July 8, 2021

Shenzhen XFT Medical Limited
% Field Fu
Senior Consultant
Shenzhen Joyantech Consulting Co., Ltd.
1713A, Zhongguan Times Square, Liuxian Avenue,
Xili Town, Nanshan District
Shenzhen, Guangdong
China

Re: K211094
Trade/Device Name: Nerve and Muscle Stimulator
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered Muscle Stimulator
Regulatory Class: Class II
Product Code: IPF, HCC
Dated: April 6, 2021
Received: April 12, 2021

Dear Field Fu:

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,

Patrick Antkowiak
Acting 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)*
K211094

Device Name
Nerve and Muscle Stimulator

Indications for Use *(Describe)*
sEMG:
Biofeedback, Relaxation & Muscle Re-Education purposes;
NMES (muscle stimulation) and sEMG triggered stimulation (IncludingETS, PAS and MIRROR Mode):
1) Relaxation of muscle spasms;
2) Prevention or retardation of disuse atrophy;
3) Increasing local blood circulation;
4) Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis;
5) Maintaining or increasing range of motion;
6) Stroke Rehab by Muscle re-education.

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

This summary of 510(K) safety and effectiveness information is submitted As Required by requirements of SMDA and 21 CFR §807.92.

1 Administrative Information

Date of Summary prepared	Apr., 6, 2021
Manufacturer information	Shenzhen XFT Medical Limited. Company address: Room 203, Building 1, Biomedicine Innovations Industrial Park, #14 Jinhui Road, Pingshan New District, Shenzhen, China. Contact person: Cindy Peng Phone: +86 755 29888818 Fax: +86-0755-28312625 E-mail: xftrs2@xft.cn
Submission Correspondent	Shenzhen Joyantech Consulting Co., Ltd. Address: 1713A, 17th Floor, Block A, Zhongguan Times Square, Liuxian Avenue, Xili Town, Nanshan District, Shenzhen, Guangdong Province, China. Contact person: Mr. Field Fu E-Mail: field@cefda.com;
Establishment registration number	

2 Device Information

Type of 510(k) submission:	Traditional
Trade Name:	Nerve and Muscle Stimulator
Model:	XFT-2003k
Classification name:	Stimulator, Muscle, Powered; Stimulator, Nerve, Transcutaneous, For Pain Relief.

Review Panel:	Physical Medicine; Neurology.
Product Code:	IPF; HCC.
Device Class:	II
Regulation Number:	890.5850

3 Predicate Device Information

Sponsor:	Thought Technology Ltd.
Device:	Powered muscle stimulator and biofeedback device
Device#:	SA9800
Trade name:	MYOTRAC INFINITI
510(K) Number:	K053266

4 Device Description

The Nerve and Muscle Stimulator (model: XFT-2003K) is an electrical muscle stimulator for contraction of muscles as indicated above. The Nerve and Muscle Stimulator (model: XFT-2003K) is also an electromyography device. It is intended for medical purposes, such as to monitor and display the bioelectric signals produced by muscles, to stimulate peripheral nerves and to monitor and display the electrical activity produced by nerves. The indications for use are muscle re-education, relaxation and biofeedback.
Nerve and Muscle Stimulator (model: XFT-2003K) is powered by MAINS SUPPLY AC 100-240V, 50-60Hz, and used together with Electrode cup （including Sponge).
The device is used for prescription. It is neither for life-supporting nor for implanting. It does not contain any drug or biological product and it does not need to be sterilized.

5 Intended Use/ Indications for Use

sEMG:
Biofeedback, Relaxation & Muscle Re-Education purposes;
NMES (muscle stimulation) and sEMG triggered stimulation (Including ETS, PAS and MIRROR Mode):
1) Relaxation of muscle spasms;
2) Prevention or retardation of disuse atrophy;

3) Increasing local blood circulation;
4) Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis;
5) Maintaining or increasing range of motion;
6) Stroke Rehab by Muscle re-education.

