

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 <a href="https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm">https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm</a> 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 <a href="https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products">https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products</a>); 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 <u>https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems</u>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<u>https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance</u>) and CDRH Learn (<u>https://www.fda.gov/training-and-continuing-education/cdrh-learn</u>). 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 (<u>https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice</u>) for more information or contact DICE by email (<u>DICE@fda.hhs.gov</u>) 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

# Indications for Use

510(k) Number *(if known)* K201354

Device Name TENS & PMS

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)
CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

#### \*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.\*

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services Food and Drug Administration Office of Chief Information Officer Paperwork Reduction Act (PRA) Staff *PRAStaff@fda.hhs.gov* 

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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
indications for use.	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.

4F, Jingcheng Building, Xicheng Industrial Zone, Xixiang Road, Bao'an District, Shenzhen City, Guangdong, China 518126

#### 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.

4F, Jingcheng Building, Xicheng Industrial Zone, Xixiang Road, Bao'an District, Shenzhen City, Guangdong, China 518126 **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

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

	ng Building,	Xicheng Industrial Zone, Xixiang Road	u, Bao an District, Shenzhen City, Gua	nguong, China 518120
Current				
-	Normal	< 10µA	<10µA	
Condition				
	ngle Fault	< 50µA	< 50µA	
Condition				
Average	DC	< 0.01µA	< 0.01µA	Same
current	through			
electrode	s when			
device is	on but no			
-	are being			
applied (µ	ıA)			
Number of	of Output	24	6	Similar
Modes				Note 1
Number of	of Output	2	2	Same
channels:				
-		Alternating	Synchronous	Similar Note 2
Synchron	ous or			
Alternatio	ng?			
- Me	ethod of	Voltage transformer	Voltage transformer	Same
Channel 1	Isolation	Isolation	Isolation	
Regulated		Voltage control	Voltage control	Same
or Regulated				
Voltage?	8			
Software/	Firmwar	Software	Software	Same
e/Microprocessor		Soltware	Software	Sume
Control?	100000000			
Automati	0	No	No	Same
Overload		110		Buille
Automati	-	No	No	Same
No-Load		110		Same
Automati	-	Yes	Yes	Same
	e Shut	Tes	Tes	Same
Off? User	Override	Yes	Yes	Sama
User Control?	Overnae	1 05	105	Same
		Vac	Vac	<u> </u>
Indicato	On/Off	Yes	Yes	Same
r Diamlari	Status	V	V	C
Display	Low	Yes	Yes	Same
	Battery	X7		C
	Voltage	Yes	Yes	Same
	/Curren			
	t Level			
Timer	Range	10 ~ 60 minutes, 10	10 ~ 60 minutes, 10	Same
(minutes)		min/step	min./step	
Compliar		Yes.	Yes.	Same
Voluntary	у	AAMI/ANSI ES 60601-1,	AAMI/ANSI	

Hong Qiangxing(Shen Zhen) Electronics Limited

Standards?	IEC 60601-1-2, IEC	ES60601-1, IEC 60601-1-	
	60601-2-10, IEC 62133,	2, IEC	
	HA 60601-1-11	60601-2-10, IEC	
		62133, IEC 60601-1-11	
Compliance with	Yes	Yes	Same
21 CFR 898?			
Weight (grams)	102g±5g	140g	Similar Note
Dimensions (mm)	60*123*12mm	83*42*9mm	
[W x H x D]			
Housing Materials	ABS	ABS	Same
& Construction			
Waveform	Pulsed, symmetric,	Pulsed, symmetric,	Same
	biphasic	biphasic	
Shape	Rectangle	Rectangle	Same
Maximum Output	42V±20% @500Ω	42V±10% @500Ω	Similar Note 3
Voltage (volts)			
Maximum Output	84mA±20% @500Ω	84mA±10% @500Ω	-
Current (specify			
units)			
Pulse width (µsec)	190µs	100µs	_
Pulse Period	40-1070ms	9.3~850ms	_
(msec)	+0 10/0115	<i>5.5</i> 050ms	
Max. pulse	0.935-25Hz±10%	110Hz	_
frequency (Hz) [or	0.755-25112-1070		
Rate (pps)]			
Net Charge (µC	$0\mu C$ @500 $\Omega$ ; Method:	0μC @500Ω; Method: Balanced	Same
per pulse)	Balanced waveform	waveform	Same
per puise)	Balanced wavelorm	wavelollii	
Maximum Phase	<u>13.30μC@500Ω</u>	16.8μC @500Ω	Similar
Charge, $(\mu C)$	<u>13.30µ0(₩,300ш</u>		billina
Maximum	0.78mA	0.924mA	Similar Note 4
Average Current,	0.70111	0.9241111	
(mA)			
Maximum Current	0.065mA/cm <sup>2</sup> @,500Ω	0.462mA/cm <sup>2</sup>	_
Density, (mA/cm <sup>2</sup> ,			
r.m.s.)			
Maximum	$2.64mW/am^2 @ 5000$	9.702mW/cm <sup>2</sup>	-
	$2.64$ mW/cm <sup>2</sup> @500 $\Omega$	7./UZIIIW/UIII <sup>-</sup>	
e			
Density,			
(mW/cm <sup>2</sup> )			Come
Accessories	Self-adhesive electrodes,	Self-adhesive electrodes,	Same
	electrode wires, Battery charger,	electrode wires,	
	USB cable	Battery charger,	
<b></b>		USB cable	
Biocompatibility	All user directly	All user directly	Same

