December 11, 2020

Hong Qiangxing (Shen Zhen) Electronics Limited
% Doris Dong
Manager
Shanghai CV Technology Co., Ltd.
Room 903, No. 19 Dongbao Road, Songjiang Area
Shanghai, Shanghai 201613
China

Re: K201354
Trade/Device Name: TENS & PMS
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered muscle stimulator
Regulatory Class: Class II
Product Code: NGX, NUH
Dated: September 3, 2020
Received: September 14, 2020

Dear Doris Dong:

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 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)*
K201354

Device Name
TENS & PMS

Indications for Use *(Describe)*
Model: SM9079
TENS(1,3,4,5,6,21):
To be used 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.
PMS(2,7,8,9,10,11,12,13,14,15,16,17,18,19,20,22,23,24):
It is intended to be used to stimulate healthy muscles in order to improve and facilitate muscle performance.

Model: SM9126
TENS(3,4,5,6,11,12,16):
To be used 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.
PMS(1,2,7,8,9,10,13,14,15):
It is intended to be used to stimulate healthy muscles in order to improve and facilitate muscle performance.

Model: SM9186
TENS(3,4,7,8,11):
To be used 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.
PMS(1,2,5,6,9,10,12):
It is intended to be used to stimulate healthy muscles in order to improve and facilitate muscle performance.

Model: SM9196
TENS(10~15):
To be used 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.
PMS(1~9):
It is intended to be used to stimulate healthy muscles in order to improve and facilitate muscle performance.

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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Hong Qiangxing(Shen Zhen) Electronics Limited
4F, Jingcheng Building, Xicheng Industrial Zone, Xixiang Road, Bao'an District, Shenzhen City, Guangdong, China 518126

510(k) Summary

[As required by 21 CFR 807.92]

1. Submission Information:

510(k) Number:	K201354
Date:	December 11, 2020
Type of 510(k) Submission:	Traditional
Basis for 510(k) Submission:	New device
Submitter/Manufacturer:	Hong Qiangxing(Shen Zhen) Electronics Limited 4F, Jingcheng Building, Xicheng Industrial Zone, Xixiang Road, Bao'an District, Shenzhen City, Guangdong, China 518126
Contact:	Doris Dong [Consultant, from Shanghai CV Technology Co., Ltd.] Add: Room 903, No. 19 Dongbao Road, Songjiang Area, Shanghai, 201613 China E-mail: doris_d@126.com Tel: 86 21-31261348 / Fax: 86 21-57712250

2. Device Description:

Proprietary Name:	TENS & PMS
Common Name:	TENS & PMS
Classification Name:	Powered muscle stimulator Transcutaneous electrical nerve stimulator for pain relief
Regulation Number:	21 CFR 890.5850, 21 CFR 882.5890
Product Code:	NGX, NUH
Device Class:	II
Review Panel:	Neurology & Physical Medicine
Device Description:	TENS & PMS is a portable and DC 3.7V battery powered multifunction device with multiple models, offering both Transcutaneous Electrical Nerve Stimulation (TENS) and Powered Muscle Stimulation (PMS) qualities in one device. The device is equipped with accessories of electrode pads, electrode cables, a battery charger, and one USB cable. The electrode cables are used to connect the pads to the device; the USB cable is used to connect the charger and the built-in lithium battery. All accessories, including USB cables, electrode pads, electrode cables, chargers can only be changed or replaced by a qualified person.
Indications for use:	Model: SM9079 TENS(1,3,4,5,6,21): To be used 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. PMS(2,7,8,9,10,11,12,13,14,15,16,17,18,19,20,22,23,24): It is intended to be used to stimulate healthy muscles in order to improve and facilitate muscle performance.

Model: SM9126

TENS(3,4,5,6,11,12,16):

To be used 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.

PMS(1,2,7,8,9,10,13,14,15):

It is intended to be used to stimulate healthy muscles in order to improve and facilitate muscle performance.

Model: SM9186

TENS(3,4,7,8,11):

To be used 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.

PMS(1,2,5,6,9,10,12):

It is intended to be used to stimulate healthy muscles in order to improve and facilitate muscle performance.

Model: SM9196

TENS(10~15):

To be used 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.

PMS(1~9):

It is intended to be used to stimulate healthy muscles in order to improve and facilitate muscle performance.

3. Working principle

The device uses electrodes to send a specific electric current to the skin. TENS(Transcutaneous electrical nerve stimulation) mode is to relieve pain using electrical stimulation. PMS(Powered Muscle Stimulation) mode is to stimulate healthy muscles in order to improve performance by electrical stimulation.

4. Substantial Equivalence to Predicate device: Basic Unit Characteristics

Table 1-

Parameters	**New Device**	**Predicate Device**	**Remark**
510(k) Number	K201354	K121719	--
Device Name	TENS & PMS	SM TENS & PMS	--
Model	SM9079	No	--
Manufacturer	Hong Qiangxing (Shenzhen) Electronics Limited	Hong Qiangxing (Shenzhen) Electronics Limited	Same
Intended use	TENS(1,3~6,21): To be used 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. PMS(2,7~20,22~24): It is intended to be used to stimulate healthy muscles in order to improve and facilitate muscle performance.	TENS(1,3,4,5,6): To be used 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. PMS(1,2,3,6): It is intended to be used to stimulate healthy muscles in order to improve and facilitate muscle performance.	Same
Type of use	OTC	OTC	Same
Power Source(s)	DC 3.7V lithium battery	DC 3.7V lithium battery	Same
- Method of Line Current Isolation	Type BF	Type BF	Same
- Patient Leakage	--	--	Same

Current - Normal Condition (μA) - Single Fault Condition (μA)		< 10μA < 50μA	< 10μA < 50μA	
Average DC current through electrodes when device is on but no pulses are being applied (μA)		< 0.01μA	< 0.01μA	Same
Number of Output Modes		24	6	Similar Note 1
Number of Output channels:		2	2	Same
- Synchronous or Alternating?		Alternating	Synchronous	Similar Note 2
- Method of Channel Isolation		Voltage transformer Isolation	Voltage transformer Isolation	Same
Regulated Current or Regulated Voltage?		Voltage control	Voltage control	Same
Software/Firmware/Microprocessor Control?		Software	Software	Same
Automatic Overload Trip?		No	No	Same
Automatic No-Load Trip?		No	No	Same
Automatic Shut Off?		Yes	Yes	Same
User Override Control?		Yes	Yes	Same
Indicator Display	On/Off Status	Yes	Yes	Same
	Low Battery	Yes	Yes	Same
	Voltage /Current Level	Yes	Yes	Same
Timer Range (minutes)		10 ~ 60 minutes, 10 min/step	10 ~ 60 minutes, 10 min./step	Same
Compliance with Voluntary		Yes. AAMI/ANSI ES 60601-1,	Yes. AAMI/ANSI	Same

