September 1, 2022

ZMI Electronics Ltd.
Yuta Lee
President
6F-1, 286-4, Shin Ya Road
Kaohsiung, R.O.C. 806
Taiwan

Re: K220997
Trade/Device Name: Wireless TENS/EMS, Bruno, Aela
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous electrical nerve stimulator for pain relief
Regulatory Class: Class II
Product Code: NUH, NGX, NYN
Dated: July 29, 2022
Received: August 2, 2022

Dear Yuta Lee:

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,

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K220997

Device Name
Wireless Electrical Stimulator (Models RS-18, RS-28, RS-38)

Indications for Use *(Describe)*
TENS:
[RS-18, RS-28, RS-38 models]: 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.

[RS-18, RS-38 models]: For temporary relief of pain associated with dysmenorrhea (menstrual cramps) when used with over-the-counter pain medications.

[RS-18, RS-28 models]: It is also intended for symptomatic relief and management of chronic, intractable pain and relief of pain associated with arthritis.

EMS:
[RS-18, RS-28 models]: To stimulate healthy muscles in order to improve and facilitate muscle performance.

Environments of Use: Clinics, hospital and home environments (over-the-counter)
Patient Population: Adult

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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510(k) Summary

1. Submitter Information

Applicant

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Date Summary Prepared: February 10, 2022

2. Device Information

Device Name: Wireless Electrical Stimulator
Model: RS-18, RS-28, RS-38
Regulation Number: 21 CFR 882.5890
Classification Name: Transcutaneous electrical nerve stimulator for pain relief
Regulatory Class: Class II
Product Code: NUH
Subsequent Product Code: NGX, NYN

3. Predicate device

Primary Predicate

510K Number: K161453
Device Name: Well Life Wireless TENS/EMS Stimulator, Models WR-2605A/2605
Regulation Number: 21 CFR 882.5890
Classification Name: Transcutaneous electrical nerve stimulator for pain relief
Regulatory Class: Class II
Product Code: NUH
Subsequent Product Code: NGX, NYN

Secondary Predicate

510K Number: K183215
Device Name: Focus TENS Therapy, Model PM710-M/-L
Regulation Number: 21 CFR 882.5890
Classification Name: Transcutaneous electrical nerve stimulator for pain relief

Regulatory Class: Class II
Product Code: NUH
Subsequent Product Code: NYN

Third Predicate

510K Number: K183110
Trade/Device Name: Livia
Regulation Number: 21 CFR 882.5890
Classification Name: Transcutaneous electrical nerve stimulator for pain relief
Regulatory Class: Class II
Product Code: NUH
Subsequent Product Code: NGX

4. Device Description

"Wireless Electrical Stimulator" is a battery-powered wireless electrical stimulator designed and intended to provide Transcutaneous Electrical Nerve Stimulation (TENS) and Electrical Muscular Stimulation (EMS) for the use of non-pharmacological pain relief and improve muscle performance and recovery.

The "Wireless Electrical Stimulator" includes a remote control, stimulator pod(s) and several accessories. Both the remote control and the stimulator pod are powered by a 3.7V lithium-ion polymer battery. The remote control has a 1.77" TFT LCD screen and 4 buttons to control multiple stimulator pod(s) at the same time. Each stimulator pod has two output channels, and will perform electrical stimulation according to the parameter settings sent by the remote control. The stimulator pods can also be used independently via its own 3 buttons based on preset parameter.

The accessories include self-adhesive electrodes, knee/elbow brace, and the USB Type-C charging cable. The adhesive electrodes for "Wireless Electrical Stimulator" are connected with the Stimulator Pod(s) via magnetic snap and lead wire. There are replaceable hydrogel pads on the self-adhesive electrode pads. Users can replace the hydrogel when it exceeds its useful life, but does not need to discard the entire electrode. To apply electrical stimulation to body joints (e.g. knees and elbows), users can easily place electrodes on specific body parts using the Knee/elbow brace. The remote control and stimulator pods are the same for all models. The 3 models have different accessories to match their specific usage instructions. Below are the accessory variants for each model.

Product Name	Wireless TENS/EMS	Brace TENS/EMS	Menstrual Pain Relief TENS
Model	RS-18	RS-28	RS-38
Indication of Use	General TENS/EMS	TENS/EMS for joint (knee & elbow)	TENS for period pain (dysmenorrhea)
Adhesive Electrodes	●	●	●
Electrode Lead Wire	●	●	●
Knee/Elbow Brace	n/a	●	n/a

USB Type C Charge Cable	•	•	•

Besides the accessory variants, the programs of all models also have some variants depend on the indication. RS-18 model has a “General TENS/EMS” indication, it includes all therapy programs. RS-28 model is indicated for “TENS/EMS for joint (knee & elbow)” and the RS-38 model is indicated for “TENS for period pain (dysmenorrhea).” Following are the program variants for each models.