6 Technological characteristics of the subject device compared to the predicate device

Table 01: SE Comprehensive Comparison Table

Elements of Comparison	Subject Device	Predicate Device	Remarks
510(k) Number	Pending	K053266	
Manufacturer	Shenzhen XFT Medical Limited	Thought Technology Ltd.	
Device type/model	XFT-2003K	MYOTRAC INFINITI	/
Intended use/ Indication for use	sEMG: Biofeedback, Relaxation & Muscle Re-Education purposes; NMES (muscle stimulation) and sEMG triggered stimulation (IncludingETS, PAS and MIRROR Mode): 1) Relaxation of muscle spasms; 2) Prevention or retardation of disuse atrophy; 3) Increasing local blood circulation; 4) Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis; 5) Maintaining or increasing range of motion; 6) Stroke Rehab by Muscle re-education.	1) Biofeedback, Relaxation and Muscle Re-Education purposes; 2) Relaxation of muscle spasms; 3) Prevention or retardation of disuse atrophy; 4) Increasing local blood circulation; 5) Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis; 6) Maintaining or increasing range of motion. 7) Stroke Rehab by Muscle re-education.	SE
Prescription or OTC	RX	RX	SE
Electrode	EC002: 25.57cm^2; EC001: 9.621cm^2;	Axelgaard Model 895340: 75 cm^2; Axelgaard Model 895220: 25cm^2;	**Note 01**

Elements of Comparison	Subject Device	Predicate Device	Remarks
Waveform	Pulsed,Symmetrical balanced biphasic wave (rectangular)	Asymmetrical balanced pulsed current	SE
Performance	Compliance with IEC 60601-2-10	Compliance with IEC 60601-2-10	Same
Biocompatibility	All the patient contacting materials are in compliance with ISO 10993-1/-5/-10	All the patient contacting materials are in compliance with ISO 10993-1/-5/-10	Same
Electrical Safety	Compliance with IEC 60601-1	Compliance with IEC 60601-1	Same
EMC	Compliance with IEC 60601-1-2	Compliance with IEC 60601-1-2	Same
Connecting Safety	21CFR 898	21CFR 898	Same

Note 01: Maximum Current Density and Maximum Power Density are equivalent respectively.

Table 02: SE General Specification Comparison Table

Parameter	Subject Device	Predicate Device	Remarks
510(k) Number	Pending	K053266	/
Device Name and Model	XFT-2003K	MYOTRAC INFINITI	/
Manufacturer	Shenzhen XFT Medical Limited	Thought Technology Ltd.	/
Power Source(s)	AC 110-240 50-60Hz	4 AAA batteries, single use alkaline or Rechargeable battery pack	**Note 02**
---Method of Line Current Isolation	2MOPP	2MOPP	Same
---Patient Leakage Current: Normal Condition (μA)	≤1	≤1	Same
---Patient Leakage Current: Single Fault Condition (μA)	≤1	≤1	Same
Number of Output Modes(programs)	4	2	SE
Number of Output Channels:	Double	Double	Same
---Synchronous or Alternating?	Synchronous	Synchronous	Same
---Method of Channel Isolation	Transformer	Transformer	Same
Regulated Current or Regulated Voltage?	Regulated Current	Regulated Voltage	SE
Software/Firmware/Microproces	Yes	Yes	Same

Parameter		Subject Device	Predicate Device	Remarks
sor Control?				
Automatic Overload Trip?		Yes	Yes	Same
Automatic No-Load Trip?		Yes	Yes	Same
Automatic Shut Off?		Yes	No	SE
Patient Override Control?		Yes	Yes	Same
Indicator Display:	On/Off Status?	yes	Yes	Same
	Low Battery?	No.	Yes	**Note 03**
	Voltage/Current Level?	Yes	Yes	Same
Timer Range (minutes)		1-60min，step 1min	1-120min	SE
sEMG detection		Bipolar	Bipolar	same
sEMG range (μV)		1-2000	0-5, 0-10, 5-10, 0-20, 5-20, 10-20, 0-50, 10-50, 0-100, 50-100,0-200, 50-200, 100-200, 0-500,100-500, 0-1000, 0-2000	SE
Feedback response frequency bands(Hz)		20-500	20-500	Same
sEMG indication accuracy		±10%or±2μV, whichever is greater	unknown	The triggering of electrical stimulation is not adverse affected
Feedback threshold		±10%or±2μV, whichever is greater	unknown	
Compliance with Voluntary Standards?		IEC 60601-1 IEC 60601-1-2 IEC 60601-2-10 IEC 60601-2-40	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-10	SE
Compliance with 21 CFR 898		Yes	Yes	Same
Weight		3.8kg	330g	**Note 04**
Dimensions (mm) [W x H x D]		359×289×202mm	102*152*51mm	

Note 02: DC adaptor meets IEC 60601-1 standard**.**

Note 03: The subject device is powered by AC, not battery.

