April 11, 2020

Shenzhen XFT Medical Limited
℅ Field Fu
Senior Consultant
Shenzhen Joyantech Consulting Co., Ltd.
Room 1122#, International Mayors Communication Centre NO. 55 Shizhou middl
Shenzhen, Guangdong, China
Re: K193275
    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, GZJ
    Dated: January 6, 2020
    Received: January 13, 2020

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,

For   Vivek Pinto, PhD
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)*
K193275

Device Name
Nerve and Muscle Stimulator

Indications for Use *(Describe)*
Over-The-Counter Use:
TENS[(Program 1~9, Program 15 (Frequency$<$5Hz or $>$15Hz)]:
XFT-2000 is used for temporary relief of pain associated with sore and aching muscles due to strain from exercise or normal household and work activities.

XFT-2000 is also intended for the symptomatic relief and management of chronic, intractable pain and relief of pain associated with arthritis.

NMES[(Program 10~14, Program 15(5Hz$\leq$Frequency$\leq$50Hz)]:
XFT-2000 is used to stimulate healthy muscles in order to improve and facilitate muscle performance. To be used for the improvement of muscle tone and firmness, and for strengthening muscles in the arms, abdomen, legs, and buttocks. Not intended for use in any therapy or for the treatment of any medical conditions or diseases.

XFT-2000 is also intended to temporarily increase local blood circulation in health muscles of lower extremities.

Prescription Use:
XFT-2000 is intended for the following use:
- Relaxation of muscle spasms
- Prevention or retardation of disuse atrophy
- Increasing local blood circulation
- Muscle re-education
- Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis
- Maintaining or increasing range of motion
- Adjunctive treatment in the management of post-surgical and post-traumatic acute pain.

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.

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.

5.1 Administrative Information

Date of Summary prepared	Oct. 23, 2019
Manufacturer information	Company title: 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	

5.2 Device Information

Type of 510(k) submission:	Traditional
Trade Name:	Nerve and Muscle Stimulator
Model:	XFT-2000
Classification name:	Stimulator, Muscle, Powered; Stimulator, Nerve, Transcutaneous, For Pain Relief.

Review Panel:	Physical Medicine; Neurology.
Product Code:	IPF; GZJ.
Device Class:	II
Regulation Number:	890.5850; 882.5890.

5.3 Predicate Device Information

Sponsor:	Rio-Medical Research Ltd.
Device:	MediStim XP, Type 281;
510(K) Number:	K082011
Sponsor:	JKH Health Co., Ltd.
Device:	Electronic Pulse Stimulator
510(K) Number:	K162517

5.4 Device Description

Nerve and Muscle Stimulator (model: XFT-2000) is based on the principles of neuromuscular electrical stimulation (NMES) and transcutaneous electrical nerve stimulation (TENS).The instrument has two independent channels, easy to operate and use. It can relieve muscle spasm, prevent or delay disuse muscle atrophy, promote local blood circulation, promote muscle function recovery, stimulate calf muscle after surgery to prevent venous thrombosis and maintain or increase the range of activity, and assist in the management of post-operative and post-traumatic acute pain problems.

Nerve and Muscle Stimulator (model: XFT-2000) is powered by DC adapter or 3 dry AAA batteries, and used together with self-adhesive Electrode.

The device is for both prescription and over the counter. 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.

5.5 Intended Use/ Indications for Use

Over-The-Counter Use:
TENS[(Program 1~9, Program 15 (Frequency＜5Hz or ＞15Hz)]:
XFT-2000 is used for temporary relief of pain associated with sore and aching muscles due to strain from exercise or normal household and work activities.

XFT-2000 is also intended for the symptomatic relief and management of chronic, intractable pain and relief of pain associated with arthritis.

NMES[(Program 10~14, Program 15(5Hz≤Frequency≤50Hz)]:
XFT-2000 is used to stimulate healthy muscles in order to improve and facilitate muscle performance. To be used for the improvement of muscle tone and firmness, and for strengthening muscles in the arms, abdomen, legs, and buttocks. Not intended for use in any therapy or for the treatment of any medical conditions or diseases.

XFT-2000 is also intended to temporarily increase local blood circulation in health muscles of lower extremities.

Prescription Use:
XFT-2000 is intended for the following use:
- Relaxation of muscle spasms
- Prevention or retardation of disuse atrophy
- Increasing local blood circulation
- Muscle re-education
- Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis
- Maintaining or increasing range of motion
- Adjunctive treatment in the management of post-surgical and post-traumatic acute pain.

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

See next pages.

