May 8, 2023

Shenzhen Leqing Medical Instrument Co., Ltd
% Rain Yip
Registration engineer
Feiying Drug & Medical Consulting Technical Service Group
Rm2401, ZhenYe International Center, No.3101-90 Qianhai Road
Nanshan District
Shenzhen, Guangdong 518000
China

Re: K223428
Trade/Device Name: Electronic Stimulator (Models: uLumb-9530A, uLumb-9531A, uLumb-9532A, uLumb-9533A, LQ-9525B, uNeck-9512A, uNeck-9515A, uNeck-9517B, uNeck-9518A, uNeck-9519A, uNeck-9521A, uNeck-9529A, LQ-9535A)
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator For Pain Relief
Regulatory Class: Class II
Product Code: NUH, IRT
Dated: January 17, 2023
Received: April 12, 2023

Dear Rain Yip:

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,

Amber T. Ballard -S

Amber Ballard, PhD
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)*
K223428

Device Name
Electronic Stimulator (Models: uLumb-9530A, uLumb-9531A, uLumb-9532A, uLumb-9533A, LQ-9525B, uNeck-9512A, uNeck-9515A, uNeck-9517B, uNeck-9518A, uNeck-9519A, uNeck-9521A, uNeck-9529A, LQ-9535A)

Indications for Use *(Describe)*
Models: uLumb-9530A, uLumb-9531A, uLumb-9532A, uLumb-9533A, LQ-9525B:
Electrical simulation: To be used for temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back, back of neck, arm, and leg, due to strain from exercise or normal household and work activities.
Note1: The electrode on the stimulator is used in the waist.
Note2: The additional gel patch is used in shoulder, waist, back, back of neck, arm, and leg.
Heating: To be used for temporary relief of minor aches and pains.

Models: uNeck-9512A, uNeck-9515A, uNeck-9517B, uNeck-9518A, uNeck-9519A, uNeck-9521A, uNeck-9529A, LQ-9535A: Electrical simulation: To be used for temporary relief of pain associated with sore and aching muscles in the back of neck, due to strain from exercise or normal household and work activities.
Heating: To be used for temporary relief of minor aches and pains.

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

"510(k) Summary" as required by 21 CFR Part 807.92.

Date: May 8, 2023

I. Submitter

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II. Device

Trade Name: Electronic Stimulator (Models: uLumb-9530A, uLumb-9531A, uLumb-9532A, uLumb-9533A, LQ-9525B, uNeck- 9512A, uNeck-9515A, uNeck-9517B, uNeck-9518A, uNeck-9519A, uNeck-9521A, uNeck- 9529A, LQ-9535A)
Common Name: Transcutaneous electrical nerve stimulator
Classification Name: Stimulator, Nerve, Transcutaneous, Over-The-Counter
Regulatory Class: II
Product Code: NUH, IRT
Regulation Number: 21 CFR 882.5890

III. Predicate Device

Primary Predicate device:
510(k) number: K211942
Manufacturer: Shenzhen OSTO Technology Company Limited
Trade name: Heating Lumbar Therapy Cushion/AST-622
Product code: NGX, NUH, IRT
Approval date: December 13, 2021

Secondary predicate device:
510(k) number: K190783
Manufacturer: Shenzhen OSTO Technology Company Limited
Trade name: Health Expert Electronic Stimulator/AST-300L
Product code: NUH, NGX
Approval date: March 14, 2020

IV. Device Description

The Electronic Stimulator is a portable and battery-powered TENS device with multiple models, offering both electrical pulse stimulation and heating function in one device.

The device consists of a controller that has built-in metal electrodes and accessories of a remote control, an adapter, and/or a pair of gel electrodes, an external connection coupling. The external connection coupling is used to connect the gel electrodes to the device. All models are powered by internal rechargeable battery and charged by the adapter. And all accessories, including the remote control, adapter, gel electrodes, external connection coupling can only be changed or replaced by a qualified person.