Note 04: The subject device is not a portable device.

Table 03: SE Detailed Comparison Table

Parameter	Subject Device		Predicate Device K053326	Remarks
Maximum Output Voltage (volts) (+/- 20%)	NMES Mode: P1 ~ P6, P8 ~ P10, P12 ~ P29, P33, P37, P39, P41 ~P42.	50V@500Ω	50V@ 500 Ω	SE The NMES Modeof the Subject Device is compared to the STIMMode of the Predicate Device. The ETS Mode of the Subject Device is compared to the Threshold Mode of the Predicate Device. The PAS Mode of the Subject Device is compared to the Triggered Mode of the Predicate Device. The Mirror Mode of the Subject Device is compared to the Triggered Mode of the Predicate Device.
		125V@ 2 kΩ	100V@ 2 kΩ	
		125V@10 kΩ	100V@ 10 kΩ	
	NMES Mode: P7, P11, P30, P34.	48.4V@500Ω	50V@ 500 Ω	
		125V@ 2 kΩ	100V@ 2 kΩ	
		125V@10 kΩ	100V@ 10 kΩ	
	NMES Mode: P31.	34.2V@500Ω	50V@ 500 Ω	
		125V@ 2 kΩ	100V@ 2 kΩ	
		125V@10 kΩ	100V@ 10 kΩ	
	NMES Mode: P32, P36, P40.	41.9V@500Ω	50V@ 500 Ω	
		125V@ 2 kΩ	100V@ 2 kΩ	
		125V@10 kΩ	100V@ 10 kΩ	
	NMES Mode: P35.	39.5V@500Ω	50V@ 500 Ω	
		125V@ 2 kΩ	100V@ 2 kΩ	
		125V@10 kΩ	100V@ 10 kΩ	
	NMES Mode: P38.	44.8V@500Ω	50V@ 500 Ω	
		125V@ 2 kΩ	100V@ 2 kΩ	
		125V@10 kΩ	100V@ 10 kΩ	
	NMES Mode: P43.	15V@500Ω	50V@ 500 Ω	
		60V@ 2 kΩ	100V@ 2 kΩ	
		125V@10 kΩ	100V@ 10 kΩ	
	ETS Mode.	23.7V@500Ω	50V@ 500 Ω	
		94.6V@ 2 kΩ	100V@ 2 kΩ	
		125V@10 kΩ	100V@ 10 kΩ	
	PAS Mode.	50V@500Ω	50V@ 500 Ω	
		125V@ 2 kΩ	100V@ 2 kΩ	
		125V@10 kΩ	100V@ 10 kΩ	
	MIRROR Mode.	50V@500Ω	50V@ 500 Ω	
		125V@ 2 kΩ	100V@ 2 kΩ	
		125V@10 kΩ	100V@ 10 kΩ	
Maximum Output Current (specify units) (+/- 20%)	NMES Mode: P1 ~ P6, P8 ~ P10, P12 ~ P29, P33, P37, P39, P41 ~P42.	100mA@500Ω	100.0mA@500Ω	SE The NMES Modeof the Subject Device is compared to the STIMMode of the Predicate Device.
		62.5mA@ 2 kΩ	50mA@ 2 kΩ	
		12.5mA@10 kΩ	10mA@10 kΩ	
	NMES Mode: P7, P11, P30, P34.	96.8mA@500Ω	100.0mA@500Ω	
		62.5mA@ 2 kΩ	50mA@ 2 kΩ	
		12.5mA@10 kΩ	10mA@10 kΩ	
	NMES Mode: P31.	68.4mA@500Ω	100.0mA@500Ω	
		62.5mA@ 2 kΩ	50mA@ 2 kΩ	
		12.5mA@10 kΩ	10mA@10 kΩ	
	NMES Mode:	83.8mA@500Ω	100.0mA@500Ω	