Therapy Type	Program	RS-18	RS-28	RS-38
Pain Relief	Acute Pain	•	•	•
	Chronic Pain	•	•	•
	Soreness	•	•	•
	Back Pain	•	n/a	•
	Menstrual Cramping	•	n/a	•
	Arthritis	•	•	n/a
Training	Warm-up	•	•	n/a
	Recovery	•	•	n/a
	Atrophy	•	•	n/a
	Strength	•	•	n/a
	Endurance	•	•	n/a
	Resistance	•	•	n/a
Massage	Comfort	•	•	•
	Kneading	•	•	•
	Tapping	•	•	•
	Relaxation	•	•	•
	Tingling	•	•	•
	Alternating	•	•	•

5. Indications for Use

TENS:

[RS-18, RS-28, RS-38 models]: 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.

[RS-18, RS-38 models]: For temporary relief of pain associated with dysmenorrhea (menstrual cramps) when used with over-the-counter pain medications.

[RS-18, RS-28 models]: It is also intended for symptomatic relief and management of chronic, intractable pain and relief of pain associated with arthritis.

EMS:

[RS-18, RS-28]: To stimulate healthy muscles in order to improve and facilitate muscle performance.

Environments of Use: Clinics, hospital and home environments (over-the-counter)

Patient Population: Adult

Comparison of Technological Characteristics with The Predicate Device

The “Wireless Electrical Stimulator” has been carefully compared to legally marketed devices with respect to intended use, indications for use (Table 1), technological characteristics (Table 2), and Output Specification (Table 3).

Table 1. Substantial Equivalence Table – Regulatory Information

	Subject Device	Primary Predicate	Secondary Predicate	Third Predicate
Trade/Device Name	Wireless Electrical Stimulator	Well Life Wireless TENS/EMS Stimulator, Models WR-2605A/2605	Focus TENS Therapy, Model PM710-M/-L	Livia
510(k) Number	K220997	K161453	K183215	K183110
Manufacturer	ZMI Electronics Ltd.	Well-life Healthcare Limited	Omron Healthcare, Inc.	LifeCare Ltd.
Classification Product Code	NUH	NUH	NUH	NUH
Subsequent Product Codes	NGX, NYN	NGX, NYN	NYN	NGX
Regulation Number	21 CFR 882.5890	21 CFR 882.5890	21 CFR 882.5890	21 CFR 882.5890
Regulation Name	Transcutaneous electrical nerve stimulator for pain relief	Transcutaneous electrical nerve stimulator for pain relief	Transcutaneous electrical nerve stimulator for pain relief	Transcutaneous electrical nerve stimulator for pain relief
Regulatory Class	Class II	Class II	Class II	Class II
Indications for	For temporary relief of	For temporary relief of	The device is intended	For temporary relief of

Use	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. For temporary relief of pain associated with dysmenorrhea (menstrual cramps) when used with over-the-counter pain medications. For symptomatic relief and management of chronic, intractable pain and relief of pain associated with arthritis. To stimulate healthy muscles in order to	pain associated with sore and aching muscles in the lower back due to strain from exercise or normal household and work activities. 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. For symptomatic relief and management of chronic, intractable pain and relief of pain associated with arthritis. For the stimulation of healthy muscles in order to improve or	for the relief of pain associated with sore or aching muscles of the lower extremities (leg) due to strain from exercise or normal household work activities. It is also intended for the use of symptomatic relief and management of chronic, intractable pain associated with arthritis.	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. For temporary relief of pain associated with dysmenorrhea (menstrual cramps) when used with over-the-counter pain medications.

	improve and facilitate muscle performance.	facilitate muscle performance.		
Environments of Use	Clinics, hospital and home environments (over-the-counter)	for home use, indoor, not intended for professional use (over-the-counter)	Clinics, hospital and home environments (over-the-counter)	home healthcare environment (over-the-counter)
Patient Population	Adult	At least 15 years old and 8 years intensive reading experience (school), no maximum.	Adult	Be used only by women aged 16 and above.
Over-the-Counter (OTC)	Yes	Yes	Yes	Yes

Table 2. Substantial Equivalence Table – Technological Characteristics Comparison