The functions of the device are controlled by the device controller and the remote control, where the remote control establishes a connection with the device controller through wireless signals. The device has five stimulation modes and one heating mode, through the metal electrodes to provide users with waist or nape stimulation and heat generation to warm and comfortable waist or nape muscles. And the heating function is controlled by a heat/temperature key and can only be run on metal electrodes, it is cannot be operated alone. The heating temperature does not exceed 43 degrees Celsius at the same time. In addition, the device is also equipped with a pair of gel electrodes, which can be used to stimulate different parts of the body (shoulder, waist, back, back of neck (nape), arm, and leg).

The device has 13 models: uLumb-9530A, uLumb-9531A, uLumb-9532A, uLumb-9533A, LQ-9525B, uNeck-9512A, uNeck-9515A, uNeck-9517B, uNeck-9518A, uNeck-9519A, uNeck-9521A, uNeck-9529A, LQ-9535A, the 13 models differ in appearance, size, battery capacity, number of keys on the stimulator, the specification of electrodes equipped, and some output parameters, the details can refer to the „Model list form“ of the Device Description file in this application.

V. Indications for Use

Models: uLumb-9530A, uLumb-9531A, uLumb-9532A, uLumb-9533A, LQ-9525B: Electrical simulation: To be used for temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back, back of neck, arm, and leg, due to strain from exercise or normal household and work activities.
Note1: The electrode on the stimulator is used in the waist.
Note2: The additional gel patch is used in shoulder, waist, back, back of neck, arm, and leg.
Heating: To be used for temporary relief of minor aches and pains.

Model): uNeck-9512A, uNeck-9515A, uNeck-9517B, uNeck-9518A, uNeck-9519A, uNeck-9521A, uNeck-9529A, LQ-9535A:
Electrical simulation: To be used for temporary relief of pain associated with sore and aching muscles in the back of neck, due to strain from exercise or normal household and work activities.
Heating: To be used for temporary relief of minor aches and pains.

VI. Comparison of Technological Characteristics With the Predicate Device

Compare with predicate devices, the Electronic Stimulator is very similar in the same technical characteristics, features, specifications, materials, mode of operation, intended use, and the applicable standards. The differences between subject device and the predicate devices do not raise new questions of safety or effectiveness.

Table.1 Comparison table between the subject device and the selected predicate devices

Comparison items	Subject device		Secondary Predicate devices	Primary predicate device
510(k) number	Pending		K190783	K211942
Device name	Electronic Stimulator		Health Expert Electronic Stimulator	Heating Lumbar Therapy Cushion
Model(s)	uLumb-9530A, uLumb-9531A, uLumb-9532A, uLumb-9533A, LQ-9525B	uNeck-9512A, uNeck-9515A, uNeck-9517B, uNeck-9518A, uNeck-9519A, uNeck-9521A, uNeck-9529A, LQ-9535A	AST-300L	AST-622
Manufacturer	Shenzhen Leqing Medical Instrument Co.,LTD		Shenzhen OSTO Technology Company Limited	Shenzhen OSTO Technology Company Limited
Indication for use/Intended use	Electrical simulation: To be used for temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back, back of neck, arm, and leg, due to strain from exercise or normal household and work activities. Note1: The electrode on the stimulator is used in the waist. Note2: The additional gel patch is used in shoulder, waist, back, back of neck, arm,	Electrical simulation: To be used for temporary relief of pain associated with sore and aching muscles in the back of neck, due to strain from exercise or normal household and work activities. Heating: To be used for temporary relief of minor aches and pains.	PMS (Mode 1~8) It is intended to stimulate healthy muscles in order to improve and facilitate muscle performance. TENS (Mode 9~25) To be used for temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back, back of the neck, arm, leg, and foot due to strain from exercise or normal household work activities by applying current to stimulate nerve.	PMS(1 ~ 2): It is intended to stimulate healthy muscles in order to improve and facilitate muscle performance. TENS(3 ~ 5): To be used for temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back, arm and leg due to strain from exercise or normal household work activities by applying current to stimulate nerve. Heating: The Heating Lumbar Therapy Cushion is intended for temporary relief of minor aches and pains.

