December 2, 2019

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

Re: K190009
Trade/Device Name: Sunmas TENS & PMS (Model SM9187, SM9180L, SM9180S)
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator For Pain Relief
Regulatory Class: Class II
Product Code: NUH, NGX
Dated: November 27, 2018
Received: January 3, 2019

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 Vivek Pinto, Ph.D.
Acting Division 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)*
K190009

Device Name
Sunmas TENS & PMS (Model SM9187, SM9180L, SM9180S)

Indications for Use *(Describe)*

Model SM9187:
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, neck, upper extremities (arm), and lower extremities (leg) due to strain from exercise or normal household work activities.
PMS (Mode 1, 2, 3, 4, 5, 6):
It is intended to be used to stimulate healthy muscles in order to improve and facilitate muscle performance.

Model SM9180L & SM9180S:
TENS (Mode 1, 3, 4, 5, 6):
To be used for temporary relief of pain associated with sore and aching muscles in the shoulder, back due to strain from exercise or normal household work activities.
PMS (Mode 1, 2, 3, 4, 5, 6):
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:	K190009
Date:	December 12, 2019
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:	Sunmas TENS & PMS (Model SM9187, SM9180L, SM9180S)
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:	Sunmas TENS & PMS (Model SM9187, SM9180L & SM9180S) is a portable battery powered device with a wireless feature for over-the-counter use, offering both Transcutaneous Electrical Nerve Stimulation (TENS) and Powered Muscle Stimulation (PMS) qualities in one device. Sunmas TENS & PMS has totally 6 modes, applying electrical current to electrodes on a patient's skin to relieve pain or build up muscle. Due to different electrode shapes and sizes, Model SM9187 can be used on the shoulder, waist, back, neck, upper extremities (arm), and lower extremities (legs), while Model SM9180L and SM9180S can be used on the shoulder, back and abdomen. Model SM9187 is designed to be controlled by a mobile phone application program (APP) named "Dr.Stim", through Bluetooth 4.0 technology (Frequency: 2402.0 - 2480.0MHz). The APP is developed by Hong Qiangxing (Shenzhen) electronics Limited. SM9187 consists of a round main unit, two sets of self-adhesive electrode pad, a mobile application (APP), an AC charger and a USB cable. Model SM9180L and SM9180S both have a butterfly-shaped main unit (Frequency: 2450MHz) and can be remotely controlled through wireless technology. SM9180L has a black remote control with an electronic display screen which is powered by two AAA alkaline batteries, while SM9180S

has a white remote control powered by a CR2032 coin battery. The radio frequency of remote control (both black and white) is 2405.0 - 2470.0MHz. Model SM9180L and SM9180S consists of a unit, two pairs of electrode gels, a remote control (black or white), an AC charger and a USB cable.

Indications for use:

Model SM9187:

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, neck, upper extremities (arm), and lower extremities (leg) due to strain from exercise or normal household work activities.

PMS (Mode 1, 2, 3, 4, 5, 6):

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

Model SM9180L & SM9180S:

TENS (Mode 1, 3, 4, 5, 6):

To be used for temporary relief of pain associated with sore and aching muscles in the shoulder, back due to strain from exercise or normal household work activities.

PMS (Mode 1, 2, 3, 4, 5, 6):

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

3. Substantial Equivalence to Predicate device:

Table 1 -

Parameters		**New Device**	**Predicate Device 1**	**Predicate Device 2**
1.	510(k) Number:	K190009	K121719	K143430
2.	Marketing clearance date:		May 10, 2013	May 29, 2015
3.	Device Name	SM9187	SM TENS & PMS	SmartTENS
4.	Manufacturer	Hong Qiangxing (Shenzhen) Electronics Limited	Hong Qiangxing (Shenzhen) Electronics Limited	EasyMed Instruments Co., Ltd.
5.	Product code	NUH, NGX	NGX, NUH	NUH
6.	Accessories	Self-adhesive electrodes, Battery charger, USB cable	Self-adhesive electrodes, electrode wires, Battery charger, USB cable	Button-affixed electrode, Replaceable Hydrogel Pads((gel-pads))73mm x 62mm, charger cradle, charging adapter
7.	Intended use	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, neck, upper extremities (arm), and lower extremities (leg) due to strain from exercise or normal household work activities. PMS (Mode 1, 2, 3, 4, 5, 6): 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, neck, upper extremities (arm), and lower extremities (leg) due to strain from exercise or normal household work activities. PMS (Mode 1, 2, 3, 6): It is intended to be used to stimulate healthy muscles in order to improve and facilitate muscle performance.	This device is intended for the relief of pain associated with sore or aching muscles of the lower back, arms, or legs due to strain from exercise or normal household and work activities.
8.	Target Population	Adult	Adult	Adult
9.	Type of use	OTC	OTC	OTC
10.	Wireless Control	Yes(Bluetooth device controlled by Application)	No	Yes(Bluetooth device controlled by Application)
11.	Number of Output Modes	6	6	7