		Subject Device	Primary Predicate	Secondary Predicate	Third Predicate
Trade/Device Name		Wireless Electrical Stimulator	Well Life Wireless TENS/EMS Stimulator, Models WR-2605A/2605	Focus TENS Therapy, Model PM710-M/-L	Livia
510(k) Number		K220997	K161453	K183215	K183110
Power Source(s)		3.7V Lithium polymer (LiPo) battery	3.7V Lithium polymer (LiPo) battery	Rechargeable Lithium-ion battery	3.7V Lithium ion battery (rechargeable)
Method of Line Current Isolation		Output is electrically disabled when connect to charger, by means of microprocessor charging circuit	Output is electrically disabled when connect to charger, by means of microprocessor charging circuit	N/A (internal power source)	Output is electrically disabled when connect to charger, by means of microprocessor charging circuit
Patient Leakage Current - Normal Condition (μA)		<10uA	<10uA	<10uA	<10uA
Patient Leakage Current - Single Fault Condition (μA)		<50uA	<50uA	<50uA	<50uA
Average DC current through electrodes when device is on but no pulse are being applied (uA)		0	0	0	0
Number of output Modes		1	1	1	1
Number of	Synchronous or	2 channel each	1 channel each	1 channel each	1 channel each

Output Channels:	Alternating	Stimulator Pod Alternating in one Stimulator Pod	Stimulator Pod	Stimulator device	Stimulator device
	Method of Channel Isolation	Microprocessor stagger output time of 2 channels	N/A	N/A	N/A
Regulated Current or Regulated Voltage		Regulated Voltage	Regulated Current	Regulated Current	Regulated Current
Software/Firmware/ Microprocessor Control?		Yes	Yes	Yes	Yes
Automatic Overload Trip		No	No	No	Yes
Automatic No-Load Trip		Yes	No	Yes	Yes
Automatic Shut Off		Yes	Yes	Yes	Yes
User Override Control		Yes	Yes	Yes	Yes
Indicator Display:	On/Off Status	Yes	Yes	Yes	Yes
	Low Battery	Yes	Yes	Yes	Yes
	Voltage/Current Level	Yes	Yes	Yes	Yes
Timer Range (minutes)		5~60	5 ~ 60	30	The Livia has no internal timer as there is no treatment time limitation for using

				the Livia.
Compliance with 21 CFR 898?	Yes	N/A (no patient cable)	N/A (no patient cable)	Yes
Weight (g)	Remote Control: 44.1g (1.6oz) Stimulator Pod: 34.2g (12.1oz) Brace:	Remote Control: 60g (2.1oz) Stimulator Pod: 30g (1.1oz)	Device: 55g (1.9oz) Knee pad: 20g (0.7oz) Knee band M: 27g (1.0oz) Knee band L: 29g (1.0oz) Charger: 100g (3.5oz)	36g (1.3oz)
Dimensions (mm)	Remote Control: 120 (4.73") x 40 (1.58") x 12.5 (0.49") Stimulator Pod: φ61 (2.36") x 14.77 (0.58”) Brace: 461 (18.15”) x 207 (8.15”)	Remote Control: 156.98 (6.18”) x 47 (1.85”) x 15.50 (0.61”) Stimulator Pod: φ60 (2.36”) x 15.65 (0.62”)	Device: 60 (2.36”) × 72 (2.83”) × 16 (0.63”) Charger: 90 (3.54”) x 80 (3.15”) × 23.5 (0.93”) Knee pad: 130 (5.12”) × 60 (2.36”) × 16 (0.63”)	55 (2.17”) x 55 (2.17”) x 18 (0.71”)

			Knee Band M: 385 (15.16”) × 64 (2.52”) Knee Band L: 450 (17.72”) × 64 (2.52”)	
Housing Materials and Construction	PC/ABS plastic	PC/ABS plastic	Not publicly available	PC/ABS plastic
Operating conditions	0 to 40°C (32 to 104°F) 10 to 90% RH 700 to 1060 hPa	10 to 40°C (50 to 104°F) 40-90% RH 700 to 1013 hPa	10 to 40°C (50 to 104°F) 30 to 80 %RH 700 to 1060 hPa (noncondensing)	5 to 40°C (41 to 104°F) 15 to 93% RH 700 to 1060 hPa
Storage conditions	-5 to 40°C (23 to 104°F) 0 to 90% RH	-10 to 60°C (14 to 140°F) 30-95% RH.	0 to 40 °C (32 to 104°F) 30 to 80 % RH (noncondensing)	-25 to 70°C (-13 to 158°F) 15 to 93% RH
Transporting conditions	-5 to 40 °C (23 to 104°F) 0 to 90% RH	-10 to 60°C (14 to 140°F), 30-95% RH.	-20 to 60 °C (-4 to 140°F) 10 to 90 % RH (noncondensing)	-25 to +70°C (-13 to 158°F) 15 to 93% RH
Electrode style	Self-adhesive Reusable	Self-adhesive Reusable	HV-KNPAD-Z Reusable	Self-adhesive Reusable
Patient Contact Accessory	Yes	Yes	Yes	Yes