4F, Jingcheng Building, Xicheng Industrial Zone, Xixiang Road, Bao'an District, Shenzhen City, Guangdong, China 518126

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

Comparison in details:

# <u>Note 1:</u>

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.

# <u>Note 4:</u>

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  $<2mA/cm^2$  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 SM9079 is substantial Equivalent to the predicate device K121719.

Table 2-

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

Hong Qiangxing(Shen Zhen) Electronics Limited

4F, Jingcheng Building, Xicheng Industrial Zone, Xixiang Road, Bao'an District, Shenzhen City, Guangdong, China 518126		
	4F, Jingcheng Building, Xic	eng Industrial Zone, Xixiang Road, Bao'an District, Shenzhen City, Guangdong, China 518126

4F, Jingcheng Building, X Device Name	icheng Industrial Zone, Xixiang Road, Ba TENS & PMS	o'an District, Shenzhen City, Guangdong, China SM TENS & PMS	a 518126
Model	SM9126	No	
Manufacturer	Hong Qiangxing (Shenzhen)	Hong Qiangxing (Shenzhen)	Same
Wandfacturer	Electronics Limited	Electronics Limited	Bane
Intended use	TENS(3~6,11,12,16):	TENS(1,3,4,5,6):	Same
Intended use	To be used for temporary relief	To be used for temporary relief of	Bane
	of pain associated with sore and	pain associated with sore and aching	
	aching muscles in the shoulder,	muscles in the shoulder, waist, back,	
	waist, back, neck, upper	neck, upper extremities (arm), and	
	extremities (arm), and lower	lower extremities (leg) due to strain	
	extremities (leg) due to strain	from exercise or normal household	
	from exercise or normal	work activities.	
	household work activities.	PMS(1,2,3,6):	
	PMS(1,2,7~10,13~15):	It is intended to be used to stimulate	
	It is intended to be used to	healthy muscles in order to improve	
	stimulate healthy muscles in	and facilitate muscle performance.	
	order to improve and facilitate	r	
	muscle performance.		
Type of use	OTC	OTC	Same
Power Source(s)	DC 3.7V lithium battery	DC 3.7V lithium battery	Same
- Method of Line	Type BF	Type BF	Same
Current Isolation			
- Patient Leakage			Same
Current			
- Normal	<10µA	< 10µA	
Condition (µA)			
- Single Fault	$< 50 \mu A$	< 50µA	
Condition (µA)			
Average DC current	< 0.01µA	< 0.01µA	Same
through electrodes			
when device is on			
but no pulses are			
being applied (µA)			
Number of Output	16	6	Similar
Modes			Note 1
Number of Output	2	2	Same
channels:			
- Synchronous	Synchronous	Synchronous	Same
or Alternating?			
- Method of	Voltage transformer Isolation	Voltage transformer Isolation	Same
Channel Isolation			
Regulated Current	Voltage control	Voltage control	Same
or Regulated			
Voltage?			
Software/Firmware/	Software	Software	Same