Comparison items	Subject device		Secondary Predicate devices	Primary predicate device
	and leg. Heating: To be used for temporary relief of minor aches and pains.			
Location for use	OTC		OTC	OTC
Power source(s)	Powered by the internal rechargeable battery, 7.4Vd.c., 2600mAh	Powered by the internal rechargeable battery, 3.7Vd.c., 700mAh (uNeck-9512A, uNeck-9515A, uNeck-9517B, uNeck-9518A, uNeck-9519A) Powered by the internal rechargeable battery, 3.7Vd.c., 280mAh*2 (uNeck-9521A) Powered by the internal rechargeable battery, 3.7Vd.c., 1200mAh (uNeck-9529A, LQ-9535A)	Adaptor Input: 100-240Vac, 50-60Hz, 0.1A, Output: 5Vdc, 2A Unit Input: 5Vdc, 2A	Power by adapter, 100-240VAC, 50-60Hz, Output: 5Vdc, 2A Unit Input: 5Vdc, 2A
	Charged by the external adapter:	Charged by the external adapter:		

Comparison items		Subject device		Secondary Predicate devices	Primary predicate device
		Input: 100-240Va.c., 50/60Hz, 0.4A Max. Output: 5.0Vd.c., 2.0A	Input: 100-240Va.c., 50/60Hz, 0.4A Max. Output: 5.0Vd.c., 1.0A		
-Method of Line Current Isolation		Not applicable		Type BF Applied Part	Type BF Applied Part
-Patient Leakage Current	NC (μA)	<50μA		AC: 54.5μA DC: 0.5μA	AC: 54.5μA DC: 0μA
	SFC (μA)	<100μA		AC: 120μA DC: 0.6μA	AC: 13.4μA DC: 0μA
Average DC current through electrodes when device is on but no pulses are being applied (μA)		0μA		<0.01μA	Not publicly available
Function and design		Electrical stimulation and heat		Electrical stimulation and heat	Electrical stimulation and heat
Function output patterns		Electrical stimulation only Electrical stimulation + Heat simultaneously		Electrical stimulation only Alternating combinations of Electrical stimulation and Heat	Electrical stimulation only Heat only Electrical stimulation + Heat simultaneously
Heating setting		(+/-2℃) Level LOW: 39℃ Level HIGH: 41℃	(+/-2℃) Level LOW: 39℃ Level HIGH: 41℃	Adjustable Heating temperature is from 30~40℃	Level 1: 37℃ Level 2: 41℃ Level 3: 43℃
Maximum temperature setting		43℃		40℃	43℃
Number of Output Modes		Electrical simulation: 5 modes Heat: 1 mode		25 modes	For stimulation: 5 modes For heating: 1 mode
Number of Output Levels		Electrical simulation: 60 levels Heat: 2 levels	Electrical simulation: 30 levels Heat: 2 levels	99 levels	For stimulation: 50 levels For heating: 3 levels
Number of Output		2 channels	1 channel	2 channels	1 channel

Comparison items		Subject device		Secondary Predicate devices	Primary predicate device
Channels					
Number of Output Channels	Synchronous or Alternating?	Alternating	Not applicable	Synchronous	Synchronous
	Method of Channel Isolation	Potential transformer, RELAY, Software isolation	Not applicable	Voltage Transform Isolation "Body+" and "Body-" buttons for body channel, "Sole+" and "Sole-" buttons for feet channel	Not applicable
Regulated Current or Regulated Voltage?		Regulated Voltage		Voltage Control	Regulated Voltage
Software/Firmware/ Microprocessor Control?		Yes		Yes	Yes
Automatic Overload Trip?		No		No	No
Automatic No-Load Trip?		No		No	No
Automatic Shut Off?		Yes		Yes	Yes
User Override Control?		No		Yes	Yes
Indicator Display	On/Off Status?	Yes		Yes	Yes
	Low Battery?	Yes		No	No
	Voltage/ Current Level?	Yes		Yes	Yes
Timer Range		Default 30 minutes. Adjustable to 15, 30, 45, 60 minutes	15minutes	25~60min	5~30min