Standards?	IEC 60601-1-2, IEC 60601-2-10, IEC 62133, HA 60601-1-11	ES60601-1, IEC 60601-1-2, IEC 60601-2-10, IEC 62133, IEC 60601-1-11	
Compliance with 21 CFR 898?	Yes	Yes	Same
Weight (grams)	102g±5g	140g	Similar Note 1
Dimensions (mm) [W x H x D]	60*123*12mm	83*42*9mm	
Housing Materials & Construction	ABS	ABS	Same
Waveform	Pulsed, symmetric, biphasic	Pulsed, symmetric, biphasic	Same
Shape	Rectangle	Rectangle	Same
Maximum Output Voltage (volts)	42V±20% @500Ω	42V±10% @500Ω	Similar Note 3
Maximum Output Current (specify units)	84mA±20% @500Ω	84mA±10% @500Ω	
Pulse width (μsec)	190μs	100μs	
Pulse Period (msec)	40-1070ms	9.3~850ms	
Max. pulse frequency (Hz) [or Rate (pps)]	0.935-25Hz±10%	110Hz	
Net Charge (μC per pulse)	0μC @500Ω; Method: Balanced waveform	0μC @500Ω; Method: Balanced waveform	Same
Maximum Phase Charge, (μC)	13.30μC@500Ω	16.8μC @500Ω	Similar
Maximum Average Current, (mA)	0.78mA	0.924mA	Similar Note 4
Maximum Current Density, (mA/cm², r.m.s.)	0.065mA/cm² @500Ω	0.462mA/cm²	
Maximum Average Power Density, (mW/cm²)	2.64mW/cm² @500Ω	9.702mW/cm²	
Accessories	Self-adhesive electrodes, electrode wires, Battery charger, USB cable	Self-adhesive electrodes, electrode wires, Battery charger, USB cable	Same
Biocompatibility	All user directly	All user directly	Same

	contacting materials are compliance with ISO10993-5 and ISO10993-10 requirements.	contacting materials are compliance with ISO10993-5 and ISO10993-10 requirements.	

Comparison in details:

Note 1:

The proposed device SM9079 has more treatment programs than the predicate device K121719, all treatment programs of proposed device are comparable to the mode 1 to mode 3 of the predicate device. The proposed device doesn't have treatment program to compare with the mode 4 to mode 6 of the predicate device because predicate device's mode 4 to mode 6 are variation waveform of the mode 1 to mode 3. All of the treatment programs have passed the IEC 60601-2-10 and AAMI / ANSI ES60601-1 test codes. So this difference doesn't raise any safety or effectiveness issue. And the weight, dimensions, appearance of proposed device SM9079 are a little different from predicate device K121719, but these differences will not raise any safety or effectiveness issue.

Note 2:

The output channels of the proposed device is alternating while the predicate device is synchronous. Because the proposed device and predicate device adopt the same fundamental output technology and similar treatment effect. Therefore, this item is considered to be substantially equivalent. Also, the proposed device had passed AAMI / ANSI ES60601-1 and IEC 60601-2-10 test codes, so these differences won't raise any new safety and effectiveness issues.

Note 3:

There are some differences on the pulse width, frequency, pulse period and deviation between proposed device and predicate device. Based on the calculation of maximum current density, maximum average power density, these parameters don't exceed the safety limit. All deviation and the worst case have been considered in risk analysis report, and these parameters have passed IEC 60601-2-10 test codes. Therefore, these differences won't raise any new safety and effectiveness issues.

Note 4:

The maximum average current of proposed device is smaller than that of the predicate device which means the better safety. The maximum current density, maximum average power density have some differences between proposed device and predicate device due to they are calculated by different electrode area. Both of them meet maximum current density <2mA/cm² and maximum average power density <0.25W/cm². Therefore these differences won't raise any new safety and effectiveness issues.

Final conclusion:

The subject device SM9079 is substantial Equivalent to the predicate device K121719.

Table 2-

Parameters	**New Device**	**Predicate Device**	**Remark**
510(k) Number	K201354	K121719	--

Device Name	TENS & PMS	SM TENS & PMS	--
Model	SM9126	No	--
Manufacturer	Hong Qiangxing (Shenzhen) Electronics Limited	Hong Qiangxing (Shenzhen) Electronics Limited	Same
Intended use	TENS(3~6,11,12,16): To be used 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. PMS(1,2,7~10,13~15): It is intended to be used to stimulate healthy muscles in order to improve and facilitate muscle performance.	TENS(1,3,4,5,6): To be used 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. PMS(1,2,3,6): It is intended to be used to stimulate healthy muscles in order to improve and facilitate muscle performance.	Same
Type of use	OTC	OTC	Same
Power Source(s)	DC 3.7V lithium battery	DC 3.7V lithium battery	Same
- Method of Line Current Isolation	Type BF	Type BF	Same
- Patient Leakage Current - Normal Condition (μA) - Single Fault Condition (μA)	-- < 10μA < 50μA	-- < 10μA < 50μA	Same
Average DC current through electrodes when device is on but no pulses are being applied (μA)	< 0.01μA	< 0.01μA	Same
Number of Output Modes	16	6	Similar Note 1
Number of Output channels:	2	2	Same
- Synchronous or Alternating?	Synchronous	Synchronous	Same
- Method of Channel Isolation	Voltage transformer Isolation	Voltage transformer Isolation	Same
Regulated Current or Regulated Voltage?	Voltage control	Voltage control	Same
Software/Firmware/	Software	Software	Same

Microprocessor Control?				
Automatic Overload Trip?		No	No	Same
Automatic No-Load Trip?		No	No	Same
Automatic Shut Off?		Yes	Yes	Same
User Override Control?		Yes	Yes	Same
Indicator Display	On/Off Status?	Yes	Yes	Same
	Low Battery?	Yes	Yes	Same
	Voltage/Current Level?	Yes	Yes	Same
Timer Range (minutes)		10 ~ 60 minutes, 10 min/step	10 ~ 60 minutes, 10 min./step	Same
Compliance with Voluntary Standards?		Yes. AAMI/ANSI ES 60601-1, IEC 60601-1-2, IEC 60601-2-10, IEC 62133, HA 60601-1-11	Yes. AAMI/ANSI ES60601-1, IEC 60601-1-2, IEC 60601-2-10, IEC 62133, IEC 60601-1-11	Same
Compliance with 21 CFR 8988?		Yes	Yes	Same
Weight (grams)		55g±5g	140g	Similar Note 1
Dimensions (mm) [W x H x D]		50.37*93.4*10.4mm	83*42*9mm	
Housing Materials & Construction		ABS	ABS	Same
Waveform		Pulsed, symmetric, biphasic	Pulsed, symmetric, biphasic	Same
Shape		Rectangular	Rectangular	Same
Maximum Output Voltage (volts)		46.4V±20% @500Ω	42V±10% @500Ω	Similar Note 2
Maximum Output Current (specify units)		92.8mA±20% @500Ω	84mA±10% @500Ω	
Pulse width (μsec)		220μs	100μs	
Pulse Period (msec)		5-680ms	9.3~850ms	
Max. pulse frequency (Hz) [or Rate (pps)]		1.47-212.5Hz±10%	110Hz	
Net Charge (μC per pulse)		0μC @500Ω; Method: Balanced waveform	0μC @500Ω; Method: Balanced waveform	Same
Maximum Phase Charge, (μC)		17.26μC@500Ω	16.8μC @500Ω	Similar