Table 01: SE Comprehensive Comparison Table

Elements of Comparison	Subject Device	Predicate Device	Predicate Device	Remarks
510(k) Number	K193275	K082011	K162517	
Manufacturer	Shenzhen XFT Medical Limited	Rio-Medical Research Ltd	JKH USA, LLC	
Device type/model	XFT-2000	Medistim XP Type 281;	PL-029K12;	/
Intended use/ Indication for use	Neuromuscular Electrical Stimulation (NMES) for relaxation of muscle spasms, prevention or retardation of disuse atrophy, increasing local blood circulation, muscle re-education, immediate post-surgical stimulation of calf muscles to prevent venous thrombosis and maintaining or increasing range of motion. Transcutaneous Electrical Nerve Stimulation (TENS) for an adjunctive treatment in the management of post-surgical and post-traumatic acute pain problems.	Medistim XP delivers stimulation based on the principles of Neuromuscular Electrical NerveStimulation (NMIES) and also Transcutaneous Electrical Nerve Stimulation (TENS). Theindications for use are as follows: Neuromuscular Electrical Stimulation for relaxation ofmuscle spasms, prevention or retardation of disuse atrophy, increasing local blood circulation,muscle re-education, immediate post-surgical stimulation of calf muscles to prevent venousthrombosis and maintaining or increasing range of motion. Transcutaneous Electrical NerveStimulation (TENS) for an adjunctive treatment in the management of post-surgical and post-traumatic acute pain problems.	TENS (Modes 1, 2, 4, 5, 6, 8): To be used for temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back, arm, and leg, due to strain from exercise or normal household and work activities. It is also intended for symptomatic relief and management of chronic, intractable pain and relief of pain associated with arthritis. PMS (also called EMS, Modes 1, 3, 7): To stimulate healthy muscles in order to improve and facilitate muscle performance. To be used for the improvement of muscle tone and firmness, and for strengthening muscles in the arms, abdomen, legs, and buttocks. Not intended for use in any therapy or for the treatment of	SE

Elements of Comparison	Subject Device	Predicate Device	Predicate Device	Remarks
			any medical conditions or diseases. t is also intended to temporarily increase local blood circulation in the healthy muscles of lower extremities.	
Prescription or OTC	Prescription and OTC	Prescription	OTC	SE
Electrode	5cm round;K132588	5×5cm;7cm round; 5cm×9cm etc. K970426, K874469,K965194	unknown	SE
Waveform	Pulsed,Symmetrical balanced biphasic wave (rectangular)	Pulsed, Symmetrical Biphasic, Rectangular with interphase interval	Biphasic, Rectangular	SE
Performance	Compliance with IEC 60601-2-10	Compliance with IEC 60601-2-10	Compliance with IEC 60601-2-10	Same
Biocompatibility	All the patient contacting materials are compliance with ISO 10993-1/-5/-10	All the patient contacting materials are compliance with ISO 10993-1/-5/-10	All the patient contacting materials are compliance with ISO 10993-1/-5/-10	Same
Electrical Safety	Compliance with IEC 60601-1	Compliance with IEC 60601-1	Compliance with IEC 60601-1	Same
EMC	Compliance with IEC 60601-1-2	Compliance with IEC 60601-1-2	Compliance with IEC 60601-1-2	Same
Connecting Safety	21CFR 898	21CFR 898	21CFR 898	Same

Table 02: SE General Specification Comparison Table

Parameter		Subject Device	Predicate Device	Predicate Device	Remarks
510(k) Number		K193275	K082011	K162517	/
Device Name and Model		Nerve and Muscle Stimulator, XFT-2000	MediStimi XP, Type 281	JKH Stimulator: PL-029K12,	/
Manufacturer		Shenzhen XFT Medical Limited	Rio-Medical Research Ltd	JKH USA, LLC	/
Power Source(s)		DC4.5V, 3 × AAA batteries; DC Adapter.	9V Battery (type 6LR61)	Rechargeable or non-rechargeable battery	**Note 01**
---Method of Line Current Isolation		Battery Supply, or DC Adapter	Battery Supply	Battery Supply	**Note 01**
---Patient Leakage Current: Normal Condition (µA)		N/A	N/A	N/A	/
---Patient Leakage Current: Single Fault Condition (µA)		N/A	N/A	N/A	/
Number of Output Modes(programs)		15	9	8	**Note 02**
Number of Output Channels:		2	2	1	SE
---Synchronous or Alternating?		Both	Synchronous(Multiplexed)	N/A	SE
---Method of Channel Isolation		Transistor	Transistor	N/A	SE
Regulated Current or Regulated Voltage?		Regulated Current	Regulated Current	Regulated Voltage	SE
Software/Firmware/Microprocessor Control?		Yes	Yes	Yes	SE
Automatic Overload Trip?		Yes	Yes	No	SE
Automatic No-Load Trip?		Yes	Yes	Yes	Same
Automatic Shut Off?		Yes	Yes	Yes	Same
Patient Override Control?		Yes, Pause button.	Yes, Pause button.	Yes	Same
Indicator Display:	On/Off Status?	yes	yes	Yes	Same
	Low Battery?	yes	yes	Yes	Same
	Voltage/Current Level?	Yes	yes	Yes	Same
Timer Range (minutes)		60mins	30mins--open	10-540mins;	SE
Compliance with Voluntary Standards?		yes	yes	Yes	Same
Compliance with 21 CFR 898[7]?		Yes	yes	Yes	Same
Weight		96g	93g (without battery)	25g	SE

Parameter	Subject Device	Predicate Device	Predicate Device	Remarks
		140g(with battery)		
Dimensions (mm) [W x H x D]	114×66×20	105 x 71 x 31	69.5x36.8x14	SE
Housing Materials and Construction	Silicone & ABS	not publicly available	Silicone & ABS	SE

Note 01: DC adaptor meets IEC 60601-1 standard.