Parameter	Subject Device		Predicate Device K053326	Remarks
	P32, P36, P40.	62.5mA@ 2 kΩ	50mA@ 2 kΩ	The ETS Mode of the Subject Device is compared to the Threshold Mode of the Predicate Device. The PAS Mode of the Subject Device is compared to the Triggered Mode of the Predicate Device. The Mirror Mode of the Subject Device is compared to the Triggered Mode of the Predicate Device.
		12.5mA@10 kΩ	10mA@10 kΩ	
	NMES Mode: P35.	79mA@500Ω	100.0mA@500Ω	
		62.5mA@ 2 kΩ	50mA@ 2 kΩ	
		12.5mA@10 kΩ	10mA@10 kΩ	
	NMES Mode: P38.	89.6mA@500Ω	100.0mA@500Ω	
		62.5mA@ 2 kΩ	50mA@ 2 kΩ	
		12.5mA@10 kΩ	10mA@10 kΩ	
	NMES Mode: P43.	30mA@500Ω	100.0mA@500Ω	
		30mA@ 2 kΩ	50mA@ 2 kΩ	
		12.5mA@10 kΩ	10mA@10 kΩ	
	ETS Mode.	47.4mA@500Ω	100.0mA@500Ω	
		47.4mA@ 2 kΩ	50mA@ 2 kΩ	
		12.5mA@10 kΩ	10mA@10 kΩ	
	PAS Mode.	100mA@500Ω	100.0mA@500Ω	
		62.5mA@ 2 kΩ	50mA@ 2 kΩ	
		12.5mA@10 kΩ	10mA@10 kΩ	
	MIRROR Mode.	100mA@500Ω	100.0mA@500Ω	
		62.5mA@ 2 kΩ	50mA@ 2 kΩ	
		12.5mA@10 kΩ	10mA@10 kΩ	
Pulse Duration/width† (μsec)	NMES Mode: P1.	250μs	50-400μs	SE
	NMES Mode: P2, P14, P24.	150μs	50-400μs	SE
	NMES Mode: P3, P16, P19, P26.	50μs	50-400μs	SE
	NMES Mode: P4.	45μs	50-400μs	SE
	NMES Mode: P5~P12, P18, P28, P41, P42. PAS Mode. MIRROR Mode.	200μs	50-400μs	SE
	NMES Mode: P13, P17, P21~P23, P25, P35.	300μs	50-400μs	SE
	NMES Mode: P15, P20, P27, P39.	100μs	50-400μs	SE
	NMES Mode: P29~P34, P36~P38, P40.	400μs	50-400μs	SE
	NMES Mode: P43. ETS Mode.	50-500μs	50-400μs	SE

Parameter		Subject Device		Predicate Device K053326	Remarks
Frequency† (Hz) [or Rate† (pps)]		NMES Mode: P1, P5, P9, P13, P17, P21, P25, P29, P33, P37, P41.	5Hz	2-100Hz	SE
		NMES Mode: P2, P15, P18, P23, P38.	35Hz	2-100Hz	SE
		NMES Mode: P3, P7, P11, P19, P26, P31,P35, P39.	60Hz	2-100Hz	SE
		NMES Mode: P4.	100Hz	2-100Hz	SE
		NMES Mode: P6, P30, P34. MIRROR Mode.	30Hz	2-100Hz	SE
		NMES Mode: P8.	45Hz	2-100Hz	SE
		NMES Mode: P10, P12, P16, P20, P24, P27, P28, P32, P36, P40,P42.	40Hz	2-100Hz	SE
		NMES Mode: P14, P22.	25Hz	2-100Hz	SE
		NMES Mode: P43.	2~250Hz	2-100Hz	SE
		ETS Mode.	2-100Hz	2-100Hz	SE
		PAS Mode.	18Hz	2-100Hz	SE
For interferential modes only: -Beat Frequency (Hz)		NMES Mode: P1~P43, ETS Mode, PAS Mode, MIRROR Mode.	N/A	N/A	/
For multiphasic waveforms only:	Symmetrical phases?	NMES Mode: P1~P43, ETS Mode, PAS Mode, MIRROR Mode.	N/A	N/A	/
	Phase Duration† (include units), (state range, if applicable), (both phases, if asymmetrical)	NMES Mode: P1~P43, ETS Mode, PAS Mode, MIRROR Mode.	N/A	N/A	/
Net Charge (microcoulombs (μC) per pulse) (If zero, state method of achieving zero		NMES Mode: P1~P43, ETS Mode, PAS Mode, MIRROR Mode	0@500Ω	0@500Ω	Same