Maximum Average Current, (mA)	2.056mA	0.924mA	Similar Note 3
Maximum Current Density, (mA/cm², r.m.s.)	0.119mA/cm² @500Ω	0.462mA/cm²	
Maximum Average Power Density, (mW/cm²)	5.21mW/cm² @500Ω	9.702mW/cm²	
Biocompatibility	All user directly contacting materials are compliance with ISO10993-5 and ISO10993-10 requirements.	All user directly contacting materials are compliance with ISO10993-5 and ISO10993-10 requirements.	Same
Accessories	Self-adhesive electrodes, electrode wires, Battery charger, USB cable	Self-adhesive electrodes, electrode wires, Battery charger, USB cable	Same

Comparison in details:

Note 1:

The proposed device SM9126 has more treatment programs than the predicate device K121719, all treatment programs of proposed device are comparable to the mode 1 to mode 3 of the predicate device. The proposed device doesn't have treatment program to compare with the mode 4 to mode 6 of the predicate device because predicate device's mode 4 to mode 6 are variation waveform of the mode 1 to mode 3. All of the treatment programs have passed the IEC 60601-2-10 and AAMI / ANSI ES60601-1 test codes. So this difference doesn't raise any safety or effectiveness issue. And the weight, dimensions, appearance of proposed device SM9126 are a little different from predicate device K121719, but these differences are insignificant in the terms of safety or effectiveness.

Note 2:

There are some differences on the maximum output voltage, maximum output current, pulse width, frequency, pulse period, deviation between proposed device and predicate device. Based on the calculation of maximum current density, maximum average power density, these parameters don't exceed the safety limit. All deviation and the worst case have been considered in risk analysis report, and these parameters have passed IEC 60601-2-10 test codes. So these differences won't raise any new safety and effectiveness issues.

Note 3:

The maximum current density, maximum average power density have some differences between proposed device and predicate device due to they are calculated by different electrode area. Both of them meet maximum current density <2mA/cm² and maximum average power density <0.25W/cm². Therefore these differences won't raise any new safety and effectiveness issues.

Final conclusion:

The subject device SM9126 is substantial Equivalent to the predicate device K121719.

Table 3-

Parameters	**New Device**	**Predicate Device**	**Remark**
510(k) Number	K201354	K121719	--
Device Name	TENS & PMS	SM TENS & PMS	--
Model	SM9186	No	--
Manufacturer	Hong Qiangxing (Shenzhen) Electronics Limited	Hong Qiangxing (Shenzhen) Electronics Limited	--
Intended use	TENS(3,4,7,8,11): To be used 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. PMS(1,2,5,6,9,10,12): It is intended to be used to stimulate healthy muscles in order to improve and facilitate muscle performance.	TENS(1,3,4,5,6): To be used 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. PMS(1,2,3,6): It is intended to be used to stimulate healthy muscles in order to improve and facilitate muscle performance.	Same
Type of use	OTC	OTC	Same
Power Source(s)	DC 3.7V lithium battery	DC 3.7V lithium battery	Same
- Method of Line Current Isolation	Type BF	Type BF	Same
- Patient Leakage Current - Normal Condition (μA) - Single Fault Condition (μA)	-- < 10μA < 50μA	-- < 10μA < 50μA	Same
Average DC current through electrodes when device is on but no pulses are being applied (μA)	< 0.01μA	< 0.01μA	Same
Number of Output Modes	12	6	Similar Note 1
Number of Output channels:	2	2	Same
- Synchronous or Alternating?	Alternating	Synchronous	Similar Note 2
- Method of Channel Isolation	Voltage transformer Isolation	Voltage transformer Isolation	Same
Regulated Current or Regulated Voltage?	Voltage control	Voltage control	Same
Software/Firmware/Microprocessor Control?	Software	Software	Same
Automatic Overload Trip?	No	No	Same
Automatic No-Load Trip?	No	No	Same
Automatic Shut Off?	Yes	Yes	Same
User Override Control?	Yes	Yes	Same
Indicator Display – On/Off Status	Yes	Yes	Same
Indicator Display – Low Battery	Yes	Yes	Same
Indicator Display – Voltage/Current Level	Yes	Yes	Same
Timer Range (minutes)	10 ~ 60 minutes, 10 min/step	10 ~ 60 minutes, 10 min./step	Same
Compliance with Voluntary Standards?	Yes. AAMI/ANSI ES 60601-1,	Yes. AAMI/ANSI ES60601-1, IEC	Same

	IEC 60601-1-2, IEC 60601-2-10, IEC 62133, HA 60601-1-11	60601-1-2, IEC 60601-2-10, IEC 62133, IEC 60601-1-11	
Compliance with 21 CFR 8988?	Yes	Yes	Same
Weight (grams)	50±5g	140g	Similar Note 1
Dimensions (mm) [W x H x D]	52.9*92*11mm	83*42*9mm	
Housing Materials & Construction	ABS	ABS	Same
Waveform	Pulsed, symmetric, biphasic	Pulsed, symmetric, biphasic	Same
Shape	Rectangular	Rectangular	Same
Maximum Output Voltage (volts)	68V±20% @500Ω	42V±10% @500Ω	Similar Note 3
Maximum Output Current (specify units)	136mA±20% @500Ω	84mA±10% @500Ω	
Pulse width (μsec)	220-230μs	100μs	
Pulse Period (msec)	6.4-901ms	9.3~850ms	
Max. pulse frequency (Hz) [or Rate (pps)]	1.11-155.6Hz	110Hz	
Net Charge (μC per pulse)	0μC @500Ω; Method: Balanced waveform	0μC @500Ω; Method: Balanced waveform	Same
Maximum Phase Charge, (μC)	26μC@500Ω	16.8μC @500Ω	Similar Note 4
Maximum Average Current, (mA)	5.54mA@500Ω	0.924mA	
Maximum Current Density, (mA/cm², r.m.s.)	0.46mA/cm² @500Ω	0.462mA/cm²	Same
Maximum Average Power Density, (mW/cm²)	31.40mW/cm² @500Ω	9.702mW/cm²	Similar Note 4
Biocompatibility	All user directly contacting materials are compliance with ISO10993-5 and ISO10993-10 requirements.	All user directly contacting materials are compliance with ISO10993-5 and ISO10993-10 requirements.	Same
Accessories	Self-adhesive electrodes, electrode wires, Battery charger, USB cable	Self-adhesive electrodes, electrode wires, Battery charger, USB cable	Same