Comparison items	Subject device	Secondary Predicate devices	Primary predicate device
Compliance with Voluntary Standards?	IEC60601-1-2 IEC60601-1 IEC60601-1-11 IEC60601-2-10	IEC60601-1-2 IEC60601-1 IEC60601-1-11 IEC60601-2-10	IEC60601-1-2 IEC60601-1 IEC60601-1-11 IEC60601-2-10
Compliance with 21 CFR 898?	Yes	Yes	Yes
Weight	(the weight that included the internal battery and the electrodes on the stimulator) uLumb-9530A: 2700g uLumb-9531A: 2400g uLumb-9532A: 1800g uLumb-9533A: 2000g LQ-9525B: 750g uNeck-9512A: 141g uNeck-9515A: 146g uNeck-9517B: 172g uNeck-9518A: 172g uNeck-9519A: 172g uNeck-9521A: 156g uNeck-9529A: 177g LQ-9535A: 320g	2.1kg (Without accessories)	Unit: 1704.5g
Dimensions	Dimensions of the stimulator body [L*W*H]: uLumb-9530A: 351*392*88mm uLumb-9531A: 365*325*83mm uLumb-9532A: 351*298*88mm uLumb-9533A: 469.5*348*102mm LQ-9525B: 261*267*104mm uNeck-9512A: 154*149*37mm uNeck-9515A: 152*147*43mm uNeck-9517B: 180*151*40mm uNeck-9518A: 152*91*178mm uNeck-9519A: 178*152*91mm	429.2mm x 401mm x 152.8mm	AST-622 Unit: 456mm×354mm×86.7mm Stainless steel: For AST-622: 224mm×96mm

Comparison items	Subject device	Secondary Predicate devices	Primary predicate device
	uNeck-9521A: 145*143*36mm uNeck-9529A: 152*147*40mm LQ-9535A: 195*92*45mm Dimensions of each electrode on the stimulator [L*W, thickness]: uLumb-9530A, uLumb-9532A: (Spec.1) 98.3×84×0. 5mm, (Spec.2) 86×66×0. 5mm uLumb-9531A: (Spec.1) 81×60×0. 5mm, (Spec.2) 87×84×0. 5mm uLumb-9533A: (Spec.1) 40.8×40.8×0.5 , (Spec.2) 40.8×40.8×0.5 mm LQ-9525B: 114.8×55.7×62 mm uNeck-9512A, uNeck-9515A, uNeck-9517B, uNeck-9518A, uNeck-9521A, uNeck-9529A: 26.6×41.8×0. 3mm uNeck-9519A: (Spec.1) 20.7×31.8×0.4 mm, (Spec.2) 21.7×31 .8×0.4 mm LQ-9535A: 51×33×0.4 mm Dimensions of an additional gel electrode [L*W, thickness]: uLumb-9530A, uLumb-9531A, uLumb-9532A, uLumb-9533A, LQ-9525B : 40×70×3mm uNeck-9512A, uNeck-9515A, uNeck-9517B, uNeck-9518A, uNeck-9519A, uNeck-9521A, uNeck-9529A, LQ-9535A: not applicable		
Housing Materials and Construction	ABS and PC plastic enclosure	ABS plastic	Main unit: ABS Plastic, Stainless steel Red Transparent Plastic: ABS plastic
Electrodes materials	Electrode on the stimulator: metal Additional gel electrode: conductive hydrogel	Not publicly available	Electrode pads: stainless steel plate Electrode pads: White silica gel, Black

