June 18, 2020

Shenzhen As Tec Technology Co., Ltd
% Doris Dong
Manager
Shanghai CV Technology Co., Ltd
Room 903, No. 19 Dongbao Road, Songjiang Area
Shanghai, China 201613

Re: K200727
Trade/Device Name: TENS and Muscle Stimulator
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator For Pain Relief
Regulatory Class: Class II
Product Code: NUH, NGX
Dated: March 10, 2020
Received: March 20, 2020

Dear Ms. 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,

Pamela Scott
Assistant Director
DHT5B: Division of Neuromodulation
and Physical Medicine Devices
OHT5: Office of Neurological
and Physical Medicine Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200727

Device Name
TENS and Muscle Stimulator (Model AS8012 & AS8015)

Indications for Use *(Describe)*

TENS (Transcutaneous Electric Nerve Stimulation):
To be used for temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back, upper extremities (arm), and lower extremities (leg) due to strain from exercise or normal household work activities.

PMS (Powered Muscle Stimulation):
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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510(k) Summary

[As required by 21 CFR 807.92]

1. Submission Information:

510(k) Number:	K200727
Date:	December 27, 2019
Type of 510(k) Submission:	Traditional
Basis for 510(k) Submission:	New device
Submitter/Manufacturer:	Shenzhen As-Tec Technology Co., Ltd. 8E XinBaoYi Industrial Bld, Houting Village Beiting Road, Shajing Shenzhen Guangdong, CHINA 518012
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 and Muscle Stimulator (Model AS8012, AS8015)
Common Name:	TENS & PMS
Classification Name:	Stimulator, nerve, transcutaneous, over-the-counter, Stimulator, muscle, powered, for muscle conditioning
Regulation Number:	882.5890, 890.5850
Product Code:	NUH, NGX
Device Class:	II
Review Panel:	Neurology & Physical Medicine
Device Description:	TENS and Muscle Stimulator is a portable and DC 3.7V battery powered multifunction device, offering both Transcutaneous Electrical Nerve Stimulation (TENS) and Powered Muscle Stimulation (PMS) qualities in one device. TENS and Muscle Stimulator can give certain electrical pulses through electrode adhesive pads to the suggested area of the body where the electrodes are placed. AS8012 has 20 operation programs and AS8015 has 24 operation programs. The electronic stimulatory module has the operating elements of an On/Off Switch, LCD display screen, Intensity buttons, Output channel buttons, T button, Output ports, and USB port for battery charging,etc. The LCD display screen can show time remaining of an application program, battery power, program icons, output channel and intensity,etc. 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:	***TENS(Transcutaneous Electric Nerve Stimulation):*** To be used for temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back, upper extremities (arm), and lower extremities (leg) due to strain from exercise or normal household work activities. ***PMS(Powered Muscle Stimulation):*** It is intended to be used to stimulate healthy muscles in order to improve and facilitate muscle performance.

3. Substantial Equivalence to Predicate device:

Detailed comparison data is included in "Section 10.1 - Substantial Equivalence Discussion" of this 510(k) submission.

Table 1 -

Parameters		**New Device**	**Predicate Device**	**Same/Different**
1.	510(k) Number	Unassigned	K143268	
2.	Marketing clearance date	/	07/21/2015	
3.	Device Name	TENS and Muscle Stimulator	TENS AND POWERED MUSCLE STIMULATOR	
4.	Model	AS8012	N/A	
5.	Manufacturer	Shenzhen As-Tec Technology Co., Ltd.	Shenzhen As-Tec Technology Co., Ltd.	SE
6.	Intended use	TENS (Program 3, 4, 8, 9,12, 13, 14, 15, 17, 18, 19, 20): To be used for temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back, upper extremities (arm), and lower extremities (leg) due to strain from exercise or normal household work activities. PMS (Program 1, 2, 5, 6, 7, 10, 11, 16): It is intended to be used to stimulate healthy muscles in order to improve and facilitate muscle performance.	TENS (Mode 1, 3, 4, 5, 6): To be used for temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back, upper extremities (arm), and lower extremities (leg) due to strain from exercise or normal household work activities. PMS (Mode 1, 2, 3, 5): It is intended to be used to stimulate healthy muscles in order to improve and facilitate muscle performance.	Same Note 1
7.	Type of use	OTC	OTC	Same
7.8.	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)	-- 0.1μA 0.1μA	-- 0.1μA 0.1μA	Same
9.	Average DC current through electrodes when device is on	< 0.01μA	< 0.01μA	Same