Comparison in details:

Note 1:

The proposed device SM9186 has more treatment programs than the predicate device K121719, all treatment programs of proposed device are comparable to the mode 1 to mode 3 of the predicate device. The proposed device doesn't have treatment program to compare with the mode 4 to mode 6 of the predicate device because predicate device's mode 4 to mode 6 are variation waveform of the mode 1 to mode 3. All of the treatment programs have passed the IEC 60601-2-10 and AAMI / ANSI ES60601-1 test codes. So this difference doesn't raise any safety or effectiveness issue. And the weight, dimensions, appearance of proposed device SM9186 are a little different from predicate device K121719, but these differences are insignificant in the terms of safety or effectiveness.

Note 2:

The output channels of the proposed device is alternating while the predicate device is synchronous. Because the proposed device and predicate device adopt the same fundamental output technology and similar treatment effect. Therefore, this item is considered to be substantially equivalent. Also, the proposed device had passed AAMI / ANSI ES60601-1 and IEC 60601-2-10 test codes, so these differences won't raise any new safety and effectiveness issues.

Note 3:

There are some differences on the maximum output voltage, maximum output current, pulse width, frequency, pulse period, deviation between proposed device and predicate device. Based on the calculation of maximum

current density, maximum average power density, these parameters don't exceed the safety limit. All deviation and the worst case have been considered in risk analysis report, and these parameters have passed IEC 60601-2-10 test codes. So these differences won't raise any new safety and effectiveness issues.

Note 4:

The maximum phase charge of the proposed device SM9186 is larger than that of the predicate device. Both of them have passed the IEC 60601-2-10 and AAMI / ANSI ES60601-1 test codes. The maximum average power density of proposed device is different from the predicate device due to they are calculated by different electrode area. Both of them meet maximum average power density **<**0.25W/cm^2 . Therefore these differences won't raise any new safety and effectiveness issues.

Final conclusion:
The subject device SM9186 is substantial Equivalent to the predicate device K121719.

Table 4-

Parameters	**New Device**	**Predicate Device**	**Remark**
510(k) Number	K201354	K121719	--
Device Name	TENS & PMS	SM TENS & PMS	--
Model	SM9196	No	--
Manufacturer	Hong Qiangxing (Shenzhen) Electronics Limited	Hong Qiangxing (Shenzhen) Electronics Limited	Same
Intended use	TENS(10~15): To be used 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. PMS(1~9): It is intended to be used to stimulate healthy muscles in order to improve and facilitate muscle performance.	TENS(1,3,4,5,6): To be used 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. PMS(1,2,3,6): It is intended to be used to stimulate healthy muscles in order to improve and facilitate muscle performance.	Same
Type of use	OTC	OTC	Same
Power Source(s)	DC 3.7V lithium battery	DC 3.7V lithium battery	Same
- Method of Line Current Isolation	Type BF	Type BF	Same
- Patient Leakage Current - Normal Condition (μA) - Single Fault Condition (μA)	-- < 10μA < 50μA	-- < 10μA < 50μA	Same
Average DC current through electrodes when device is on but no pulses are being applied (μA)	< 0.01μA	< 0.01μA	Same
Number of Output Modes	15	6	Similar Note 1
Number of Output channels:	4	2	Similar Note 2
- Synchronous or Alternating?	Synchronous & Alternating	Synchronous	
- Method of Channel Isolation	Voltage transformer Isolation	Voltage transformer Isolation	

Regulated Current or Regulated Voltage?		Voltage control	Voltage control	Same
Software/Firmware/ Microprocessor Control?		Software	Software	Same
Automatic Overload Trip?		No	No	Same
Automatic No-Load Trip?		No	No	Same
Automatic Shut Off?		Yes	Yes	Same
User Override Control?		Yes	Yes	Same
Indicator Display	On/Off Status?	Yes	Yes	Same
	Low Battery?	Yes	Yes	Same
	Voltage/ Current Level?	Yes	Yes	Same
Timer Range (minutes)		60 minutes	10 ~ 60 minutes, 10 min./step	Similar Note 2
Compliance with Voluntary Standards?		Yes. AAMI/ANSI ES60601-1, IEC 60601-1-2, IEC 60601-2-10, IEC 62133, HA 60601-1-11	Yes. AAMI/ANSI ES60601-1, IEC 60601-1-2, IEC 60601-2-10, IEC 62133, IEC 60601-1-11	Same
Compliance with 21 CFR 8988?		Yes	Yes	Same
Weight (grams)		100g±5g	140g	Similar Note 1
Dimensions (mm) [W x H x D]		58mm*180mm*15.5mm	83*42*9mm	
Housing Materials & Construction		ABS	ABS	Same
Waveform		Pulsed, symmetric, biphasic	Pulsed, symmetric, biphasic	Same
Shape		Rectangle	Rectangle	Same
Maximum Output Voltage (volts)		54V±20% @500Ω	42V±10% @500Ω	Similar Note 3
Maximum Output Current (specify units)		108mA±20% @500Ω	84mA±10% @500Ω	
Pulse width (μsec)		200-210μs	100μs	
Pulse Period (msec)		20.4-620ms	9.3~850ms	
Max. pulse frequency (Hz) [or Rate (pps)]		1.613-49.02Hz	110Hz	
Net Charge (μC per pulse)		0μC @500Ω; Method: Balanced waveform	0μC @500Ω; Method: Balanced waveform	Same
Maximum Phase Charge, (μC)		17μC@500Ω	16.8μC @500Ω	Similar
Maximum Average Current, (mA)		1.88mA	0.924mA	Similar Note 4
Maximum Current Density, (mA/cm², r.m.s.)		0.08mA/cm² @500Ω	0.462mA/cm²	
Maximum Average Power Density, (mW/cm²)		3.65mW/cm² @500Ω	9.702mW/cm²	
Biocompatibility		All user directly contacting materials	All user directly contacting materials	Same

	are compliance with ISO10993-5 and ISO10993-10 requirements.	are compliance with ISO10993-5 and ISO10993-10 requirements.	
Accessories	Self-adhesive electrodes, electrode wires, Battery charger, USB cable	Self-adhesive electrodes, electrode wires, Battery charger, USB cable	Same

Comparison in details:

Note 1:

The proposed device SM9196 has more treatment programs than the predicate device K121719, all treatment programs of proposed device are comparable to the mode 1 to mode 3 of the predicate device. The proposed device doesn't have treatment program to compare with the mode 4 to mode 6 of the predicate device because predicate device's mode 4 to mode 6 are variation waveform of the mode 1 to mode 3. All of the treatment programs have passed the IEC 60601-2-10 and AAMI / ANSI ES60601-1 test codes. So this difference doesn't raise any safety or effectiveness issue. And the weight, dimensions, appearance of proposed device SM9196 are a little different from predicate device K121719, but these differences are insignificant in the terms of safety or effectiveness.