Table 3. Substantial Equivalence Table – D Comparison

		Subject Device	Primary Predicate	Secondary Predicate	Third Predicate
Trade/Device Name		Wireless Electrical Stimulator (RS-18, RS-28, RS-38)	Well Life Wireless TENS/EMS Stimulator, Models WR-2605A/2605	Focus TENS Therapy, Model PM710-M/-L	Livia
510(k) Number		K220997	K161453	K183215	K183110
Waveform		Biphasic, Symmetrical	Biphasic, Symmetrical	Biphasic, Symmetrical	Biphasic, Symmetrical
Shape		Rectangular	Rectangular	Rectangular	Rectangular
Maximum Output Voltage (volts)	@500Ω	40	40	45	50
	@2kΩ	40	75	68.6	64
	@10kΩ	40	133.5	78.5	64
Maximum Output Current (mA)	@500Ω	80	80	90	50
	@2kΩ	20	37.5	34.3	31
	@10kΩ	4	1.34	7.9	6.4
Pulse Width (μsec)		40-400	100-520	60	100
Frequency (Hz)		1-150	2-60	1-250	100
For multiphasic waveforms only:	Symmetrical phases	Yes	Yes	N/A	Yes
	Phase Duration (μsec)	40-400	50-260	N/A	100
Net Charge(μC per pulse) (@500Ω) (uC)		0	0	0	0
Maximum Phase Charge		16	20.8	5.4	6.4

(@500Ω) (µC)					
Maximum Current Density (@500Ω) (mA/cm^2) r.m.s.		0.96	0.25	0.97	0.38
Maximum Average Current (average absolute value), (mA)		4.8	2.496	2.7	1.19
Maximum Average Power Density (@500Ω) (W/cm^2)		9.4E-03	1.76E-03	7.59E-03	2.05E-03
Burst Mode	(a) Pulses per burst	N/A	N/A	N/A	N/A
	(b) Bursts per second	N/A	N/A	N/A	N/A
	(c) Burst duration	N/A	N/A	N/A	N/A
	(d) Duty cycle: Line(b) x Line (c)	N/A	N/A	N/A	N/A
ON Time (seconds)		N/A	N/A	N/A	N/A
OFF Time (seconds)		N/A	N/A	N/A	N/A
Additional Features		N/A	N/A	N/A	N/A
Electrical Safety & EMC		IEC 60601-1, IEC 60601-1-2, IEC 60601-2-10, IEC 60601-1-11	ES 60601-1, IEC60601-1-2, IEC60601-2-10, IEC 60601-1-11	ES 60601-1, IEC60601-1-2, IEC60601-2-10, IEC 60601-1-11	IEC 60601-1, IEC 60601-1-2, IEC 60601-2-10
Biocompatibility		ISO 10993-1 ISO 10993-5 ISO 10993-10	Not publicly available	Not publicly available	ISO 10993-5 ISO 10993-10

Table 4. Comparison of Programs

Subject Device			Predicate / Reference Device				
Program	Pulse Width(us)	Frequency (Hz)	Trade/Device Name	510(k) Number	Program	Pulse Width(us)	Frequency (Hz)
Acute Pain	175	2, 4	DJO Primera	K153224	P03	175	2
Chronic Pain	210	2/10/20/40/80	Well-Life	K161453	TENS-P8	210	2.45~245
Soreness	200	150	DJO Primera	K153224	P04	200	150
Back Pain	250/150	2/70	DJO Primera	K153224	HAN	250/150	2/70
Menstrual Cramping	100	100	Livia	K183110	N/A	100	100
Arthritis	210	2.45~245	Well-Life	K161453	TENS-P8	210	2.45~245
Warm-up	200	12	DJO Primera	K153224	P10	200	12
Recovery	220	10/8/6/4/2/1	PowerDot	K172876	Active Recovery	200	10/8/6/4/2/1
Atrophy	250	50/1	Cefar	K020803	P10	250	50/1
Strength	400	85/100	PowerDot	K172876	Strength	400	75~100
Endurance	300	5/10/15/20	PowerDot	K172876	Endurance	300	10~25
Resistance	300	35/50	PowerDot	K172876	Resistance I & II	300	35/50
Comfort	220	7/5/3/1	PowerDot	K172876	General	200	7/5/3/1
Kneading	300	40-99	Well-Life	K161453	EMS-P1	300	40-99
Tingling	200/100	65/100	DJO Primera	K153224	P06	200/100	65/100
Tapping	300	5	Well-Life	K161453	EMS-P3	300	5