12.	Number of Output channels:		1	2	1
	- Synchronous or Alternating?		NA	Synchronous	NA
	- Method of Channel Isolation		NA	Voltage transformer Isolation	NA
13.	Waveform (e.g. pulsed monophasic, biphasic)		Biphasic rectangular Monophasic rectangular	Biphasic rectangular	Biphasic rectangular Monophasic rectangular
14.	Power Source(s)		3.7V rechargeable lithium battery	3.7V rechargeable lithium battery	3.7V rechargeable lithium battery
	- Method of Line Current Isolation		Type BF	Type BF	Type BF
	- Patient Leakage Current - Normal Condition (μA) Single Fault Condition (μA)		-- < 10μA < 50μA	-- < 10μA < 50μA	-- Not publicly available
15.	Average DC current through electrodes when device is on but no pulses are being applied (μA)		<0.01μA	<0.01μA	Not publicly available
16.	Regulated Current or Regulated Voltage?		Voltage control	Voltage control	Not publicly available
17.	Software/Firmware/Microprocessor Control?		Yes	Yes	Yes
18.	Automatic Overload Trip?		No	No	Yes
19.	Automatic No-Load Trip?		No	No	Yes
20.	Automatic Shut Off?		Yes	Yes	Yes
21.	User Override Control?		Yes	Yes	Yes
22.	Indicator Display:	On/Off Status?	Yes	Yes	Yes
		Low Battery?	No	Yes	Yes
		Voltage/Current	Yes	Yes	Yes

		Level?			
		Output mode	Yes	Yes	Yes
		Time to cut-off	Yes	Yes	Yes
23.	Timer Range (minutes)		0 ~ 60 minutes	10 ~ 60 minutes, 10 min./step	20min, 25min, 30min, 40min depending on preset program
24.	Weight (grams)		43g	140g	64g
25.	Dimensions (mm) [W x H x D]		60 x 60 x 13.7mm	83*42*9mm	155.4 x 64.6 x 19.1mm
26.	Housing Materials & Construction		ABS	ABS	TPE & ABS
27.	Maximum Output Voltage (volts)		47.6V±10% @500Ω	42V±10% @500Ω	68V@500Ω
			104V±10% @2kΩ	84V±10% @2kΩ	102V@2kΩ
			157V±10% @10kΩ	130V±10% @10kΩ	110V@10kΩ
28.	Maximum Output Current (specify units)		95.2mA±10% @500Ω	84mA±10% @500Ω	133mA@500Ω
			52mA±10% @2kΩ	42mA±10% @2kΩ	51mA@2kΩ
			15.7mA±10% @10kΩ	13mA±10% @10kΩ	11mA@10kΩ
29.	Pulse width (μsec)		100μs	100μs	50~250μs
30.	Pulse Period (msec)		9.5~855ms	9.3~850ms	Not publicly available
31.	Max. pulse frequency (Hz) [or Rate (pps)]		105.5Hz	110Hz	From 1Hz to 150Hz
32.	Net Charge (μC per pulse)		0μC @500Ω (Method: Balanced waveform) or 9.6μC @500Ω	0μC @500Ω; Method: Balanced waveform	0μC @500Ω (Method: Balanced waveform) or maximum 10.01μC @500Ω
33.	Burst Mode		Yes	Yes	Yes
34.	Maximum Phase Charge, (μC)		19.04μC@500Ω	16.8μC @500Ω	20.02μC @500Ω
35.	Maximum Average Current, (mA)		1.004mA	0.924mA	3.0375mA
36.	Maximum Current Density, (mA/cm², r.m.s.)		0.11mA/cm² @500Ω (Smallest electrode area 19cm²)	0.462mA/cm² (Smallest electrode area 4cm²)	0.066mA/cm²
37.	Maximum Average Power		2.52mA/cm² @500Ω (Smallest electrode area 19cm²)	9.702mW/cm² (Smallest electrode area 4cm²)	2.66mW/cm²