Comparison items		Subject device		Secondary Predicate devices	Primary predicate device
					conductive silicone, Transparent conductive adhesive silicone, Transparent PET silicone
Biocompatibility safety		ISO10993-1 ISO10993-5 ISO10993-10		ISO10993-1 ISO10993-5 ISO10993-10	ISO10993-1 ISO10993-5 ISO10993-10
Accessories		Remote control, adapter, gel electrodes and external connection coupling	Remote control, and adapter	Remote controller, adapter, electrode pads, and electrode wire	Remote control, adapter, electrode pads and electrode wire
Waveform (e.g., pulsed monophasic, biphasic)		Pulsed, symmetric, biphasic		Pulsed, symmetric, biphasic	Symmetric Biphasic
Shape (e.g., rectangular, spike, rectified sinusoidal)		Rectangular, with interphase interval		Rectangular, with interphase interval	Rectangular
Maximum Output Voltage (Vp)		(+/-20%) 40V@500Ω 120V@2kΩ 140V@10kΩ	(+/-20%) 21.6V@500Ω 32V@2kΩ 36V@10kΩ	(+/-10%) 44V@500Ω 80V@2kΩ 112V@10kΩ	(+/-10%) 23.2V@500Ω 39.2V@2kΩ 73.2V@10kΩ
Maximum Output Current (mAp)		(+/-20%) 80mA@500Ω 60mA@2kΩ 14mA@10kΩ	(+/-20%) 43.2mA@500Ω 16mA@2kΩ 3.6mA@10kΩ	(+/-10%) 88mA@500Ω 40mA@2kΩ 11.2mA@10kΩ	(+/-10%) 46.4mA@500Ω 19.6mA@2kΩ 7.32mA@10kΩ
Pulse Duration (μsec)		0~200μs +/-10%		120μs	180μs
Frequency (Hz)		1~100Hz +/-10%		77.3Hz	133Hz
For multiphasic waveforms only:	Symmetrical phases?	Not applicable	Not applicable	Not applicable	Not applicable
	Phase Duratio	Not applicable	Not applicable	Not applicable	Not applicable

Comparison items		Subject device		Secondary Predicate devices	Primary predicate device
	n(include units), (state range, if applicable), (both phases, if asymmetrical)				
Net Charge (microcoulombs (μC) per pulse) (If zero, state method of achieving zero net charge.)		0μC@500Ω	0μC@500Ω	0μC@500Ω Method: Balanced waveform	0μC@500Ω Method: Balanced waveform
Maximum Phase Charge, (μC)		19.90μC@500Ω	12.40μC@500Ω	10.56μC@500Ω	8.352μC@500Ω
Maximum Average Current (average absolute value), mA		11.8mA@500Ω	6.83mA@500Ω	1.63mA@500Ω	4.44mA@500Ω
Maximum Current Density, (mA/cm², r.m.s.)		uLumb-9530A, uLumb-9532A, uLumb-9531A: 0.469mA/cm^2@500Ω uLumb-9533A: 0.859mA/cm^2@500Ω LQ-9525B:	uNeck-9512A, uNeck-9515A, uNeck-9517B, uNeck-9518A, uNeck-9521A, uNeck-9529A: 0.786mA/cm^2@500Ω uNeck-9519A:	0.0326mA/cm^2@500Ω	Not publicly available