	but no pulses are being applied (μA)				
10.	Number of Output Modes		20	6	Same Note 1
11.	Number of Output channels:		2	2	Same
	- Synchronous or Alternating?		Alternating	Synchronous	Same Note 2
	- Method of Channel Isolation		Voltage transformer Isolation	Voltage transformer Isolation	Same
12.	Regulated Current or Regulated Voltage?		Voltage control	Voltage control	Same
13.	Software/Firmware/ Microprocessor Control?		Software	Software	Same
14.	Automatic Overload Trip?		No	No	Same
15.	Automatic No-Load Trip?		Yes	No	Same Note 2
16.	Automatic Shut Off?		Yes	Yes	Same
17.	User Override Control?		Yes	Yes	Same
18.	Indicator Display	On/Off Status?	Yes	Yes	Same
		Low Battery?	Yes	Yes	Same
		Voltage/ Current Level?	Yes	Yes	Same
19.	Timer Range (minutes)		10 ~ 60 minutes, 10 min/step	10 ~ 60 minutes, 10 min/step	Same
20.	Compliance with Voluntary Standards?		Yes. AAMI/ANSI ES 60601-1, IEC 60601-1-2, IEC 60601-2-10, IEC 62133, IEC 60601-1-11	Yes. AAMI/ANSI ES60601-1, IEC 60601-1-2, IEC 60601-2-10, IEC 62133, IEC 60601-1-11	Same
21.	Compliance with 21 CFR 8988?		Yes	Yes	Same
22.	Weight (grams)		72g	170g	Same Note 1
23.	Dimensions (mm) [W x H x D]		55.4*103*12mm	93*50*9mm	
24.	Housing Materials & Construction		ABS+Stainless iron	ABS	

25.	Waveform	Pulsed, symmetric, biphasic	Pulsed, symmetric, biphasic	Same
26.	Shape	Rectangular, with interphase interval	Rectangular, with interphase interval	Same
27.	Maximum Output Voltage (volts)	49.6V±20% @500Ω	53.5V±20% @500Ω	Same Note 3
		90V±20% @2kΩ	67V±20% @2kΩ	
		120V±20% @10kΩ	68V±20% @10kΩ	
28.	Maximum Output Current (specify units)	99.2mA±20% @500Ω	107mA±20% @500Ω	
		45mA±20% @2kΩ	33.5mA±20% @2kΩ	
		12mA±20% @10kΩ	6.8±20% @10kΩ	
29.	Pulse width (μsec)	Positive phase: 80μs±10% Negative phase: 80μs±10% Interphase interval: 80μs±10%	Positive phase: 225μs Negative phase: 225μs Interphase interval: 225μs	
30.	Pulse Period (msec)	10-1000ms	8.9~617ms	
31.	Pulse frequency (Hz) [or Rate (pps)]	1-100Hz±10%	1.62Hz~113Hz	
32.	Net Charge (μC per pulse)	0μC @500Ω; Method: Balanced waveform	0μC @500Ω; Method: Balanced waveform	Same
33.	Maximum Phase Charge, (μC)	15.87μC@500Ω	48μC @500Ω	Same Note 4
34.	Maximum Average Current, (mA)	0.793mA@500Ω	2.72mA @500Ω	
35.	Maximum Current Density, (mA/cm², r.m.s.)	0.06mA/cm^2 @500Ω (Smallest electrode area 25cm^2)	1.36mA/cm^2 (Smallest electrode area 4cm^2)	
36.	Maximum Average Power Density, (mW/cm²)	1.57mW/cm^2 @500Ω (Smallest electrode area 25cm^2)	36.4mW/cm^2 (Smallest electrode area 4cm^2)	
37.	Battery charge	① The Lithium battery can be recharged through both AC adaptor and computer USB input. ② When charging is finished, the LCD will show full cell of battery.	① The Lithium battery can be recharged through both AC adaptor and computer USB input. ② When charging is finished, the LCD will show full cell of battery.	Same
38.	Accessories	Self-adhesive electrodes, electrode wires, Battery charger, USB cable	Self-adhesive electrodes, electrode wires, Battery charger, USB cable	Same

Differences between proposed device and predicate device:

Note 1:

The proposed device AS8012 has more treatment programs than the predicate device K143268, but all of the treatment programs have passed the IEC 60601-2-10 test codes. So this difference doesn't raise any safety or effectiveness issue. And the weight, dimensions, housing material, appearance of proposed device AS8012 are a little different from predicate device K143268. Consider the same intended use, components, working principle, test standards, these differences are insignificant in the terms of safety or effectiveness.

Note 2:

The output two 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.

The proposed device has automatic no-Load trip function and the predicate device doesn't have. This function makes the proposed device has no output current when it is not connected to the human body. It is a safety protection function so this difference doesn't raise any new safety and effectiveness issues.