Relaxation	200	12	DJO Primera	K153224	P08	200	12
Alternating	70/180	80	Cefar	K020803	P7	70/180	80

Based on the comparison of indications for use (Table 1), all subject device and primary predicate devices (Well Life Wireless TENS/EMS K161453) have the same intended use on TENS and EMS. Subject device and third predicate (Livia K183110) both have the indications for use for temporary relief of pain associated with dysmenorrhea. And subject device also has the same environments of use and patient population as secondary predicate (Focus TENS K183215).

From the technical characteristics (Table 2) and technical characteristics comparison (Table 3), the following conclusions can be drawn. Although there are some differences in mechanical, environmental conditions, and output specifications among the subject device and the predicate devices, the subject device complies with a range of FDA- Recognized consensus standards and guidelines. This demonstrates that these differences do not raise any new questions about safety or efficacy.

Performance Data

The following performance data are provided to support the substantial equivalence determination.

Non-clinical Testing

A series of safety and performance tests, as follows, were conducted on the subject device in accordance with FDA recognized consensus standards and/or guidance:

Biocompatibility testing

The biocompatibility evaluation for the “Wireless Electrical Stimulator” was conducted in accordance with the FDA Blue Book Memorandum #G95-1 “Use of International Standard ISO-10993, ‘Biological Evaluation of Medical Devices Part 1: Evaluation and Testing,’”, and International Standard ISO 10993-1 as recognized by FDA. The self-adhesive reusable electrode for “Wireless Electrical Stimulator” is identical to the reference device (ZMI Self-Adhesive Electrodes K180865). The brace was tested for the following:

- ISO 10993-5 Cytotoxicity
- ISO 10993-10 Sensitization & Irritation

Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on the “Wireless Electrical Stimulator”. The system complies with the IEC 60601-1, IEC 60601-1-11 and IEC 60601-2-10 standards for safety and the IEC 60601-1-2 standard for EMC. The stimulation function test has also been conducted to verify the output specifications of the device according to “Guidance for Transcutaneous Electrical Nerve Stimulator for Pain Relief Intended for Over the Counter Use and Guidance for Powered Muscle Stimulator for Muscle Conditioning”.

Software Verification and Validation Testing

Software verification and validation testing were conducted and documented which provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" The software for this device was considered as a "Moderate" level of concern, since a failure in the software could result in minor injury to the patient or operator.

Human Factor and Usability Testing

Usability test were conducted and documented according to the recognized consensus standards of IEC 62366-1. The result of the usability demonstrated all the users in testing did not show any critical errors and represented the performance of using can be smoother by extra practices without specific usability problems. The "Wireless Electrical Stimulator" has been found to be reasonably safe and effective for the intended users, uses and use environments.

Performance Bench Testing (Devices)

To make sure the device has met the intended functions and specifications, the function performance tests had proven the Remote Control and Stimulator (or Receiver) Pod of "Wireless Electrical Stimulator" is safe and effective for the intended users, uses and use environments.

Performance Bench Testing (Electrode)

AC Impedance, Current Dispersion, Retention Force Test, and Reusability Test proof the Self-Adhesive Electrode for "Wireless Electrical Stimulator" is identical to and even better than the Referencing Device. The results also indicating that the electrodes are safe and effective for the intended users, uses and use environments.

Mechanical and Stability Testing

- Button reliability testing
- Lead wire connector and bending life testing
- Drop/Vibration Testing
- Temperature and humidity cycle test
- Device life test

By conducting those mechanical and stability test, the result shown that the device can work well during the whole service life and being safe and effective for the intended users, uses and use environments.

Clinical Studies

Not applicable. Clinical testing was not performed to support this 510(k) submission.

Conclusions

The information submitted to the FDA for the "Wireless Electrical Stimulator" does not raise new questions about safety or effectiveness and demonstrates with reasonable assurance based on established controls that the device is as safe and effective as a legally marketed device.