	Density, (W/cm²)			
38.	Battery charge	The Lithium battery can be recharged through both AC adaptor and computer USB input.	The Lithium battery can be recharged through both AC adaptor and computer USB input.	The Lithium battery can be recharged through both AC adaptor and computer USB input.
39.	Compliance with Voluntary Standards?	IEC 60601-1, IEC 60601-1-2, IEC 60601-2-10, IEC 60601-1-11, IEC 62133, FCC 47 CFR Part15, ISO10993-5, ISO10993-10, AAMI TIR 69: 2017, ANSI C63.27: 2017	IEC 60601-1, IEC 60601-1-2, IEC 60601-2-10, IEC 62133, FCC 47 CFR Part 18, IEC 60601-1-6, ISO10993-5, ISO10993-10	AAMI/ANSI ES60601-1, IEC 60601-1-2, IEC 60601-2-10, IEC 60601-1-11, IEC 60601-1-6, ISO10993-5, ISO10993-10
40.	Compliance with 21 CFR 898?	N/A, device does not contain electrode lead wires or patient cables.	Yes	Yes

Table 2 -

Parameters		**New Device**	**Predicate Device 1**	**Predicate Device 2**
1.	510(k) Number:	K190009	K121719	K152852
2.	Marketing clearance date:		May 10, 2013	Dec 22, 2015
3.	Device Name	SM9180L&SM9180S	SM TENS & PMS	ALEVE Direct Therapy TENS Device
4.	Manufacturer	Hong Qiangxing (Shenzhen) Electronics Limited	Hong Qiangxing (Shenzhen) Electronics Limited	Bayer HealthCare LLC, Consumer Care
5.	Product code	NUH, NGX	NGX, NUH	NUH
6.	Accessories	Self-adhesive electrodes, Battery charger, USB cable, Remote control with CR2032 battery or AAA alkaline batteries	Self-adhesive electrodes, electrode wires, Battery charger, USB cable	#0 Phillips head screwdriver, Remote control with CR2032 battery, AAA alkaline batteries, Hydrogel Gel Pad
7.	Intended use	TENS (Mode 1, 3, 4, 5, 6):	TENS (Mode 1, 3, 4, 5, 6):	Temporary relief of pain associated with sore and

		To be used for temporary relief of pain associated with sore and aching muscles in shoulder, back due to strain from exercise or normal household work activities. PMS (Mode 1, 2, 3, 4, 5, 6): It is intended to be used to stimulate healthy muscles in order to improve and facilitate muscle performance.	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 (Mode 1, 2, 3, 6): It is intended to be used to stimulate healthy muscles in order to improve and facilitate muscle performance.	aching muscles in the lower back due to strain from exercise or normal household and work activities.
8.	Patient Population	Adult	Adult	Adult
9.	Prescriptive or OTC	OTC	OTC	OTC
10.	Wireless Control	Yes(Wireless device controlled by remote control)	No	Yes(Wireless device controlled by remote control)
11.	Number of Output Modes	6	6	1
12.	Number of Output channels:	1	2	1
	- Synchronous or Alternating?	NA	Synchronous	N/A
	- Method of Channel Isolation	NA	Voltage transformer Isolation	N/A
13.	Power Source(s)	3.7V rechargeable lithium battery (TENS device) 2 AAA 1.5v DC batteries or 1 Lithium coin battery 3.0v DC (wireless remote)	3.7V rechargeable lithium battery	2 AAA 1.5v DC batteries (TENS device) 1 Lithium coin battery 3.0v DC (wireless remote)
	- Method of Line Current Isolation	Type BF	Type BF	Not publicly available
	- Patient Leakage Current - Normal Condition (μA) - Single Fault Condition (μA)	-- < 10μA < 50μA	-- < 10μA < 50μA	-- Not publicly available