Micropro	ocessor			
Control?				
Automat	ic Overload	No	No	Same
Trip?				
Automat	ic No-Load	No	No	Same
Trip?				
Automat	ic Shut Off?	Yes	Yes	Same
User	Override	Yes	Yes	Same
Control?	1			
Indicat	On/Off	Yes	Yes	Same
or	Status?			
Displa	Low	Yes	Yes	Same
У	Battery?			
	Voltage/C	Yes	Yes	Same
	urrent			
	Level?			
Timer	Range	10 ~ 60 minutes, 10 min/step	10 ~ 60 minutes, 10 min./step	Same
(minutes	)			
Complia	nce with	Yes.	Yes.	Same
Voluntar	у	AAMI/ANSI ES 60601-1, IEC	AAMI/ANSI ES60601-1, IEC	
Standards?		60601-1-2, IEC 60601-2-10, IEC	60601-1-2, IEC 60601-2-10, IEC	
		62133, HA 60601-1-11	62133, IEC 60601-1-11	
Complia	nce with 21	Yes	Yes	Same
CFR 898	38?			
Weight (	grams)	55g±5g	140g	Similar
Dimensi	ons (mm)	50.37*93.4*10.4mm	83*42*9mm	Note 1
[W x H >	x D]			
Housing	Materials	ABS	ABS	Same
& Constr	ruction			
Wavefor	m	Pulsed, symmetric, biphasic	Pulsed, symmetric, biphasic	Same
Shape		Rectangular	Rectangular	Same
Maximu	m Output	46.4V±20% @500Ω	42V±10% @500Ω	Similar
Voltage (volts)		Ŭ T	Ŭ, Ŭ,	Note 2
Maximum Output		92.8mA±20% @500Ω	84mA±10% @500Ω	
Current (specify		Ŭ T		
units)	· I - J			
Pulse width (µsec)		220µs	100µs	
Pulse Period (msec)		5-680ms	9.3~850ms	
Max. pulse		1.47-212.5Hz±10%	110Hz	
	y (Hz) [or			
Rate (pp	• • • •			
	rge (µC per	0μC @500Ω; Method: Balanced	$0\mu C$ @500 $\Omega$ ; Method: Balanced	Same
pulse)		waveform	waveform	Zanie
Maximu	m Phase	<u>17.26μC@500Ω</u>	16.8µC @500Ω	Similar
TTUAIIIIU.	111111111111111111111111111111111111111	11.20µ0(0,20022	10.040 (0.00022	Suma

4F, Jingcheng Building, Xicheng Industrial Zone	, Xixiang Road, Bao'an Distric	t, Shenzhen City, Guangdong, China 518126

Maximum Average	2.056mA	0.924mA	Similar
Current, (mA)			Note 3
Maximum Current	0.119mA/cm <sup>2</sup> @500Ω	0.462mA/cm <sup>2</sup>	
Density, (mA/cm <sup>2</sup> ,			
r.m.s.)			
Maximum Average	5.21mW/cm <sup>2</sup> @500Ω	9.702mW/cm <sup>2</sup>	
Power Density,			
(mW/cm <sup>2</sup> )			
Biocompatibility	All user directly contacting	All user directly contacting materials	Same
	materials are compliance with	are compliance with ISO10993-5 and	
	ISO10993-5 and ISO10993-10	ISO10993-10 requirements.	
	requirements.		
Accessories	Self-adhesive electrodes,	Self-adhesive electrodes, electrode	Same
	electrode wires, Battery charger,	wires, Battery charger, USB cable	
	USB cable		

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/cm<sup>2</sup> and maximum average power density <0.25W/cm<sup>2</sup>. 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.

Hong Qiangxing(Shen Zhen) Electronics Limited 4F, Jingcheng Building, Xicheng Industrial Zone, Xixiang Road, Bao'an District, Shenzhen City, Guangdong, China 518126 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	Hong Qiangxing (Shenzhen)		
		(Shenzhen) Electronics	Electronics Limited		
		Limited			
Intended use		TENS(3,4,7,8,11):	TENS(1,3,4,5,6):	Same	
		To be used for temporary	To be used for temporary relief		
		relief of pain associated	of pain associated with sore and		
		with sore and aching	aching muscles in the shoulder,		
		muscles in the shoulder,	waist, back, neck, upper extremities (arm), and lower		
		waist, back, neck, upper extremities (arm), and	extremities (leg) due to strain		
		lower extremities (leg) due	from exercise or normal		
		to strain from exercise or	household work activities.		
		normal household work	PMS(1,2,3,6):		
		activities.	It is intended to be used to		
		PMS(1,2,5,6,9,10,12):	stimulate healthy muscles in		
		It is intended to be used to	order to improve and facilitate		
		stimulate healthy muscles	muscle performance.		
		in order to improve and			
		facilitate muscle			
Type of use		performance. 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	
- Normal Cor		< 10µA	< 10µA	Buille	
	t Condition (µA)	< 50µA	< 50µA		
Average DC		< 0.01µA	< 0.01µA	Same	
electrodes when d	evice is on but no				
pulses are being a					
Number of Output	Modes	12	6	Similar	
	1 1			Note 1	
Number of Output		2	2	Same	
- Synchronou	is or Alternating?	Alternating	Synchronous	Similar Note 2	
- Method of (	Channel Isolation	Voltage transformer	Voltage transformer Isolation	Same	
		Isolation	Voltage transformer isolation	Same	
Regulated Curren	nt or Regulated	Voltage control	Voltage control	Same	
Voltage?			· ····································		
Software/Firmware	/Microprocessor	Software	Software	Same	
Control?	_				
Automatic Overlo	-	No	No	Same	
Automatic No-Lo	1	No	No	Same	
Automatic Shut Off? User Override Control? Indicator On/Off Status		Yes	Yes	Same	
		Yes	Yes Yes	Same	
Indicator Display		Yes Yes	Yes	Same	
Display	Low Battery			Same	
	Voltage/Current Level	Yes	Yes	Same	
Timer Range (min		10 ~ 60 minutes, 10	10 ~ 60 minutes, 10 min./step	Same	
		min/step			
Compliance w	vith Voluntary	Yes.	Yes.	Same	
Standards?		AAMI/ANSI ES 60601-1,	AAMI/ANSI ES60601-1, IEC		