Also, the proposed device had passed AAMI / ANSI ES60601-1 and IEC 60601-2-10 test codes, so these differences don'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 width 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. And these parameters have passed IEC 60601-2-10 test codes. So these differences don't raise any new safety and effectiveness issues.

Note 4:

The maximum phase charge of the proposed device (15.87μC@500Ω) is less than the predicate device (48μC @500Ω), but the cleared device K121719, which is the predicate device of K143268, has the maximum phase charge of 16.8μC@500Ω. The value of the proposed device is similar to that of the 510K clearance device K121719, therefore this difference doesn't raise any new safety and effectiveness issues.

The maximum average current, 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 don't raise any new safety and effectiveness issues.

The burst mode, on time and off time between proposed device and predicate device are little different. Because each program of proposed device is compared to the predicate's modes, and they adopt similar treatment effect. The TENS programs of proposed device are compared to the predicate's TENS modes, the PMS programs of proposed device are compared to the predicate's PMS modes. Also, all programs have passed AAMI/ANSI ES 60601-1 and IEC 60601-2-10 test codes. Therefore these differences don't raise any new safety and effectiveness issues.

Detailed comparison data is included in "Section 10.2 - Substantial Equivalence Discussion" of this 510(k) submission.

Table 2 -

Parameters		**New Device**	**Predicate Device**	**Same/Different**
1.	510(k) Number	Unassigned	K190115	
2.	Marketing clearance date	/	06/19/2019	
3.	Device Name	TENS AND POWERED MUSCLE STIMULATOR	MHD TENS	
4.	Model	AS8015	MH-1085	
5.	Manufacturer	Shenzhen As-Tec Technology Co.,	MingHuangDa	

		Ltd.	Electronic Co.,Ltd	
6.	Intended use	TENS (Program 1, 4, 7, 10, 14, 15, 20, 23, 24): To be used for temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back, upper extremities (arm), and lower extremities (leg) due to strain from exercise or normal household work activities. PMS (Program 2, 3, 5, 6, 8, 9, 11, 12, 13, 16, 17, 18, 19, 21, 22): It is intended to be used to stimulate healthy muscles in order to improve and facilitate muscle performance.	TENS (Program 2, 3, 4, 6, 8, 9): To be used for temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back, upper extremities (arm), and lower extremities (leg) due to strain from exercise or normal household work activities. PMS (Program 1, 5, 7, 10, 11, 12): It is intended to be used to stimulate healthy muscles in order to improve and facilitate muscle performance.	Same Note 1
7.	Type of use	OTC	OTC	Same
8.	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
9.	Average DC current through electrodes when device is on but no pulses are being applied (μA)	< 0.01μA	< 0.01μA	Same
10.	Number of Output Modes	24	12	Same Note 1
10.	Number of Output channels:	2	2	Same
	- Synchronous	Alternating	Alternating	Same

	or Alternating?				
	- Method of Channel Isolation		Voltage transformer Isolation	Voltage transformer Isolation	Same
12.	Regulated Current or Regulated Voltage?		Regulated Voltage	Regulated current	Same
13.	Software/Firmware /Microprocessor Control?		Software	Software	Same
14.	Automatic Overload Trip?		No	No	Same
15.	Automatic No-Load Trip?		Yes	No	Same Note 2
16.	Automatic Shut Off?		Yes	Yes	Same
17.	User Override Control?		Yes	Yes	Same
17.	Indicator Display	On/Off Status	Yes	Yes	Same
		Low Battery	Yes	Yes	Same
		Voltage /Current Level	Yes	Yes	Same
19.	Timer Range (minutes)		10 ~ 60 minutes, 10 min/step	10 ~ 60 minutes, 10 min/step	Same
20.	Compliance with Voluntary Standards?		Yes. AAMI/ANSI ES 60601-1, IEC 60601-1-2, IEC 60601-2-10, IEC 62133, IEC 60601-1-11	Yes. AAMI/ANSI ES 60601-1, IEC 60601-1-2, IEC 60601-2-10, IEC 62133, IEC 60601-1-11	Same
21.	Compliance with 21 CFR 8988?		Yes	Yes	Same
22.	Weight (grams)		110g	110g	Same
23.	Dimensions (mm) [W x H x D]		66.1*129.2*11mm	132.8*65.8*13.8mm	Same Note 1
24.	Housing Materials & Construction		ABS+aluminium alloy	ABS+aluminium alloy	Same
25.	Waveform		Pulsed, symmetric, biphasic	Pulsed, symmetric, biphasic	Same
26.	Shape		Rectangular, with interphase interval	Rectangular, with interphase interval	Same
26.	Maximum Output		63V±15% @500Ω	78V±15% @500Ω	Same