Note 02: Number of Output Modes(programs) do not directly affect the affect safety and effectiveness of the subject device, for instance, the number of output modes for electrical stimulator model SEM44 (K171803) is respectively 35(EMS) and 15(TENS), and the number of output modes its predicate device model MT9001/LT3060 (K130802) is respectively 1(EMS) and 1(TENS). In addition, based on "Table 03: SE Detailed Comparison Table", P1, P2 , P3 of the subject device corresponds to P4 of K082011(type 281)and P7 of K162517 (PL-029K12); P4 corresponds to corresponds to P1 of K082011(type 281)and P3 of K162517 (PL-029K12), P5~P15 of the subject device corresponds also corresponds to one mode of K082011(type 281)and one mode of K162517 (PL-029K12). Also, according to the discussion in Note 03, Note 04, the difference between the parameters of mode of the subject device and the parameters of mode the predicate devices do not affect safety and effectiveness of the subject device, therefore, the difference of output mode number do not the determination of substantial equivalence.

Table 03: SE Detailed Comparison Table

Table 03-1：

Parameter		Subject Device K193275	Predicate Device K082011: Type 281	Predicate Device K162517: PL-029K12
Mode or Program Name		P1	P4	P7
Maximum Output Voltage (volts) (+/-20%)		30.0V@500Ω	37.5V@500Ω	40.8V@500Ω
		90.6V@ 2 kΩ	not publicly available	86.4V@ 2 kΩ
		123V@10 kΩ	not publicly available	129V@10 kΩ
Maximum Output Current (specify units) (+/- 20%)		60.0mA@500Ω	75.0mA@500Ω	81.6mA@500Ω
		45.3mA@ 2 kΩ	not publicly available	43.2mA@ 2 kΩ
		12.3mA@10 kΩ	not publicly available	12.9mA@10 kΩ
Pulse Duration/width† (μsec)		250	300	100 **(Note 03)**
Frequency† (Hz) [or Rate† (pps)]		35	35	19.8
For interferential modes only: -Beat Frequency (Hz)		N/A	N/A	N/A
For multiphasic waveforms only:	Symmetrical phases?	N/A	N/A	N/A
	Phase Duration† (include units), (state range, if applicable), (both phases, if asymmetrical)	N/A	N/A	N/A
Net Charge (microcoulombs (μC) per pulse) (If zero, state method of achieving zero net charge.)		15@500Ω	22.5@500Ω	16.3@500Ω
Maximum Phase Charge, (μC)		15@500Ω	22.5@500Ω	16.3@500Ω
Maximum Current Density,††(mA/cm².)		0.46@500Ω	0.43@500Ω	3.26@500Ω
Maximum Power Density,†† (W/cm²), (using smallest electrode conductive surface area)		0.0018@500Ω	0.0024@500Ω	0.00053@500Ω
Burst Mode (i.e., pulse trains):	(a) Pulses per burst	315 **(Note 04)**	245	NA
	(b) Bursts per second	0.11	0.14	NA
	(c) Burst duration (seconds)	9	7	NA
	(d) Duty Cycle: Line (b) x Line (c)	1	1	NA
ON Time (seconds)		9	7	3.4~20
OFF Time (seconds)		5	5	1~2.5
Additional Features (specify, if applicable)		N/A	N/A	N/A