14.	Average DC current through electrodes when device is on but no pulses are being applied (μA)		<0.01μA	<0.01μA	Not publicly available
15.	Regulated Current or Regulated Voltage?		Voltage control	Voltage control	Voltage control
16.	Indicator Display:	On/Off Status?	Yes	Yes	Yes
		Low Battery?	No	Yes	Yes
		Voltage/Current Level?	Yes	No	Yes
17.	Software/Firmware/Microprocessor Control?		Yes	Yes	Yes
18.	Automatic Overload Trip?		No	No	No
19.	Automatic No-Load Trip?		No	No	No
20.	Automatic Shut Off?		Yes	Yes	Yes
21.	User Override Control?		Yes	Yes	Yes
22.	Compliance with 21 CFR 898?		N/A, device does not contain electrode lead wires or patient cables.	Yes	N/A, device does not contain electrode lead wires or patient cables.
23.	Weight (grams)		95g	140g	4.8 oz.w/ batteries included
24.	Dimensions (mm) [W x H x D]		196.8*90*15.9mm	83*42*9mm	7.5 (w) x 3.5 (h) x 0.7 in (d)
25.	Housing Materials & Construction		ABS	ABS	plastic enclosure (Housing) Integral silicone electrodes with conductive (carbon rubber) area and non-conductive area with ultramarine blue colorant (CAS # 57455-37-5)
26.	Maximum Output Voltage (volts)		47.6V±10% @500Ω	42V±10% @500Ω	Not publicly available
			104V±10% @2kΩ	84V±10% @2kΩ	
			157V±10% @10kΩ	130V±10% @10kΩ	
27.	Maximum Output Current		95.2mA±10% @500Ω	84mA±10% @500Ω	Not publicly available

	(specify units)	52mA±10% @2kΩ	42mA±10% @2kΩ	
		15.7mA±10% @10kΩ	13mA±10% @10kΩ	
28.	Pulse width (μsec)	100μs	100μs	Not publicly available
29.	Pulse Period (msec)	9.5~855ms	9.3~850ms	Not publicly available
30.	Max. pulse frequency (Hz) [or Rate (pps)]	105.5Hz	110Hz	Not publicly available
31.	Maximum Phase Charge, (μC)	19.04μC@500Ω	16.8μC @500Ω	Not publicly available
32.	Maximum Average Current, (mA)	1.004mA	0.924mA	Not publicly available
33.	Waveform (e.g. pulsed monophasic, biphasic)	Biphasic rectangular Monophasic rectangular	Biphasic rectangular	Not publicly available
34.	Net Charge (μC per pulse)	0μC @500Ω (Method: Balanced waveform) or 9.6μC @500Ω	0μC @500Ω; Method: Balanced waveform	Not publicly available
35.	Timer Range (minutes)	Nonadjustable 20min	10 ~ 60 minutes, 10 min/step	Nonadjustable 30 minutes 42 seconds
36.	Burst Mode	Yes	Yes	Not publicly available
37.	Maximum Current Density, (mA/cm^2, r.m.s.)	0.04mA/cm^2 @500Ω (Smallest electrode area 57cm^2)	0.462mA/cm^2 (Smallest electrode area 4cm^2)	0.056mA/cm^2 @500Ω (Smallest electrode area 114cm^2)
38.	Maximum Average Power Density, (W/cm^2)	0.84mW/cm^2 @500Ω (Smallest electrode area 57cm^2)	9.702mW/cm^2 (Smallest electrode area 4cm^2)	1.53mW/cm^2 @500Ω (Smallest electrode area 114cm^2)
39.	Compliance with Voluntary Standards?	IEC 60601-1, IEC 60601-1-2, IEC 60601-2-10, IEC 60601-1-11, IEC 62133, FCC 47 CFR Part15, ISO10993-5, ISO10993-10, AAMI TIR 69: 2017, ANSI C63.27: 2017	IEC 60601-1, IEC 60601-1-2, IEC 60601-2-10, IEC 62133, IEC 60601-1-6, FCC 47 CFR Part 18, ISO10993-5, ISO10993-10	• AAMI ANSI ES60601-1:2005/(R)2012 And A1:2012 IEC 60601-1-2 Edition 2014-02 • IEC 60601-1-11 Edition 1.0 2010-04 • IEC 60601-2-10 Edition 1.0 2012-06 • AAMI/ANSI/ISO 10993-5:2009(R)2014 AAMI/ANSI/ISO 10993-10:2010

4. Safety and Effectiveness of the device:

Sunmas TENS & PMS is safe and effective as the predicate devices cited above. The new device has 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 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) 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))
6) FCC 47 CFR Part 15 RADIO FREQUENCY DEVICES;
7) AAMI TIR69: 2017 Technical Information Report Risk Management Of Radio-Frequency Wireless Coexistence For Medical Devices And Systems;
8) ANSI IEEE C63.27-2017 American National Standard For Evaluation Of Wireless Coexistence.

The conclusion drawn from the safety testing is that the new device is 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.