Parameter	Subject Device		Predicate Device K053326	Remarks
net charge.)				
Maximum Phase Charge, (μC)	NMES Mode: P1, P6.	25@500Ω	60@500Ω	SE
	NMES Mode: P2, P14, P24,	15@500Ω	60@500Ω	
	NMES Mode: P3, P16, P19, P26.	5@500Ω	60@500Ω	
	NMES Mode: P4,P15, P20, P27, P39.	10@500Ω	60@500Ω	
	NMES Mode: P5, P8~P10, P12, P18, P28, P41, P42. PAS Mode. MIRROR Mode.	20@500Ω	60@500Ω	
	NMES Mode: P7, P11.	19.36@500Ω	60@500Ω	
	NMES Mode: P13, P17, P21~P23, P25.	30@500Ω	60@500Ω	
	NMES Mode: P29, P33, P37.	40@500Ω	60@500Ω	
	NMES Mode: P30, P34,.	38.72@500Ω	60@500Ω	
	NMES Mode: P31.	27.36@500Ω	60@500Ω	
	NMES Mode: P32, P36, P40.	33.52@500Ω	60@500Ω	
	NMES Mode: P35.	23.7@500Ω	60@500Ω	
	NMES Mode: P38.	35.84@500Ω	60@500Ω	
	NMES Mode: P43. ETS Mode.	50@500Ω	60@500Ω	
Maximum Current Density,††(mA/cm².)	NMES: P43.	0.38977@500Ω (EC001) 0.14696@500Ω (EC002)	Axelgaard Model 895220 0.24mA/cm2 Axelgaard Model 895340 0.08mA/cm2	**Note 05**
Maximum Power Density,†† (mW/cm²) , (using smallest electrode conductive surface area)	NMES: P30, P34, P43.	11.69@500Ω (EC001) 4.41@500Ω (EC002)	Axelgaard Model 895220 16mW/cm2 Axelgaard Model 895340 5.3mW/cm2	**Note 06**

Parameter		Subject Device		Predicate Device K053326	Remarks
Burst Mode (i.e., pulse trains):	(a) Pulses per burst		2~6000	4-2000	**Note 07**
	(b) Bursts per second		0.05~1	0.05-0.5	/
	(c) Burst duration (seconds)		1~20	2-20	/
	(d) Duty Cycle: Line (b) x Line (c)		1	1	Same
ON Time (seconds)			1~20	2-20	/
OFF Time (seconds)			1~20	2-50	/

Note 05: The treatment effect is mainly determined by Maximum Power Density.

Note 06: The Maximum Power Density at this level is effective, for instance, Maximum Power Density is effective when it is as small as 1.38 mW/cm2 (K172933), 1.44 mW/cm2 (K182203, model PL-029K12) , 1.26 mW/cm2 (K182203, model PL-029K13:), 1.68 mW/cm2 (K191151, model PL-029K15) and even as low as 0. 32 mW/cm2 (K162517, PL-029K12, P3.)

Note 07: subject device's pulses per burst rate is significantly different than the predicate device, but the duty cycle of the subject device is same as the duty cycle of the predicate, so the differences do not affect safety and effectiveness of the subject device.

Maximum Output Voltage, Maximum Output Current, Pulse Duration/width, Frequency range of the subject device are respectively SE to or similar with the predicate; there are little differences between the Maximum Current Density, Maximum Power Density, Burst Mode (i.e., pulse trains) of the subject device and the predicate, but the differences do not exert adverse effect on the proposed device.

7 Brief discussion of the nonclinical tests

The subject device conforms to the following standards:
IEC 60601-1:2005+CORR.1:2006+CORR.2007+A1:2012 Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential

Performance.

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

IEC 60601-2-40:2016 Medical Electrical Equipment - Part 2-40: Particular requirements for the basic safety and essential performance of electromyographs and evoked response equipment

IEC 60601-2-10:2016 Medical Electrical Equipment - Part 2-10: Particular Requirements For The Basic Safety And Essential Performance Of Nerve And Muscle Stimulators

ISO 10993-5:2009 Biological Evaluation Of Medical Devices - Part 5: Tests For In Vitro Cytotoxicity.

ISO 10993-10:2010 Biological Evaluation of Medical Devices- Part 10: Tests for Irritation and Skin Sensitization.

8 Brief discussion of clinical tests
N/A.

9 Other information (such as required by FDA guidance/Test)
No.

10 Conclusions
The subject device has features that are similar to the predicate device. The few differences do not affect the safety and effectiveness of the subject device.
Thus, the subject device is substantially equivalent to the predicate device.