Note 2:

The proposed device has 4 output channels and these channels are alternating & synchronous while the predicate device has 2 output channels and these channels are synchronous. The proposed device gives users more choices. Because the proposed device and predicate device adopt the same fundamental output technology and similar treatment effect. Therefore, this item is considered to be substantially equivalent. Also, the proposed device had passed AAMI / ANSI ES60601-1 and IEC 60601-2-10 test codes, so these differences won't raise any new safety and effectiveness issues.

Note 3:

There are some differences on the maximum output voltage, maximum output current, pulse width, frequency, pulse period, deviation between proposed device and predicate device. Based on the calculation of maximum current density, maximum average power density, these parameters don't exceed the safety limit. All deviation and the worst case have been considered in risk analysis report, and these parameters have passed IEC 60601-2-10 test codes. So these differences won't raise any new safety and effectiveness issues.

Note 4:

The maximum current density, maximum average power density have some differences between proposed device and predicate device due to they are calculated by different electrode area. Both of them meet maximum current density $<2mA/cm^2$ and maximum average power density $<0.25W/cm^2$. Therefore these differences won't raise any new safety and effectiveness issues.

Final conclusion:

The subject device SM9196 is substantial Equivalent to the predicate device K121719.

4. Substantial Equivalence to Predicate device: Output Specifications

Table 5-SM 9079

Parameter		**New Device**						**Predicate**	**New Device**		
Mode or program name		Program 1	Program 3	Program 4	Program 5	Program 6	Program 21	Mode 3	Program 2	Program 7	Program 8
Waveform		Biphasic	Biphasic	Biphasic	Biphasic	Biphasic	Biphasic	Biphasic	Biphasic	Biphasic	Biphasic
Shape		Rectangular	Rectangular	Rectangular	Rectangular	Rectangular	Rectangular	Rectangular	Rectangular	Rectangular	Rectangular
Maximum Output Voltage (V)	@500Ω	34.4	42	34.4	34.4	40.8	40.8	42	38.4	33.6	33.6
	@2kΩ	58.4	83	58.4	58.4	70	70	84	65.2	56.8	56.8
	@10kΩ	107	144	107	107	123	123	130	117	104	104
Maximum Output Current (mA)	@500Ω	68.8	84	68.8	68.8	81.6	81.6	84	76.8	67.2	67.2
	@2kΩ	29.2	41.5	29.2	29.2	35	35	42	32.6	28.4	28.4
	@10kΩ	10.7	14.4	10.7	10.7	12.3	12.3	13	11.7	10.4	10.4
Pulse Width(μs)		190	190	190	190	190	190	100	190	190	190
Frequency (Hz)		23.8	1.613	24.04	1.667~25.0	0.935~7.69	0.935~25	1.17	4.762	24.04	23.8
For interferential modes only: -Beat Frequency (Hz)		N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
For multiphasic waveforms only:	Symmetrical phases	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
	Phase duration	190	190	190	190	190	190	100	190	190	190
Net Charge (@500Ω) [uC]		0	0	0	0	0	0	0	0	0	0
Maximum Phase Charge (uC)		11.094	13.87	11.36	11.36	13.32	13.22	16.8	12.12	11.35	11.08
Maximum Current Density (mA/cm^2)		0.052	0.004	0.05	0.054	0.02	0.065	0.0049	0.0116	0.051	0.051
Maximum Power Density, (mW/cm^2)		1.78	0.18	1.8	1.87	0.81	2.64	0.103	0.44	1.72	1.70
Burst Mode	(a) Pulses per burst	NA	NA	NA	NA	NA	NA	NA	17	79	49

	(b) Bursts per second	NA	NA	NA	NA	NA	NA	NA	0.196	0.164	0.327
	(c) Burst duration (seconds)	NA	NA	NA	NA	NA	NA	NA	3.52	3.3	2.05
	(d) Duty Cycle: Line (b) x Line (c)	NA	NA	NA	NA	NA	NA	NA	0.69	0.54	0.67
ON Time (seconds)		NA	NA	NA	NA	NA	NA	NA	3.52	3.3	2.05
OFF Time (seconds)		NA	NA	NA	NA	NA	NA	NA	1.58	2.79	1
Additional Features		N/A	N/A	N/A	N/A	NA	NA	N/A	N/A	N/A	N/A

Continue

Parameter		**New device**	**Predicate**	**New Device**							
Mode or program name		Program 14	Mode 2	Program 9	Program 10	Program 11	Program 12	Program 13	Program 15	Program 16	Program 17
Waveform		Biphasic	Biphasic	Biphasic	Biphasic	Biphasic	Biphasic	Biphasic	Biphasic	Biphasic	Biphasic
Shape		Rectangular	Rectangular	Rectangular	Rectangular	Rectangular	Rectangular	Rectangular	Rectangular	Rectangular	Rectangular
Maximum Output Voltage (V)	@500Ω	32.8	42	34.8	34.8	34.4	34.4	34.4	34.4	34.4	34.4
	@2kΩ	56	84	58.8	58.8	58.4	58.4	58.4	58.4	58.4	58.4
	@10kΩ	103	130	107	107	107	107	107	107	107	107
Maximum Output Current (mA)	@500Ω	65.6	84	69.6	69.6	68.8	68.8	68.8	68.8	68.8	68.8
	@2kΩ	28	42	29.4	29.4	29.2	29.2	29.2	29.2	29.2	29.2
	@10kΩ	10.3	13	10.7	10.7	10.7	10.7	10.7	10.7	10.7	10.7
Pulse Width(μs)		190	100	190	190	190	190	190	190	190	190
Frequency (Hz)		25	12.5~55.5	25	23.8	25	23.8	24.39	25	24.04	25
For interferential modes only: Beat Frequency (Hz)		N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
For multiphasic waveforms	Symmetrical phases	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes

only:	Phase Duration	190	100	190	190	190	190	190	190	190	190
Net Charge (@500Ω) [uC]		0	0	0	0	0	0	0	0	0	0
Maximum Phase Charge (uC)		10.56	16.8	11.415	11.42	11.17	11.08	11.49	11.53	11.55	11.65
Maximum Current Density (mA/cm²)		0.052	0.2331	0.055	0.053	0.054	0.052	0.053	0.054	0.052	0.054
Maximum Power Density, (mW/cm²)		1.70	4.895	1.92	1.83	1.87	1.78	1.83	1.87	1.8	1.87
Burst Mode	(a) Pulses per burst	130	250~1110	291	129	124	218	161	76.5	149	291
	(b) Bursts per second	0.124	0.048	0.067	0.133	0.167	0.083	0.116	0.245	0.139	0.067
	(c) Burst duration (seconds)	5.18	20	11.62	5.4	4.96	9.14	6.62	3.06	6.2	11.64
	(d) Duty Cycle: Line (b) x Line (c)	0.64	0.96	0.78	0.72	0.83	0.76	0.77	0.75	0.86	0.78
ON Time (seconds)		5.18	20	11.62	5.4	4.96	9.14	6.62	3.06	6.2	11.64
OFF Time (seconds)		2.94	1	3.24	2.12	1	2.96	1.97	1	1	3.26
Additional Features		N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A

Continue

Parameter		**New Device**						**Predicated Device**
Mode or program name		Program 18	Program 19	Program 20	Program 22	Program 23	Program 24	Mode 1
Waveform		Biphasic	Biphasic	Biphasic	Biphasic	Biphasic	Biphasic	Biphasic
Shape		Rectangular	Rectangular	Rectangular	Rectangular	Rectangular	Rectangular	Rectangular
Maximum Output Voltage	@500Ω	34.4	34.4	34.4	38	34.4	34.4	42
	@2kΩ	58.4	58.4	58.4	58.4	58.4	58.4	84

(V)	@10kΩ	107	107	107	115	107	107	130
Maximum Output Current(mA)	@500Ω	68.8	68.8	68.8	76	68.8	68.8	84
	@2kΩ	29.2	29.2	29.2	29.2	29.2	29.2	42
	@10kΩ	10.7	10.7	10.7	11.5	10.7	10.7	13
Pulse Width(μs)		190	190	190	190	190	190	100
Frequency (Hz)		24.5	24.5	24.04	4.76~25.0	23.8	23.8	68
For interferential modes only: -Beat Frequency (Hz)		N/A	N/A	N/A	N/A	N/A	N/A	N/A
For multiphasic waveforms only:	Symmetrical phases	Yes	Yes	Yes	Yes	Yes	Yes	Yes
	Phase Duration	190	190	190	190	190	190	100
Net Charge (@500Ω) [uC]		0	0	0	0	0	0	0
Maximum Phase Charge (uC)		11.32	11.40	11.55	12.29	11.06	11.59	16.8
Maximum Current Density (mA/cm²)		0.053	0.053	0.052	0.06	0.052	0.052	0.2856
Maximum Power Density, (mW/cm²)		1.84	1.84	1.8	2.29	1.78	1.78	5.998
Burst Mode	(a) Pulses per burst	141	127	208	34-179	404	415	204
	(b) Bursts per second	0.137	0.162	0.095	0.098	0.045	0.045	0.219
	(c) Burst duration (seconds)	5.76	5.17	8.66	7.14	16.98	17.44	3
	(d) Duty Cycle: Line (b) x Line (c)	0.79	0.84	0.82	0.7	0.76	0.78	0.66
ON Time (seconds)		5.76	5.17	8.66	7.14	16.98	17.44	3
OFF Time (seconds)		1.52	1	1.96	3.02	5.41	4.78	1.56
Additional Features (specify, if applicable)		N/A	N/A	N/A	N/A	N/A	N/A	N/A

Table 6-SM 9126

Parameter	**New Device**						**Predicate**	**New Device**		
Mode or program name	Program 1	Program 8	Program 9	Program 10	Program 13	Program 14	Mode 1	Program 2	Program 7	Program 15
Waveform	Biphasic	Biphasic	Biphasic	Biphasic	Biphasic	Biphasic	Biphasic	Biphasic	Biphasic	Biphasic
Shape	Rectangular	Rectangular	Rectangular	Rectangular	Rectangular	Rectangular	Rectangular	Rectangular	Rectangular	Rectangular

Maximum Output Voltage (V)	@500Ω	30.8	30.4	30.8	30.8	30.8	30.8	42	41.2	30.4	4.6
	@2kΩ	84	72.4	84	84	84	84	84	113	72.4	15.6
	@10kΩ	159	124	159	159	159	159	130	163	123	24
Maximum Output Current (mA)	@500Ω	61.6	60.8	61.6	61.6	61.6	61.6	84	82.4	60.8	9.2
	@2kΩ	42	36.2	42	42	42	42	42	56.5	36.2	7.8
	@10kΩ	15.9	12.4	15.9	15.9	15.9	15.9	13	16.3	12.3	2.4
Pulse Width(μs)		220	220	220	220	220	220	100	220	220	220
Frequency (Hz)		52.08	40.98	40.98	40.98	41.67	52.63	68	9.26	38.46	57.47
For interferential modes only: -Beat Frequency (Hz)		N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
For multiphasic waveforms only:	Symmetrical phases	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
	Phase duration	220	220	220	220	220	220	100	220	220	220
Net Charge (@500Ω) [uC]		0	0	0	0	0	0	0	0	0	0
Maximum Phase Charge (uC)		13.7	10.5	13.7	13.7	13.7	13.7	16.8	15	10.5	1.4
Maximum Current Density (mA/cm^2)		0.117	0.091	0.093	0.093	0.094	0.119	0.2856	0.03	0.09	0.019
Maximum Power Density, (mW/cm^2)		3.62	2.78	2.85	2.85	2.9	3.66	5.998	1.15	5.21	0.09
Burst Mode	(a) Pulses per burst	212	520	254	127	521	216	204	34	149	488
	(b) Bursts per second	0.17	0.061	0.12	0.230	0.0625	0.173	0.219	0.18	0.145	0.098
	(c) Burst duration (seconds)	4.07	12.7	6.21	3.09	12.48	4.1	3	3.72	3.87	8.5
	(d) Duty	0.71	0.78	0.73	0.71	0.78	0.71	0.66	0.67	0.56	0.83

	Cycle: Line (b) x Line (c)										
ON Time (seconds)		4.07	12.7	6.21	3.09	12.48	4.1	3	3.72	3.87	8.5
OFF Time (seconds)		1.68	3.52	2.3	1.28	3.52	1.66	1.56	1.84	2.98	1.7
Additional Features		N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A