Table 03-2：

Parameter	Subject Device K193275	Predicate Device K082011: Type 281	Predicate Device K162517: PL-029K12
Mode or Program Name	P2	P4	P7
Maximum Output Voltage (volts) (+/-20%)	30.0V@500Ω	37.5V@500Ω	40.8V@500Ω
	90.6V@ 2 kΩ	not publicly available	86.4V@ 2 kΩ
	125V@10 kΩ	not publicly available	129V@10 kΩ
Maximum Output Current (specify units) (+/- 20%)	60.0mA@500Ω	75.0mA@500Ω	81.6mA@500Ω
	45.3mA@ 2 kΩ	not publicly available	43.2mA@ 2 kΩ
	12.5mA@10 kΩ	not publicly available	12.9mA@10 kΩ
Pulse Duration/width† (μsec)	250	300	100 **(Note 03)**
Frequency† (Hz) [or Rate† (pps)]	35	35	19.8
For interferential modes only: -Beat Frequency (Hz)	N/A	N/A	N/A
For multiphasic waveforms only:	Symmetrical phases?	N/A	N/A	N/A
	Phase Duration† (include units), (state range, if applicable), (both phases, if asymmetrical)	N/A	N/A	N/A
Net Charge (microcoulombs (μC) per pulse) (If zero, state method of achieving zero net charge.)	15@500Ω	22.5@500Ω	16.3@500Ω
Maximum Phase Charge, (μC)	15@500Ω	22.5@500Ω	16.3@500Ω
Maximum Current Density,††(mA/cm².)	0.46@500Ω	0.43@500Ω	3.26@500Ω
Maximum Power Density,†† (W/cm²), (using smallest electrode conductive surface area)	0.0018@500Ω	0.0023@500Ω	0.00053@500Ω
Burst Mode (i.e., pulse trains):	(a) Pulses per burst	490**(Note 04)**	245	NA
	(b) Bursts per second	0.07	0.14	NA
	(c) Burst duration (seconds)	14	7	NA
	(d) Duty Cycle: Line (b) x Line (c)	1	1	NA
ON Time (seconds)	14	7	3.4~20
OFF Time (seconds)	10	5	1~2.5
Additional Features (specify, if applicable)	N/A	N/A	N/A

Table 03-3:

Parameter		Subject Device K193275	Predicate Device K082011: Type 281	Predicate Device K162517: PL-029K12
Mode or Program Name		P3	P4	P7
Maximum Output Voltage (volts) (+/-20%)		30.0V@500Ω	37.5V@500Ω	40.8V@500Ω
		90.6V@ 2 kΩ	not publicly available	86.4V@ 2 kΩ
		125Vpp@10 kΩ	not publicly available	129V@10 kΩ
Maximum Output Current (specify units) (+/- 20%)		60.0mA@500Ω	75.0mA@500Ω	81.6mA@500Ω
		45.3mA@ 2 kΩ	not publicly available	43.2mA@ 2 kΩ
		12.5mA@10 kΩ	not publicly available	12.9mA@10 kΩ
Pulse Duration† (μsec)		250	300	100 **(Note 03)**
Frequency† (Hz) [or Rate† (pps)]		35	35	19.8
For interferential modes only: -Beat Frequency (Hz)		N/A	N/A	N/A
For multiphasic waveforms only:	Symmetrical phases?	N/A	N/A	N/A
	Phase Duration† (include units), (state range, if applicable), (both phases, if asymmetrical)	N/A	N/A	N/A
Net Charge (microcoulombs (μC) per pulse) (If zero, state method of achieving zero net charge.)		15@500Ω	22.5@500Ω	16.3@500Ω
Maximum Phase Charge, (μC)		15@500Ω	22.5@500Ω	16.3@500Ω
Maximum Current Density,††(mA/cm².)		0.46@500Ω	0.43@500Ω	3.26@500Ω
Maximum Power Density,†† (W/cm²), (using smallest electrode conductive surface area)		0.0018@500Ω	0.0024@500Ω	0.00053@500Ω
Burst Mode (i.e., pulse trains):	(a) Pulses per burst	315**(Note 04)**	245	NA
	(b) Bursts per second	0.11	0.14	NA
	(c) Burst duration (seconds)	9	7	NA
	(d) Duty Cycle: Line (b) x Line (c)	1	1	NA
ON Time (seconds)		9	7	3.4~20
OFF Time (seconds)		5	5	1~2.5
Additional Features (specify, if applicable)		N/A	N/A	N/A

Table 03-4：

Parameter		Subject Device K193275	Predicate Device K082011: Type 281	Predicate Device K162517: PL-029K12
Mode or Program Name		P4	P1	P3
Maximum Output Voltage (volts) (+/-20%)		30.0V@500Ω	37.5V@500Ω	47.6V@500Ω
		90.6V@ 2 kΩ	not publicly available	96.0V@ 2 kΩ
		125V@10 kΩ	not publicly available	132V@10 kΩ
Maximum Output Current (specify units) (+/- 20%)		60.0mA@500Ω	75.0mA@500Ω	95.2mA@500Ω
		45.3mA@ 2 kΩ	not publicly available	48.0mA@ 2 kΩ
		12.5mA@10 kΩ	not publicly available	13.2mA@10 kΩ
Pulse Duration/width† (μsec)		250	300	100 **(Note 03)**
Frequency† (Hz) [or Rate† (pps)]		60	50	12.8~54.3
For interferential modes only: -Beat Frequency (Hz)		N/A	N/A	N/A
For multiphasic waveforms only:	Symmetrical phases?	N/A	N/A	N/A
	Phase Duration† (include units), (state range, if applicable), (both phases, if asymmetrical)	N/A	N/A	N/A
Net Charge (microcoulombs (μC) per pulse) (If zero, state method of achieving zero net charge.)		15@500Ω	22.5@500Ω	19.0@500Ω
Maximum Phase Charge, (μC)		15@500Ω	22.5@500Ω	19.0@500Ω
Maximum Current Density,††(mA/cm².)		0.60@500Ω	0.52@500Ω	2.64@500Ω
Maximum Power Density,†† (W/cm²), (using smallest electrode conductive surface area)		0.0031@500Ω	0.0034@500Ω	0.00032~0.00137@ 500Ω
Burst Mode (i.e., pulse trains):	(a) Pulses per burst	840**(Note 04)**	350	NA
	(b) Bursts per second	0.07	0.14	NA
	(c) Burst duration (seconds)	14	7	NA
	(d) Duty Cycle: Line (b) x Line (c)	1	1	NA
ON Time (seconds)		14	7	3.4~20
OFF Time (seconds)		10	5	1~2.5
Additional Features (specify, if applicable)		N/A	N/A	N/A