Comparison items		Subject device		Secondary Predicate devices	Primary predicate device
		0.923mA/cm^2@500Ω	1.337mA/cm^2@500Ω LQ-9535A: 0.508mA/cm^2@500Ω		
Maximum Average Power Density, (W/cm²), (using smallest electrode conductive surface area)		uLumb-9530A, uLumb-9532A, uLumb-9531A: 0.0028W/cm^2@500Ω uLumb-9533A: 0.0051W/cm^2@500Ω LQ-9525B: 0.0055W/cm^2@500Ω	uNeck-9512A, uNeck-9515A, uNeck-9517B, uNeck-9518A, uNeck-9521A, uNeck-9529A: 0.0027W/cm^2@500Ω uNeck-9519A: 0.0046W/cm^2@500Ω LQ-9535A: 0.0017W/cm^2@500Ω	0.0000266mW/cm^2@500Ω	0.225mW/cm^2@500Ω
Burst Mode (i.e., pulse trains):	(a) Pulses per burst	Not applicable	Not applicable	Not applicable	Not applicable
	(b) Bursts per second	Not applicable	Not applicable	Not applicable	Not applicable
	(c) Burst duration (seconds)	Not applicable	Not applicable	Not applicable	Not applicable
	(d) Duty Cycle: Line (b) x Line	Not applicable	Not applicable	Not applicable	Not applicable

Comparison items	Subject device		Secondary Predicate devices	Primary predicate device
(c)				
ON Time (seconds)	1s	≥2s	240μs	2s
OFF Time (seconds)	≥2s	≥2s	12700μs	2s

Similarity and Difference

Based on the comparison information in our application, we can determine that the subject device is almost identical to or within the range of the predicate devices selected in all aspect, except for power source, method of current isolation, patient leakage current, design of output channels, weight and dimensions, specification of electrodes equipped. On the other hand, the subject device has the same range of intended use and provides the same functions by the same operating principle as the predicate devices. Although there are still several feature specifications different between the subject device and predicate devices, the subject device has undergone and passed a series of safety tests complied with the specific FDA-recognized consensus standards to demonstrate these differences would not adversely impact the safety and effectiveness of the subject device. Therefore, the differences between the subject device and predicate devices would not raise any problem in substantial equivalence claims.

VII. Performance Data

The following performance data (nonclinical testing) were provided in support of the substantial equivalence determination.

1) Biocompatibility Safety

The materials of the patient-directly contacting components of the Electronic Stimulator is performed the biocompatibility evaluation in accordance with the "Use of International Standard ISO 10993-1, 'Biological Evaluation of Medical Devices –Part 1: Evaluation and Testing Within a Risk Management Process, Document issued on Sep. 4, 2020", as recognized by FDA. The battery of testing was performed to, and passed, including:

- ISO 10993-5 Biological Evaluation of Medical Devices –Par t 5: Tests for In Vitro Cytotoxicity
- ISO 10993-10 Biological Evaluation of Medical Devices –Par t 10: Tests for Irritation and Skin Sensitization

2) EMC and Electrical Safety

Electrical safety and Eye safety testing was performed to, and passed, the following standards:

- IEC 60601-1-2 Medical electrical equipment –Part 1-2: General requirements for basic safety and essential performance –Collateral standard: electromagnetic compatibility
- IEC 60601-1 Medical electrical equipment –Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-11 Medical Electrical Equipment –Part 1: 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 60601-2-10 Medical electrical equipment - Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators

3) Software Verification and Validation

Software documentation consistent with ***moderate level*** of concern was submitted in this 510(k). System validation testing presented in this 510(k) demonstrated that all software requirement specifications are met and all software hazards have been mitigated to acceptable risk levels.

4) Other Performance Verification

- The electrodes performance test has been conducted to verify the current dispersion and shelf-life of the electrodes used by the device in the expiration date according to the requirements of the FDA Guidance –Shelf Life of Medical Device and ASTM F1980-07 Standard.
- The waveform and output test has also been conducted to verify the output specifications of the device according to the FDA Guidance for Transcutaneous Electrical Nerve Stimulator for Pain Relief Intended for Over the Counter Use and Guidance for Powered Muscle Stimulator for Muscle Conditioning.

Summary

Based on the above performance as documented in this application, the Electronic Stimulator was found to have a safety and effectiveness profile that is similar to the predicate device.

VIII. Clinical Testing Summary

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

IX. Conclusions

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the comparison of intended use, design, materials and performance, the Electronic Stimulator is to be concluded substantial equivalent to its predicate devices.