in , this energy burnang, meneng maasa	IEC 60601-1-2, IEC 60601-	trict, Shenzhen City, Guangdong, China 5 60601-1-2, IEC 60601-2-10,	10120
	2-10, IEC 62133, HA	IEC 62133, IEC 60601-1-11	
	60601-1-11		
Compliance with 21 CFR 8988?	Yes	Yes	Same
Weight (grams)	50±5g	140g	Similar
Dimensions (mm) [W x H x D]	52.9*92*11mm	83*42*9mm	Note 1
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
Maximum Output Current (specify units)	136mA±20% @500Ω	84mA±10% @500Ω	Note 3
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)	$0\mu C$ @500 $\Omega$ ; 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	Note 4
Maximum Current Density, (mA/cm <sup>2</sup> , r.m.s.)	$0.46 \text{mA/cm}^2@500\Omega$	0.462mA/cm <sup>2</sup>	Same
Maximum Average Power Density, (mW/cm <sup>2</sup> )	31.40mW/cm <sup>2</sup> @500Ω	9.702mW/cm <sup>2</sup>	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

4F, Jingcheng Building, Xicheng Industrial Zone, Xixiang Road, Bao'an District, Shenzhen City, Guangdong, China 518126 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<sup>2</sup>. 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.

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	 < 10μΑ < 50μΑ	 < 10µА < 50µА	Same
Condition (µA)	-		
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	

Table 4-

	Current or	Voltage control	Voltage control	Same
Regulated	Voltage?	Software	Software	Same
Software/I Microprod		Software	Software	Same
Control?	28801			
	c Overload	No	No	Same
Trip?	overioud			Same
<u> </u>	No-Load	No	No	Same
Trip?	Louid			Buille
	Shut Off?	Yes	Yes	Same
User	Override	Yes	Yes	Same
Control?				
Indicato	On/Off	Yes	Yes	Same
r	Status?			
Display	Low	Yes	Yes	Same
	Battery?			
	Voltage/	Yes	Yes	Same
	Current			
	Level?			
Timer	Range	60 minutes	10 ~ 60 minutes, 10 min./step	Similar
(minutes)		X7		Note 2
Complian		Yes.	Yes.	Same
Voluntary		AAMI/ANSI ES60601-1, IEC	AAMI/ANSI ES60601-1, IEC	
Standards	?	60601-1-2, IEC 60601-2-10, IEC	60601-1-2, IEC 60601-2-10, IEC	
C 1'		62133, HA 60601-1-11	62133, IEC 60601-1-11	Const
Complian CFR 8988	ce with 21	Yes	Yes	Same
Weight (g		100g±5g	140g	Similar
Dimensio		58mm*180mm*15.5mm	83*42*9mm	Note 1
[W x H x	( /	58mm <sup>+</sup> 180mm <sup>+</sup> 15.5mm	83.42.91111	Note 1
-	Materials &	ABS	ABS	Same
Construct		ADS	ADS	Same
Waveforn		Pulsed, symmetric, biphasic	Pulsed, symmetric, biphasic	Same
Shape	1	Rectangle	Rectangle	Same
Maximum	o Output	54V±20% @500Ω	$42V\pm10\%$ @500 $\Omega$	Similar
Voltage (v	1	517 ±2070 @30022	12 1 10/0 (0 30022	Note 3
Maximum		108mA±20% @500Ω	84mA±10% @500Ω	11000 5
Current	(specify			
units)	(~1)			
Pulse wid	th (µsec)	200-210µs	100µs	
	od (msec)	20.4-620ms	9.3~850ms	
Max.	pulse	1.613-49.02Hz	110Hz	
frequency				
Rate (pps)				
	ge (µC per	$0\mu C$ @500 $\Omega$ ; Method: Balanced	$0\mu C$ @500 $\Omega$ ; Method: Balanced	Same
pulse)	_	waveform	waveform	
Maximum	hase			Similar
Charge, (µ		17μC@500Ω	16.8μC @500Ω	Similar
Maximun		1.88mA	0.924mA	Similar
Current, (		1.001111		Note 4
Maximum		$0.08$ mA/cm <sup>2</sup> @500 $\Omega$	0.462mA/cm <sup>2</sup>	
Density,	(mA/cm <sup>2</sup> ,	S.S.S.M. J. CHI. (0.5002E		
r.m.s.)	(			
Maximum	Average	3.65mW/cm <sup>2</sup> @,500Ω	9.702mW/cm <sup>2</sup>	
Power	Density,			
(mW/cm <sup>2</sup> )	/			

4F, Jingcheng Building, Xicheng Industrial Zone, Xixiang Road, Bao'an District, Shenzhen City, Guangdong, China 518126

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

# Comparison in details:

#### <u>Note 1:</u>

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.