Table 03-5：

Parameter		Subject Device K193275	Predicate Device K082011: Type 281	Predicate Device K162517: PL-029K12
Mode or Program Name		P5	P3	P7
Maximum Output Voltage (volts) (+/-20%)		30.0V@500Ω	37.5V@500Ω	40.8V@500Ω
		90.6V@ 2 kΩ	not publicly available	86.4V@ 2 kΩ
		125V@10 kΩ	not publicly available	129V@10 kΩ
Maximum Output Current (specify units) (+/- 20%)		60.0mA@500Ω	75.0mA@500Ω	81.6mA@500Ω
		45.3mA@ 2 kΩ	not publicly available	43.2mA@ 2 kΩ
		12.5mA@10 kΩ	not publicly available	12.9mA@10 kΩ
Pulse Duration† (μsec)		300	300	100 **(Note 03)**
Frequency† (Hz) [or Rate† (pps)]		35	35	19.8
For interferential modes only: -Beat Frequency (Hz)		N/A	N/A	N/A
For multiphasic waveforms only:	Symmetrical phases?	N/A	N/A	N/A
	Phase Duration† (include units), (state range, if applicable), (both phases, if asymmetrical)	N/A	N/A	N/A
Net Charge (microcoulombs (μC) per pulse) (If zero, state method of achieving zero net charge.)		18@500Ω	22.5@500Ω	16.3@500Ω
Maximum Phase Charge, (μC)		18@500Ω	22.5@500Ω	16.3@500Ω
Maximum Current Density,††(mA/cm².)		0.50@500Ω	0.60@500Ω	3.26@500Ω
Maximum Power Density,†† (W/cm²), (using smallest electrode conductive surface area)		0.0022@500Ω	0.0045@500Ω	0.00053@500Ω
Burst Mode (i.e., pulse trains):	(a) Pulses per burst	420**(Note 04)**	245	NA
	(b) Bursts per second	0.08	0.14	NA
	(c) Burst duration (seconds)	12	7	NA
	(d) Duty Cycle: Line (b) x Line (c)	1	1	NA
ON Time (seconds)		12	7	3.4~20
OFF Time (seconds)		8	5	1~2.5
Additional Features (specify, if applicable)		N/A	N/A	N/A

Table 03-6：

Parameter		Subject Device K193275	Predicate Device K082011: Type 281	Predicate Device K162517: PL-029K12
Mode or Program Name		P6	P7	P7
Maximum Output Voltage (volts) (+/-20%)		30.0V@500Ω	37.5V@500Ω	40.8V@500Ω
		90.6V@ 2 kΩ	not publicly available	86.4V@ 2 kΩ
		125V@10 kΩ	not publicly available	129V@10 kΩ
Maximum Output Current (specify units) (+/- 20%)		60.0mA@500Ω	75.0mA@500Ω	81.6mA@500Ω
		45.3mA@ 2 kΩ	not publicly available	43.2mA@ 2 kΩ
		12.5mA@10 kΩ	not publicly available	12.9mA@10 kΩ
Pulse Duration† (μsec)		350	350	100 **(Note 03)**
Frequency† (Hz) [or Rate† (pps)]		35	35	19.8
For interferential modes only: -Beat Frequency (Hz)		N/A	N/A	N/A
For multiphasic waveforms only:	Symmetrical phases?	N/A	N/A	N/A
	Phase Duration† (include units), (state range, if applicable), (both phases, if asymmetrical)	N/A	N/A	N/A
Net Charge (microcoulombs (μC) per pulse) (If zero, state method of achieving zero net charge.)		21@500Ω	26.25@500Ω	16.3@500Ω
Maximum Phase Charge, (μC)		21@500Ω	26.25@500Ω	16.3@500Ω
Maximum Current Density,††(mA/cm².)		0.54@500Ω	0.47@500Ω	3.26@500Ω
Maximum Power Density,†† (W/cm²), (using smallest electrode conductive surface area)		0.0026@500Ω	0.0028@500Ω	0.00053@500Ω
Burst Mode (i.e., pulse trains):	(a) Pulses per burst	315**(Note 04)**	227	NA
	(b) Bursts per second	0.11	0.14	NA
	(c) Burst duration (seconds)	9	6.5	NA
	(d) Duty Cycle: Line (b) x Line (c)	1	1	NA
ON Time (seconds)		14	6.5	3.4~20
OFF Time (seconds)		10	5	1~2.5
Additional Features (specify, if applicable)		N/A	N/A	N/A