	Voltage (volts)	110V±15% @2kΩ	153V±15% @2kΩ	Note 3
		136V±15% @10kΩ	161V±15% @10kΩ	
27.	Maximum Output Current (specify units)	126mA±15% @500Ω	156mA±15% @500Ω	
		55mA±15% @2kΩ	76.5mA±15% @2kΩ	
		13.6mA±15% @10kΩ	16.1mA±15% @10kΩ	
29.	Pulse width (μsec)	Positive phase: 100μs±10% Negative phase: 100μs±10% Interphase interval: 100μs±10%	Positive phase: 78μs±10% Negative phase: 78μs±10% Interphase interval: 70μs±10%	
30.	Pulse Period (msec)	7.6-833ms	14.3~1000ms	
31.	Max. pulse frequency (Hz) [or Rate (pps)]	1.2-132Hz±10%	1~70Hz	
32.	Net Charge (μC per pulse)	0μC @500Ω; Method: Balanced waveform	0μC @500Ω; Method: Balanced waveform	Same
33.	Maximum Phase Charge, (μC)	25.2μC@500Ω	24.3μC@500Ω	Same Note 4
34.	Maximum Average Current, (mA)	1.67mA@500Ω	0.852mA@500Ω	
35.	Maximum Current Density, (mA/cm², r.m.s.)	0.13mA/cm^2 @500Ω (Smallest electrode area 25cm^2)	0.142mA/cm^2 @500Ω(Smallest electrode area 12cm^2)	
36.	Maximum Average Power Density, (mW/cm²)	4.19mW/cm^2 @500Ω (Smallest electrode area 25cm^2)	5.54mW/cm^2 @500Ω (Smallest electrode area 12cm^2)	
37.	Battery charge	① The Lithium battery can be recharged through both AC adaptor and computer USB input. ② When charging is finished, the LCD will show full cell of battery.	① The Lithium battery can be recharged through both AC adaptor and computer USB input. ② When charging is finished, the LCD will show full cell of battery.	Same
38.	Accessories	Self-adhesive electrodes, electrode wires, Battery charger, USB cable	Self-adhesive electrodes, electrode wires, Battery charger, USB cable, Screen stylus	Same Note 1

Differences between proposed device and predicate device:

Note 1:

The proposed device AS8015 has more treatment programs than the predicate device K190115, but all of the

treatment programs have passed the IEC 60601-2-10 test codes. So this difference will not raise any safety or effectiveness issue. And the dimensions, appearance of proposed device AS8015 are a little different from predicate device K190115. Consider the same intended use, components, working principle, test standards, these differences are insignificant in the terms of safety or effectiveness. The accessories of AS8015 are a little different from K190115 because AS8015 doesn't have screen stylus. Both of them are touchable LCD, the screen stylus can be replaced by fingers. So this difference doesn't affect the product functionally or raise any safety and effectiveness issues.

Note 2:

The proposed device has automatic no-Load trip function and the predicate device doesn't have. This function makes the proposed device has no output current when it is not connected to the human body. It is a safety protection function so this difference doesn't raise any new safety and effectiveness issues.
Also, the proposed device had passed AAMI / ANSI ES60601-1 and IEC 60601-2-10 test codes, so this difference doesn'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 width 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. And these parameters have passed IEC 60601-2-10 test codes. So these differences don't raise any new safety and effectiveness issues.

Note 4:

The maximum phase charge of the proposed device (25.2μC@500Ω) is very similar to the predicate device (24.3μC@500Ω), therefore this difference won't raise any new safety and effectiveness issues.

The maximum average current, 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 don't raise any new safety and effectiveness issues.

The burst mode, on time and off time between proposed device and predicate device are little different. Because each program of proposed device is compared to the predicate's programs, and they adopt similar treatment effect. The TENS programs of proposed device are compared to the predicate's TENS programs, PMS programs are compared to the predicate's PMS programs. Also, all programs have passed AAMI/ANSI ES 60601-1 and IEC 60601-2-10 test codes. Therefore these differences don't raise any new safety and effectiveness issues.

4. Safety and Effectiveness of the device:

TENS and Muscle Stimulator (AS8012, AS8015) are safe and effective as the predicate devices cited above. The new devices have passed testing according to the safety 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 62133-2 Edition1.0 2017-02 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 - Part 2: Lithium Systems
5) IEC 60601-1-11 Edition 2.0 2015-01, Medical Electrical Equipment - Part 1-11: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Requirements For Medical Electrical Equipment And Medical Electrical Systems Used In The Home Healthcare Environment . (General II (ES/EMC))

The conclusion drawn from the safety testing is that the new devices are substantially equivalent to the predicate devices. Furthermore, the new devices comply with the recognized standards and perform its intended tasks as well as the legally marketed predicate devices.