#### <u>Note 2:</u>

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.

#### <u>Note 3:</u>

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.

#### <u>Note 4:</u>

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 1	Device	Predicate		New Device			
Mode or program	n name	Program 1	Program 3	Program 4	Program 5	Program 6	Program 21	Mode 3	Program 2	Program 7	Program 8
Waveform		Biphasic									
Shape		Rectangular									
Maximum	@500Ω	34.4	42	34.4	34.4	40.8	40.8	42	38.4	33.6	33.6
Output Voltage	@2kΩ	58.4	83	58.4	58.4	70	70	84	65.2	56.8	56.8
(V)	@10kΩ	107	144	107	107	123	123	130	117	104	104
Maximum	@500Ω	68.8	84	68.8	68.8	81.6	81.6	84	76.8	67.2	67.2
Output Current	@2kΩ	29.2	41.5	29.2	29.2	35	35	42	32.6	28.4	28.4
(mA)	@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:		N/A									
-Beat Frequency	(Hz)										
For multiphasic waveforms	Symmetrical phases	Yes									
only:	Phase duration	190	190	190	190	190	190	100	190	190	190
Net Charge (@50	)0Ω) [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 <sup>2</sup> )		0.052	0.004	0.05	0.054	0.02	0.065	0.0049	0.0116	0.051	0.051
Maximum Po (mW/cm <sup>2</sup> )	wer Density,	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	17	79	49						

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

	(b) Bursts per second	NA	0.196	0.164	0.327						
	(c) Burst	NA	3.52	3.3	2.05						
	duration										
	(seconds)										
	(d) Duty	NA	0.69	0.54	0.67						
	Cycle: Line										
	(b) x Line (c)										
ON Time (second	ds)	NA	3.52	3.3	2.05						
OFF Time (secon	nds)	NA	1.58	2.79	1						
Additional Featu	res	N/A	N/A	N/A	N/A	NA	NA	N/A	N/A	N/A	N/A
Continue											
Parameter		New device	Predicate				New 1	Device			
Mode or program nameProgram 14Mode 2				Program 9	Program 10	Program 11	Program 12	Program 13	Program 15	Program 16	Program 17
Waveform		Biphasic									
Shape		Rectangular									
Maximum	@500Ω	32.8	42	34.8	34.8	34.4	34.4	34.4	34.4	34.4	34.4
Output Voltage	@2kΩ	56	84	58.8	58.8	58.4	58.4	58.4	58.4	58.4	58.4
(V)	@10kΩ	103	130	107	107	107	107	107	107	107	107
Maximum	@500Ω	65.6	84	69.6	69.6	68.8	68.8	68.8	68.8	68.8	68.8
Output Current	@2kΩ	28	42	29.4	29.4	29.2	29.2	29.2	29.2	29.2	29.2
(mA)	@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: N/A N/.		N/A									
Beat Frequency (	(Hz)										
For multiphasic	Symmetrical	Yes									
waveforms	phases										

Hong Qiangxing(Shen Zhen) Electronics Limited

Shape

Maximum

Output Voltage

@500Ω

(a)2k $\Omega$ 

4F, Jingcheng Building,	Xicheng Industrial Zone,	Xixiang Road, Bao'an District, S	Shenzhen City, Guangdong, China 518126

Rectangular

34.4

58.4

Rectangular

34.4

58.4

Rectangular

34.4

58.4

Rectangular

38

58.4

Rectangular

34.4

58.4

Rectangular

34.4

58.4

41, Jingeneng Dunu	ing, Meneng maasa	iai Zone, Mixiang Roa	u, Dao an D	istrict, oner	izhen eny, oddinge	iong, cinia 510120							
only:	Phase	190 10	0	190	190	190	190	190	190	) 190		190	
	Duration												
Net Charge (@50	00Ω) [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 11.5	5	11.65	
	irrent Density	0.052 0.	2331	0.055	0.053	0.054	0.052	0.053	0.0	54 0.05	2	0.054	
(mA/cm <sup>2</sup> )													
Maximum Po (mW/cm <sup>2</sup> )	ower Density,	1.70 4.	395	1.92	1.83	1.87	1.78	1.83	1.8	7 1.8		1.87	
Burst Mode	(a) Pulses per burst	130 25	0~1110	291	129	124	218	161	76.:	5 149		291	
	(b) Bursts per second	0.124 0.	)48	0.067	0.133	0.167	0.083	0.116	0.24	45 0.13	9	0.067	
(c) durati (secon (d) Cycle	(c) Burst duration (seconds)	5.18 20		11.62	5.4	4.96	9.14	6.62	3.0	6 6.2		11.64	
	(d)DutyCycle:Line(b) x Line (c)	0.64 0.	96	0.78	0.72	0.83	0.76	0.77	0.7:	5 0.86	i	0.78	
ON Time (second	ds)	5.18 20		11.62	5.4	4.96	9.14	6.62	3.0	6 6.2		11.64	
OFF Time (secon	nds)	2.94 1		3.24	2.12	1	2.96	1.97	1	1		3.26	
Additional Featu	res	N/A N	A	N/A	N/A	N/A	N/A	N/A	N/A	A N/A		N/A	
Continue													
Parameter						New	v Device				Pred	icated Devic	
Mode or program	n name		Progra	um 18	Program 19	Program 20	Program 22	Program	n 23	Program 24	Mode	e 1	
Waveform			Bipha	sic	Biphasic	Biphasic	Biphasic	Biphasi	c	Biphasic	Bipha	Biphasic	
											-		