Table 03-7:

Parameter		Subject Device K193275	Predicate Device K082011: Type 281	Predicate Device K162517: PL-029K12
Mode or Program Name		P7	P7	P7
Maximum Output Voltage (volts) (+/-20%)		30.0V@500Ω	37.5V@500Ω	40.8V@500Ω
		89.1V@ 2 kΩ	not publicly available	86.4V@ 2 kΩ
		125V@10 kΩ	not publicly available	129V@10 kΩ
Maximum Output Current (specify units) (+/- 20%)		60.0mA@500Ω	75.0mA@500Ω	81.6mA@500Ω
		44.5mA@ 2 kΩ	not publicly available	43.2mA@ 2 kΩ
		12.5mA@10 kΩ	not publicly available	12.9mA@10 kΩ
Pulse Duration[†] (μsec)		350	350	100 **(Note 03)**
Frequency[†] (Hz) [or Rate[†] (pps)]		35	35	19.8
For interferential modes only: -Beat Frequency (Hz)		N/A	N/A	N/A
For multiphasic waveforms only:	Symmetrical phases?	N/A	N/A	N/A
	Phase Duration[†] (include units), (state range, if applicable), (both phases, if asymmetrical)	N/A	N/A	N/A
Net Charge (microcoulombs (μC) per pulse) (If zero, state method of achieving zero net charge.)		21@500Ω	26.25@500Ω	16.3@500Ω
Maximum Phase Charge, (μC)		21@500Ω	26.25@500ΩΩ	16.3@500Ω
Maximum Current Density,[††](mA/cm².)		0.54@500Ω	0.47@500Ω	3.26@500Ω
Maximum Power Density,[††] (W/cm²), (using smallest electrode conductive surface area)		0.0026@500Ω	0.0028@500Ω	0.00053@500Ω
Burst Mode (i.e., pulse trains):	(a) Pulses per burst	490**(Note 04)**	227	NA
	(b) Bursts per second	0.07	0.15	NA
	(c) Burst duration (seconds)	14	6.5	NA
	(d) Duty Cycle: Line (b) x Line (c)	1	1	NA
ON Time (seconds)		14	6.5	3.4~20
OFF Time (seconds)		10	5	1~2.5
Additional Features (specify, if applicable)		N/A	N/A	N/A

Table 03-8：

Parameter		Subject Device K193275	Predicate Device K082011: Type 281	Predicate Device K162517: PL-029K12
Mode or Program Name		P8	P7	P7
Maximum Output Voltage (volts) (+/-20%)		30.0V@500Ω	37.5V@500Ω	40.8V@500Ω
		89.1V@ 2 kΩ	not publicly available	86.4V@ 2 kΩ
		125V@10 kΩ	not publicly available	129V@10 kΩ
Maximum Output Current (specify units) (+/- 20%)		60.0mA@500Ω	75.0mA@500Ω	81.6mA@500Ω
		44.5mA@ 2 kΩ	not publicly available	43.2mA@ 2 kΩ
		12.5mA@10 kΩ	not publicly available	12.9mA@10 kΩ
Pulse Duration† (μsec)		350	350	100 **(Note 03)**
Frequency† (Hz) [or Rate† (pps)]		35	35	19.8
For interferential modes only: -Beat Frequency (Hz)		N/A	N/A	N/A
For multiphasic waveforms only:	Symmetrical phases?	N/A	N/A	N/A
	Phase Duration† (include units), (state range, if applicable), (both phases, if asymmetrical)	N/A	N/A	N/A
Net Charge (microcoulombs (μC) per pulse) (If zero, state method of achieving zero net charge.)		21@500Ω	26.25@500Ω	16.3@500Ω
Maximum Phase Charge, (μC)		21@500Ω	26.25@500Ω	16.3@500Ω
Maximum Current Density,††(mA/cm².)		0.54@500Ω	0.47@500Ω	3.26@500Ω
Maximum Power Density,†† (W/cm²), (using smallest electrode conductive surface area)		0.0026@500Ω	0.0028@500Ω	0.00053@500Ω
Burst Mode (i.e., pulse trains):	(a) Pulses per burst	315**(Note 04)**	227	NA
	(b) Bursts per second	0.11	0.15	NA
	(c) Burst duration (seconds)	9	6.5	NA
	(d) Duty Cycle: Line (b) x Line (c)	1	1	NA
ON Time (seconds)		9	6.5	3.4~20
OFF Time (seconds)		9	5	1~2.5
Additional Features (specify, if applicable)		N/A	N/A	N/A