Continue

Parameter		**Predicate**	**New Device**							**Predicate**
Mode or program name		Mode 2	Program 3	Program 4	Program 5	Program 6	Program 11	Program 12	Program 16	Mode 3
Waveform		Biphasic	Biphasic	Biphasic	Biphasic	Biphasic	Biphasic	Biphasic	Biphasic	Biphasic
Shape		Rectangular	Rectangular	Rectangular	Rectangular	Rectangular	Rectangular	Rectangular	Rectangular	Rectangular
Maximum Output Voltage (V)	@500Ω	42	46.4	30.8	28.8	37.6	4.6	11	4.6	42
	@2kΩ	84	126	84	68	100	15.6	20.8	15.6	84
	@10kΩ	130	161	159	119	153	24	37.2	24	130
Maximum Output Current (mA)	@500Ω	84	92.8	61.6	57.6	75.2	9.2	22	9.2	84
	@2kΩ	42	63	42	34	50	7.8	10.4	7.8	42
	@10kΩ	13	16.1	15.9	11.9	15.3	2.4	3.72	2.4	13
Pulse Width(μs)		100	220	220	220	220	220	220	220	100
Frequency (Hz)		12.5~55.5	1.47	40.98	3.33~37.04	1.79~13.51	212.5	113.6	57.47	1.17
For interferential modes only: Beat Frequency (Hz)		N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
For multiphasic waveforms only:	Symmetrical phases	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
	Phase Duration	100	220	220	220	220	220	220	220	100
Net Charge (@500Ω) [uC]		0	0	0	0	0	0	0	0	0
Maximum Phase Charge (uC)		16.8	17.26	13.7	10.39	14.54	2.02	4.18	2.02	16.8
Maximum Current Density (mA/cm^2)		0.2331	0.005	0.093	0.078	0.037	0.072	0.092	0.019	0.0049

Maximum Power Density, (mW/cm²)		4.895	0.23	2.85	2.25	1.4	0.33	1.01	0.09	0.103
Burst Mode	(a) Pulses per burst	250~1110	NA	NA	NA	NA	NA	NA	NA	NA
	(b) Bursts per second	0.048	NA	NA	NA	NA	NA	NA	NA	NA
	(c) Burst duration (seconds)	20	NA	NA	NA	NA	NA	NA	NA	NA
	(d) Duty Cycle: Line (b) x Line (c)	0.96	NA	NA	NA	NA	NA	NA	NA	NA
ON Time (seconds)		20	NA	NA	NA	NA	NA	NA	NA	NA
OFF Time (seconds)		1	NA	NA	NA	NA	NA	NA	NA	NA
Additional Features		N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A

Table 7-SM 9186

Parameter		**New Device**				**Predicate**	**New Device**			**Predicate**	**New Device**
Mode or program name		Program 1	Program 6	Program 9	Program 12	Mode 1	Program 2	Program 5	Program 10	Mode 2	Program 3
Waveform		Biphasic	Biphasic	Biphasic	Biphasic	Biphasic	Biphasic	Biphasic	Biphasic	Biphasic	Biphasic
Shape		Rectangular	Rectangular	Rectangular	Rectangular	Rectangular	Rectangular	Rectangular	Rectangular	Rectangular	Rectangular
Maximum Output Voltage (V)	@500Ω	43.8	48	38.4	42.4	42	43.8	36.8	7	42	63
	@2kΩ	57	74	59.6	76	84	81	66	13.1	84	116
	@10kΩ	142	156	109	152	130	149	126	24.2	130	149
Maximum Output Current (mA)	@500Ω	87.6	96	76.8	84.8	84	87.6	73.6	14	84	126
	@2kΩ	28.5	37	29.8	38	42	40.5	33	6.55	42	58
	@10kΩ	14.2	15.6	10.9	15.2	13	14.9	12.6	2.42	13	14.9

Pulse Width(μs)		220	220	230	220μs	100	220	220	230	100	224
Frequency (Hz)		31.25-58.82	32.26~58.82	34.48~58.82	37.03~59.52	68	8.33~52.63	92.59	155.6	12.5~55.5	1.11
For interferential modes only: -Beat Frequency (Hz)		N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
For multiphasic waveforms only:	Symmetrical phases	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
	Phase duration	220	220	230	220	100	220	220	230	100	224
Net Charge (@500Ω) [uC]		0	0	0	0	0	0	0	0	0	0
Maximum Phase Charge (uC)		16.7	14.5	14.5	15.2	16.8	16.7	15.1	2.6	16.8	25.07
Maximum Current Density (mA/cm^2)		0.19	0.21	0.17	0.185	0.2856	0.17	0.25	0.084	0.2331	0.005
Maximum Power Density, (mW/cm^2)		8.28	9.94	6.65	7.85	5.998	7.4	9.2	0.58	4.895	0.33
Burst Mode	(a) Pulses per burst	212	1200	711	333	204	2253	1639	1556	250~1110	N/A
	(b) Bursts per second	0.186	0.034	0.064	0.125	0.219	0.023	0.04	0.085	0.048	N/A
	(c) Burst duration (seconds)	3.6	20.4	12.08	5.6	3	42.8	17.7	10	20	N/A
	(d) Duty Cycle: Line (b) x Line (c)	0.67	0.7	0.77	0.7	0.66	0.98	0.73	0.85	0.96	N/A
ON Time (seconds)		3.6	20.4	12.08	5.6	3	42.8	17.7	10	20	N/A

OFF Time (seconds)	1.8	8.6	3.6	2.4	1.56	1	6.5	1.76	1	N/A
Additional Features	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A

Continue

Parameter		**New Device**				**Predicate**
Mode or program name		Program 4	Program 7	Program 8	Program 11	Mode 3
Waveform		Biphasic	Biphasic	Biphasic	Biphasic	Biphasic
Shape		Rectangular	Rectangular	Rectangular	Rectangular	Rectangular
Maximum Output Voltage (V)	@500Ω	43.8	59	68	26.8	42
	@2kΩ	66	94	117	44	84
	@10kΩ	128	168	174	80	130
Maximum Output Current(mA)	@500Ω	76	118	136	53.6	84
	@2kΩ	33	47	58.5	22	42
	@10kΩ	12.8	16.8	17.4	8	13
Pulse Width(μs)		220	220	220	220	100
Frequency (Hz)		50~92.59	1.136~59.52	1.11~92.59	92.59	1.17
For interferential modes only: -Beat Frequency (Hz)		N/A	N/A	N/A	N/A	N/A
For multiphasic waveforms only:	Symmetrical phases	Yes	Yes	Yes	Yes	Yes
	Phase Duration	220	220	220	220	100
Net Charge (@500Ω) [uC]		0	0	0	0	0
Maximum Phase Charge (uC)		16.72	21.5	26	9.8	16.8
Maximum Current Density (mA/cm²)		0.258	0.26	0.46	0.182	0.0049
Maximum Power Density, (mW/cm²)		9.8	15.19	31.4	4.88	0.103
Burst Mode	(a) Pulses per burst	N/A	N/A	N/A	N/A	N/A
	(b) Bursts per second	N/A	N/A	N/A	N/A	N/A
	(c) Burst duration (seconds)	N/A	N/A	N/A	N/A	N/A
	(d) Duty Cycle: Line (b) x Line (c)	N/A	N/A	N/A	N/A	N/A
ON Time (seconds)		N/A	N/A	N/A	N/A	N/A
OFF Time (seconds)		N/A	N/A	N/A	N/A	N/A