Rectangular

42

84

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

H, Jingeneng Dunun	ing, Archeng muusunai Zone, Arxiang Roau, i	Dao an District, Sile	inzhen eny, Ouangue	ng, china 510120				
(V)	@10kΩ	107	107	107	115	107	107	130
Maximum	@500Ω	68.8	68.8	68.8	76	68.8	68.8	84
Output	@2kΩ	29.2	29.2	29.2	29.2	29.2	29.2	42
Current(mA)	Current(mA) $@10k\Omega$		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:	N/A	N/A	N/A	N/A	N/A	N/A	N/A
-Beat Frequency (	(Hz)							
For multiphasic	Symmetrical phases	Yes	Yes	Yes	Yes	Yes	Yes	Yes
waveforms	aveforms Phase Duration		190	190	190	190	190	100
only:								
Net Charge (@50	0Ω) [uC]	0	0	0	0	0	0	0
Maximum Phase C	harge (uC)	11.32	11.40	11.55	12.29	11.06	11.59	16.8
Maximum Curren	t Density (mA/cm <sup>2</sup> )	0.053	0.053	0.052	0.06	0.052	0.052	0.2856
Maximum Power	Density, (mW/cm <sup>2</sup> )	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)		5.17	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 (second	ls)	5.76	5.17	8.66	7.14	16.98	17.44	3
OFF Time (secon	ds)	1.52	1	1.96	3.02	5.41	4.78	1.56
Additional Featur	es (specify, if applicable)	N/A	N/A	N/A	N/A	N/A	N/A	N/A

# Table 6-SM 9126

Parameter			New I	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									
Shape	Rectangular									

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

41, Jingeneng Dunu	ing, meneng muusu	iui Zone, Mixiang	, Dao an D	istrict, Shelizhen	City, Guanguong	0111110120					
Maximum	@500Ω	30.8	30.4	30.8	30.8	30.8	30.8	42	41.2	30.4	4.6
Output Voltage	@2kΩ	84	72.4	84	84	84	84	84	113	72.4	15.6
(V)	@10kΩ	159	124	159	159	159	159	130	163	123	24
Maximum	@500Ω	61.6	60.8	61.6	61.6	61.6	61.6	84	82.4	60.8	9.2
Output Current	@2kΩ	42	36.2	42	42	42	42	42	56.5	36.2	7.8
(mA)	@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 -Beat Frequency		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	220	220	220	220	220	220	100	220	220	220
Net Charge (@50	)0Ω) [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 Cur (mA/cm <sup>2</sup> )	rrent Density	0.117	0.091	0.093	0.093	0.094	0.119	0.2856	0.03	0.09	0.019
Maximum Pov (mW/cm <sup>2</sup> )	wer Density,	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 (second	ls)	4.07	12.7	6.21	3.09	12.48	4.1	3	3.72	3.87	7	8.5
OFF Time (secon	ds)	1.68	3.52	2.3	1.28	3.52	1.66	1.56	1.84	34 2.98		1.7
Additional Featur	es	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	1	N/A
Continue												
Parameter		Predicate				New Devi	ce				Predic	ate
Mode or program	name	Mode 2	Program 3	Program 4	Program 5	Program 6	Program 1	1 Program	n 12 Progra	am 16	Mode 3	3
Waveform		Biphasic	Biphasic	Biphasic	Biphasic	Biphasic	Biphasic	Biphasi	c Bipha	sic	Biphas	ic
Shape		Rectangular	Rectangular	Rectangular	Rectangular	Rectangular	r Rectangul	ar Rectang	ular Rectar	ngular	Rectan	gular
Maximum	@500Ω	42	46.4	30.8	28.8	37.6	4.6	11	4.6		42	
Output Voltage	@2kΩ	84	126	84	68	100	15.6	20.8	15.6		84	
(V)	@10kΩ	130	161	159	119	153	24	37.2	24		130	
Maximum	@500Ω	84	92.8	61.6	57.6	75.2	9.2	22	9.2		84	
Output Current	@2kΩ	42	63	42	34	50	7.8	10.4	7.8		42	
(mA)	@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 Beat Frequency (	2	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	
only:	Phase Duration	100	220	220	220	220	220	220	220		100	
Net Charge (@50	0Ω) [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 Cu (mA/cm <sup>2</sup> )	rrent Density	0.2331	0.005	0.093	0.078	0.037	0.072	0.092	0.019		0.0049	

