms, the voltage is 64V, with a difference of 0.0% compared to the Livia.

WL-2315E(M):
- At 500 ohms, the voltage is 30V, with a difference of -66.7% compared to the Livia.
- At 2000 ohms, the voltage is 61V, with a difference of -4.9% compared to the Livia.
- At 2700 ohms, the voltage is 64V, with a difference of 0.0% compared to the Livia.

WL-2405H(M)-P9:
- At 500 ohms, the voltage is 40V, with a difference of -25.0% compared to the Livia.
- At 2000 ohms, the voltage is 64V, with a difference of 0.0% compared to the Livia.
- At 2700 ohms, the voltage is 66V, with a difference of +3.0% compared to the Livia.

7.4 Comparison in Detail(s)

Note 1: The product's intended use is the same as the Primary Predicate Device, encompassing (1) TENS and (2) EMS functions. Additionally, it includes MENSTRUAL Relief. Therefore, we included the Secondary Predicate Device for comparison, which is cleared for both general pain relief using TENS and MENSTRUAL pain Relief.

Note 2: The differences between the product and the Primary Predicate Device are as follows: (1) WL-2405H(M) offers several additional programs, with the extra programs specifically designed for MENSTRUAL Relief. (2) These programs also apply to WL-2315E(M) and WL-2315C(M) as default output signals. The output signal specifications are similar to the Secondary Predicate Device.

Note 3: The product's effectiveness primarily depends on the pattern of electrical signals delivered to the skin (Pulse width, Frequency, DUTY TIME, etc.). After comparison, it has been verified that the electrical signal patterns utilized for relevant applications are consistent. While there are differences in voltage and current, these differences have been assessed through evaluations according to IEC 60601-2-10 and AAMI NS4 standards. It has been determined that these variances do not compromise safety or effectiveness and can be considered substantially equivalent to the predicate devices.

Note 4: A thorough evaluation based on IEC 60601-2-10 and AAMI NS4 standards has verified their compliance with electrical safety specifications when used with the cleared electrodes specified.

7.5 Conclusion:

In conclusion, the Well-Life Pain Relief (Menstrual Plus) Electrical Stimulator has the same intended use as the primary and secondary predicate devices, and has similar technological characteristics and output specifications as these devices. The indications for use of the device are encompassed by the predicate devices, including TENS, EMS, arthritis, and dysmenorrhea pain. For these reasons, the subject device does not present any safety or effectiveness concerns and can be determined substantially equivalent to the predicate devices.