Additional Features (specify, if applicable)	N/A	N/A	N/A	N/A	N/A

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Parameter		**New Device**						**Predicate**	**New Device**		
Mode or program name		Program 1	Program 2	Program 3	Program 4	Program 6	Program7	Mode 1	Program 5	Program 8	Program 9
Waveform		Biphasic	Biphasic	Biphasic	Biphasic	Biphasic	Biphasic	Biphasic	Biphasic	Biphasic	Biphasic
Shape		Rectangular	Rectangular	Rectangular	Rectangular	Rectangular	Rectangular	Rectangular	Rectangular	Rectangular	Rectangular
Maximum Output Voltage (V)	@500Ω	49.2	48	48	42.8	48	47.2	42	46	52.4	50
	@2kΩ	73.6	73.6	74	72.8	74.4	72.8	84	71.6	78.8	101
	@10kΩ	118	124	123	120	120	120	130	119	129	133
Maximum Output Current (mA)	@500Ω	98.4	96	96	85.6	96	94.4	84	92	104.8	100
	@2kΩ	36.8	36.8	37	36.4	37.2	36.4	42	35.8	39.4	50.5
	@10kΩ	11.8	12.4	12.3	12	12	12	13	11.9	12.9	13.3
Pulse Width(μs)		200	200	200	200	200	200	100	200	200	210
Frequency (Hz)		47.17	47.62	47.17	48.08	49.02	48.08	68	48.08	9.434	1.613
For interferential modes only: -Beat Frequency (Hz)		N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
For multiphasic waveforms only:	Symmetrical phases	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
	Phase duration	200	200	200	200	200	200	100	200	200	210
Net Charge (@500Ω) [uC]		0	0	0	0	0	0	0	0	0	0
Maximum Phase Charge (uC)		15.84	15.20	15.20	14.5	15.20	14.8	16.8	14.6	16.48	16.8
Maximum Current Density (mA/cm^2)		0.07	0.07	0.073	0.07	0.08	0.07	0.2856	0.07	0.02	0.0027
Maximum Power Density, (mW/cm^2)		3.65	3.51	3.48	2.82	3.61	3.43	5.998	3.26	0.83	0.14

Burst Mode	(a) Pulses per burst	257	238	434	303	152	173.1	204	249.1	33.4	7.74
	(b) Bursts per second	0.132	0.166	0.082	0.12	0.244	0.2	0.219	0.122	0.194	0.16
	(c) Burst duration (seconds)	5.44	5	9.2	6.3	3.1	3.6	3	5.18	3.54	4.8
	(d) Duty Cycle: Line (b) x Line (c)	0.72	0.83	0.75	0.76	0.76	0.71	0.66	0.63	0.69	0.76
ON Time (seconds)		5.44	5	9.2	6.3	3.1	3.6	3	5.18	3.54	4.8
OFF Time (seconds)		2.14	1.02	3	2	1	1.5	1.56	3s	1.62	1.5
Additional Features		N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A

Continue

Parameter		**Predicate**	**New Device**						**Predicate**
Mode or program name		Mode 2	Program 10	Program 11	Program 12	Program 13	Program 14	Program 15	Mode 3
Waveform		Biphasic	Biphasic	Biphasic	Biphasic	Biphasic	Biphasic	Biphasic	Biphasic
Shape		Rectangular	Rectangular	Rectangular	Rectangular	Rectangular	Rectangular	Rectangular	Rectangular
Maximum Output Voltage (V)	@500Ω	42	45.6	46	54	47.2	46.4	46	42
	@2kΩ	84	72	72	87.6	73.6	70.4	73.6	84
	@10kΩ	130	112	118	131	119	117	124	130
Maximum Output Current(mA)	@500Ω	84	91.2	92	108	94.4	92.8	92	84
	@2kΩ	42	36	36	43.8	36.8	35.2	36.8	42
	@10kΩ	13	11.2	11.8	13.1	11.9	11.7	12.4	13
Pulse Width(μs)		100	210	200	200	200	200	210	100
Frequency (Hz)		12.5~55.5	49.02	3.33~47.62	1.887~15.63	48.08	48.08	47.17	1.17
For interferential modes only: -Beat Frequency (Hz)		N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A

For multiphasic waveforms only:	Symmetrical phases	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
	Phase Duration	100	210	200	200	200	200	210	100
Net Charge (@500Ω) [uC]		0	0	0	0	0	0	0	0
Maximum Phase Charge (uC)		16.8	13.6	14.6	17.0	14.8	14.9	15.9	16.8
Maximum Current Density (mA/cm²)		0.2331	0.08	0.07	0.03	0.07	0.07	0.07	0.0049
Maximum Power Density, (mW/cm²)		4.895	3.42	3.22	1.46	3.43	3.31	3.35	0.103
Burst Mode	(a) Pulses per burst	250~1110	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	(b) Bursts per second	0.048	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	(c) Burst duration (seconds)	20	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	(d) Duty Cycle: Line (b) x Line (c)	0.96	N/A	N/A	N/A	N/A	N/A	N/A	N/A
ON Time (seconds)		20	N/A	N/A	N/A	N/A	N/A	N/A	N/A
OFF Time (seconds)		1	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Additional Features (specify, if applicable)		N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A

5. Test summary:

TENS & PMS are safe and effective as the predicate devices cited above. The new devices have passed testings according to the following standards:

1) ANSI AAMI ES60601-1: 2005/(R)2012 And A1:2012, C1:2009/(R)2012 And A2:2010/(R)2012 (Consolidated Text) Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance (IEC 60601-1:2005, MOD);

2) 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;

3) ANSI AAMI 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;

4) IEC 62133 Edition 2.0 2012-12, 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)];

5) ANSI AAMI HA60601-1-11 2015 Medical Electrical Equipment -- Part 1-11: General Requirements For Basic Safety And Essential Performance -- Collateral Standard: Requirements For Medical Electrical Equipment And Medical Electrical Equipment And Medical Electrical Systems Used In The Home Healthcare Environment (IEC 60601-1-11:2015 MOD);

The conclusion drawn from the testings are that the new devices are substantially equivalent to the predicate device. Furthermore, the new device complies with the recognized standards and performs its intended tasks as well as the legally marketed predicate devices.