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

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

Maximum Por	wer Density,	4.895	0.23	2.85	2.25	1.4	0.33	1.01	0.09	0.103
(mW/cm <sup>2</sup> )										
Burst Mode	(a) Pulses per	250~1110	NA	NA	NA	NA	NA	NA	NA	NA
	burst									
	(b) Bursts per	0.048	NA	NA	NA	NA	NA	NA	NA	NA
	second									
	(c) Burst	20	NA	NA	NA	NA	NA	NA	NA	NA
	duration									
	(seconds)									
	(d) Duty	0.96	NA	NA	NA	NA	NA	NA	NA	NA
	Cycle: Line									
	(b) x Line (c)									
ON Time (second	ls)	20	NA	NA	NA	NA	NA	NA	NA	NA
OFF Time (seconds)		1	NA	NA	NA	NA	NA	NA	NA	NA
Additional Featur	res	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 prog	gram name	Program 1	Program 6	Program 9	Program 12	Mode 1	Program 2	Program 5	Program 10	Mode 2	Program 3
Waveform		Biphasic									
Shape		Rectangular									
Maximum	@500Ω	43.8	48	38.4	42.4	42	43.8	36.8	7	42	63
Output	@2kΩ	57	74	59.6	76	84	81	66	13.1	84	116
Voltage (V)	@10kΩ	142	156	109	152	130	149	126	24.2	130	149
Maximum	@500Ω	87.6	96	76.8	84.8	84	87.6	73.6	14	84	126
Output	@2kΩ	28.5	37	29.8	38	42	40.5	33	6.55	42	58
Current	@10kΩ	14.2	15.6	10.9	15.2	13	14.9	12.6	2.42	13	14.9
(mA)											

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

<u>, tu geneng z</u>	<u></u>		intering reduce, 200		<u>, ouunguon</u>	, 0111110120		T	1		
Pulse Width(	us)	220	220	230	220µs	100	220	220	230	100	224
Frequency (H	[z)	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 interfer	ential modes	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
only:											
-Beat Freque	ncy (Hz)										
For	Symmetrical	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
multiphasic	phases										
waveforms	Phase	220	220	230	220	100	220	220	230	100	224
only:	duration										
Net Charge ((	@500Ω) [uC]	0	0	0	0	0	0	0	0	0	0
Maximum Ph	ase Charge	16.7	14.5	14.5	15.2	16.8	16.7	15.1	2.6	16.8	25.07
(uC)											
Maximum Cu	rrent Density	0.19	0.21	0.17	0.185	0.2856	0.17	0.25	0.084	0.2331	0.005
(mA/cm <sup>2</sup> )											
Maximum Po	wer Density,	8.28	9.94	6.65	7.85	5.998	7.4	9.2	0.58	4.895	0.33
(mW/cm <sup>2</sup> )											
Burst Mode	(a) Pulses	212	1200	711	333	204	2253	1639	1556	250~1110	N/A
	per burst										
	(b) Bursts	0.186	0.034	0.064	0.125	0.219	0.023	0.04	0.085	0.048	N/A
	per second										
	(c) Burst	3.6	20.4	12.08	5.6	3	42.8	17.7	10	20	N/A
	duration										
	(seconds)										
	(d) Duty	0.67	0.7	0.77	0.7	0.66	0.98	0.73	0.85	0.96	N/A
	Cycle: Line										
	(b) x Line										
	(c)										
ON Time (see	conds)	3.6	20.4	12.08	5.6	3	42.8	17.7	10	20	N/A

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

OFF Time (seconds)	1.	.8	8.6	3.6	2	.4	1.56	1		6.5	1.76	1	1 N/A	
Additional Features	Ν	I/A	N/A	N/A	N	J/A	N/A	N/A	A	N/A	N/A	N	J/A	N/A
Continue														
Parameter								New	Device				Predicate	
Mode or program nam	ne				Program	4	Program 7	Program 7		n 8	Program 11		Mode 3	
Waveform					Biphasic		Biphasic		Biphasi	с	Biphasic		Biphasic	
Shape	Shape					ılar	Rectangular		Rectang	gular	Rectangular		Rectange	ılar
Maximum Output @500Ω					43.8		59		68		26.8		42	
Voltage (V)				66		94		117		44		84		
	@10kΩ				128		168		174		80		130	
Maximum Output	@500Ω	1			76		118		136		53.6		84	
Current(mA)	@2kΩ				33		47		58.5		22		42	
	@10kΩ	1			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	2.59	92.59		1.17	
For interferential mod	es only: -I	Beat Freque	ncy (Hz)		N/A		N/A		N/A		N/A		N/A	
For multiphasic	Symmet	trical phases	6		Yes		Yes		Yes		Yes		Yes	
waveforms only:	Phase D	ouration			220		220		220		220		100	
Net Charge (@500 $\Omega$ )	[uC]				0		0		0		0		0	
Maximum Phase Char	rge (uC)				16.72		21.5		26		9.8		16.8	
Maximum Current De	ensity (mA	/cm²)			0.258		0.26		0.46		0.182		0.0049	
Maximum Power Den	sity, (mW	//cm²)			9.8		15.19		31.4		4.88		0.103	
Burst Mode	(a) Pulse	es per burst			N/A		N/A		N/A		N/A		N/A	
	(b) Burs	sts per secon	ıd		N/A		N/A		N/A		N/A		N/A	
	(c) Burs	t duration (s	seconds)		N/A		N/A		N/A		N/A		N/A	
(d) Duty Cycle: Line (b) x Line (c		(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)	DFF Time (seconds)						N/A		N/A		N/A		N/A	

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

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

## Table 8-SM 9196

Parameter				New I	Device			Predicate	New Device		
Mode or program	n name	Program 1	Program 2	Program 3	Program 4	Program 6	Program7	Mode 1	Program 5	Program 8	Program 9
Waveform		Biphasic									
Shape		Rectangular									
Maximum	@500Ω	49.2	48	48	42.8	48	47.2	42	46	52.4	50
Output Voltage	@2kΩ	73.6	73.6	74	72.8	74.4	72.8	84	71.6	78.8	101
(V)	@10kΩ	118	124	123	120	120	120	130	119	129	133
Maximum	@500Ω	98.4	96	96	85.6	96	94.4	84	92	104.8	100
Output Current	@2kΩ	36.8	36.8	37	36.4	37.2	36.4	42	35.8	39.4	50.5
(mA)	@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 -Beat Frequency	•	N/A									
For multiphasic waveforms	Symmetrical phases	Yes									
only:	Phase duration	200	200	200	200	200	200	100	200	200	210
Net Charge (@50	)0Ω) [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 Cu (mA/cm <sup>2</sup> )	rrent Density	0.07	0.07	0.073	0.07	0.08	0.07	0.2856	0.07	0.02	0.0027
Maximum Po (mW/cm <sup>2</sup> )	wer Density,	3.65	3.51	3.48	2.82	3.61	3.43	5.998	3.26	0.83	0.14

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

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)DutyCycle: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 (second	ds)	5.44	5	9.2	6.3	3.1	3.6	3	5.18	3.54	4.8
OFF Time (secon	nds)	2.14	1.02	3	2	1	1.5	1.56	3s	1.62	1.5
Additional Featu	res	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A

## Continue

Parameter		Predicate			New I	Device			Predicate
Mode or program	m name	Mode 2	Program 10	Program 11	Program 12	Program 13	Program 14	Program 15	Mode 3
Waveform		Biphasic							
Shape		Rectangular							
Maximum	@500Ω	42	45.6	46	54	47.2	46.4	46	42
Output	@2kΩ	84	72	72	87.6	73.6	70.4	73.6	84
Voltage (V)	@10kΩ	130	112	118	131	119	117	124	130
Maximum	@500Ω	84	91.2	92	108	94.4	92.8	92	84
Output	@2kΩ	42	36	36	43.8	36.8	35.2	36.8	42
Current(mA)	@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 interferentia	For interferential modes only: -Beat Frequency		N/A						
(Hz)									

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

For	Symmetrical phases	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
multiphasic	Phase Duration	100	210	200	200	200	200	210	100
waveforms									
only:									
Net Charge (@5	500Ω) [uC]	0	0	0	0	0	0	0	0
Maximum Phas	e Charge (uC)	16.8	13.6	14.6	17.0	14.8	14.9	15.9	16.8
Maximum Curre	ent Density (mA/cm <sup>2</sup> )	0.2331	0.08	0.07	0.03	0.07	0.07	0.07	0.0049
Maximum Powe	er Density, (mW/cm <sup>2</sup> )	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						
	(b) Bursts per second	0.048	N/A						
	(c) Burst duration (seconds)	20	N/A						
	(d) Duty Cycle: Line (b) x Line	0.96	N/A						
	(c)								
ON Time (secon	ON Time (seconds)		N/A						
OFF Time (seco	OFF Time (seconds)		N/A						
Additional Features (specify, if applicable)		N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A

4F, Jingcheng Building, Xicheng Industrial Zone, Xixiang Road, Bao'an District, Shenzhen City, Guangdong, China 518126 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.