Table 03-9：

Parameter		Subject Device K193275	Predicate Device K082011: Type 281	Predicate Device K162517: PL-029K12
Mode or Program Name		P9	P7	P3
Maximum Output Voltage (volts) (+/-20%)		30.0V@500Ω	37.5V@500Ω	47.6V@500Ω
		90.6V@ 2 kΩ	not publicly available	96.0V@ 2 kΩ
		125V@10 kΩ	not publicly available	132V@10 kΩ
Maximum Output Current (specify units) (+/- 20%)		60.0mA@500Ω	75.0mA@500Ω	95.2mA@500Ω
		45.3mA@ 2 kΩ	not publicly available	48.0mA@ 2 kΩ
		12.5mA@10 kΩ	not publicly available	13.2mA@10 kΩ
Pulse Duration† (μsec)		350	350	100 **(Note 03)**
Frequency† (Hz) [or Rate† (pps)]		60	35	12.8~54.3
For interferential modes only: -Beat Frequency (Hz)		N/A	N/A	N/A
For multiphasic waveforms only:	Symmetrical phases?	N/A	N/A	N/A
	Phase Duration† (include units), (state range, if applicable), (both phases, if asymmetrical)	N/A	N/A	N/A
Net Charge (microcoulombs (μC) per pulse) (If zero, state method of achieving zero net charge.)		21@500Ω	26.25@500Ω	19.0@500Ω
Maximum Phase Charge, (μC)		21@500Ω	26.25@500Ω	19.0@500Ω
Maximum Current Density,††(mA/cm².)		0.71@500Ω	0.47@500Ω	2.64@500Ω
Maximum Power Density,†† (W/cm²), (using smallest electrode conductive surface area)		0.0044@500Ω	0.0028@500Ω	0.00032~0.00137 @500Ω
Burst Mode (i.e., pulse trains):	(a) Pulses per burst	840**(Note 04)**	227	NA
	(b) Bursts per second	0.07	0.15	NA
	(c) Burst duration (seconds)	14	6.5	NA
	(d) Duty Cycle: Line (b) x Line (c)	1	1	NA
ON Time (seconds)		14	6.5	3.4~20
OFF Time (seconds)		10	5	1~2.5
Additional Features (specify, if applicable)		N/A	N/A	N/A

Table 03-10：

Parameter		Subject Device K193275	Predicate Device K082011: Type 281	Predicate Device K162517: PL-029K12
Mode or Program Name		P10	P8	P4
Maximum Output Voltage (volts) (+/-20%)		30.0V@500Ω	37.5V@500Ω	57.6V@500Ω
		89.1V@ 2 kΩ	not publicly available	93.6V@ 2 kΩ
		125V@10 kΩ	not publicly available	108V@10 kΩ
Maximum Output Current (specify units) (+/- 20%)		60.0mA@500Ω	75.0mA@500Ω	115.2mA@500Ω
		44.5mA@ 2 kΩ	not publicly available	46.8mA@ 2 kΩ
		12.5mA@10 kΩ	not publicly available	10.8mA@10 kΩ
Pulse Duration† (μsec)		200	80	100 **(Note 03)**
Frequency† (Hz) [or Rate† (pps)]		5	8	1.19
For interferential modes only: -Beat Frequency (Hz)		N/A	N/A	N/A
For multiphasic waveforms only:	Symmetrical phases?	N/A	N/A	N/A
	Phase Duration† (include units), (state range, if applicable), (both phases, if asymmetrical)	N/A	N/A	N/A
Net Charge (microcoulombs (μC) per pulse) (If zero, state method of achieving zero net charge.)		12@500Ω	6@500Ω	23.0@500Ω
Maximum Phase Charge, (μC)		12@500Ω	6@500Ω	23.0@500Ω
Maximum Current Density,††(mA/cm².)		0.16@500Ω	0.11@500Ω	3.20@500Ω
Maximum Power Density,†† (W/cm²), (using smallest electrode conductive surface area)		0.0002@500Ω	0.00014@500Ω	0.00004@500Ω
Burst Mode (i.e., pulse trains):	(a) Pulses per burst	15**(Note 04)**	52	NA
	(b) Bursts per second	0.33	0.15	NA
	(c) Burst duration (seconds)	3	6.5	NA
	(d) Duty Cycle: Line (b) x Line (c)	1	1	NA
ON Time (seconds)		3	6.5	3.4~20
OFF Time (seconds)		2	5	1~2.5
Additional Features (specify, if applicable)		N/A	N/A	N/A

Table 03-11:

Parameter		Subject Device K193275	Predicate Device K082011: Type 281	Predicate Device K162517: PL-029K12
Mode or Program Name		P11	P9	P4
Maximum Output Voltage (volts) (+/-20%)		29.7V@500Ω	37.5V@500Ω	57.6V@500Ω
		89.1V@ 2 kΩ	not publicly available	93.6V@ 2 kΩ
		125V@10 kΩ	not publicly available	108V@10 kΩ
Maximum Output Current (specify units) (+/- 20%)		59.4mA@500Ω	75.0mA@500Ω	115.2mA@500Ω
		44.5mA@ 2 kΩ	not publicly available	46.8mA@ 2 kΩ
		12.5mA@10 kΩ	not publicly available	10.8mA@10 kΩ
Pulse Duration† (μsec)		200	150	100 **(Note 03)**
Frequency† (Hz) [or Rate† (pps)]		4	4~99	1.19
For interferential modes only: -Beat Frequency (Hz)		N/A	N/A	N/A
For multiphasic waveforms only:	Symmetrical phases?	N/A	N/A	N/A
	Phase Duration† (include units), (state range, if applicable), (both phases, if asymmetrical)	N/A	N/A	N/A
Net Charge (microcoulombs (μC) per pulse) (If zero, state method of achieving zero net charge.)		11.9@500Ω	11.25@500Ω	23.0@500Ω
Maximum Phase Charge, (μC)		11.9@500Ω	11.25@500Ω	23.0@500Ω
Maximum Current Density,†† (mA/cm².)		0.14@500Ω	0.52@500Ω	3.20@500Ω
Maximum Power Density,†† (W/cm²), (using smallest electrode conductive surface area)		0.00016@500Ω	0.0033@500Ω	0.00004@500Ω
Burst Mode (i.e., pulse trains):	(a) Pulses per burst	N/A	N/A	NA
	(b) Bursts per second	N/A	N/A	NA
	(c) Burst duration (seconds)	N/A	N/A	NA
	(d) Duty Cycle: Line (b) x Line (c)	N/A	N/A	NA
ON Time (seconds)		Continuous	Continuous	3.4~20
OFF Time (seconds)		N/A	N/A	1~2.5
Additional Features (specify, if applicable)		N/A	N/A	N/A

Table 03-12：

Parameter		Subject Device K193275	Predicate Device K082011: Type 281	Predicate Device K162517: PL-029K12
Mode or Program Name		P12	P9	P5
Maximum Output Voltage (volts) (+/-20%)		29.7V@500Ω	37.5V@500Ω	29.6V@500Ω
		89.1V@ 2 kΩ	not publicly available	66.4V@ 2 kΩ
		125V@10 kΩ	not publicly available	126V@10 kΩ
Maximum Output Current (specify units) (+/- 20%)		59.4mA@500Ω	75.0mA@500Ω	59.2mA@500Ω
		44.5mA@ 2 kΩ	not publicly available	33.2mA@ 2 kΩ
		12.5mA@10 kΩ	not publicly available	12.6mA@10 kΩ
Pulse Duration† (μsec)		175	150	100 **(Note 03)**
Frequency† (Hz) [or Rate† (pps)]		125	4~99	104.1
For interferential modes only: -Beat Frequency (Hz)		N/A	N/A	N/A
For multiphasic waveforms only:	Symmetrical phases?	N/A	N/A	N/A
	Phase Duration† (include units), (state range, if applicable), (both phases, if asymmetrical)	N/A	N/A	N/A
Net Charge (microcoulombs (μC) per pulse) (If zero, state method of achieving zero net charge.)		10.4@500Ω	11.25@500Ω	11.8@500Ω
Maximum Phase Charge, (μC)		10.4@500Ω	11.25@500Ω	11.8@500Ω
Maximum Current Density,††(mA/cm².)		0.72@500Ω	0.52@500Ω	1.64@500Ω
Maximum Power Density,†† (W/cm²), (using smallest electrode conductive surface area)		0.0045@500Ω	0.0033@500Ω	0.00101@500Ω
Burst Mode (i.e., pulse trains):	(a) Pulses per burst	N/A	N/A	NA
	(b) Bursts per second	N/A	N/A	NA
	(c) Burst duration (seconds)	N/A	N/A	NA
	(d) Duty Cycle: Line (b) x Line (c)	N/A	N/A	NA
ON Time (seconds)		Continuous	Continuous	3.4~20
OFF Time (seconds)		N/A	N/A	1~2.5
Additional Features (specify, if applicable)		N/A	N/A	N/A

Table 03-13：

Parameter		Subject Device K193275	Predicate Device K082011: Type 281	Predicate Device K162517: PL-029K12
Mode or Program Name		P13	P6	P6
Maximum Output Voltage (volts) (+/-20%)		29.4V@500Ω	37.5V@500Ω	29.6V@500Ω
		89.1V@ 2 kΩ	not publicly available	66.4V@ 2 kΩ
		123V@10 kΩ	not publicly available	126V@10 kΩ
Maximum Output Current (specify units)　(+/- 20%)		58.8mA@500Ω	75.0mA@500Ω	59.2mA@500Ω
		44.5mA@ 2 kΩ	not publicly available	33.2mA@ 2 kΩ
		12.3mA@10 kΩ	not publicly available	12.6mA@10 kΩ
Pulse Duration† (μsec)		150 250	300	100 **(Note 03)**
Frequency† (Hz) [or Rate† (pps)]		125 4	50 10	104.1
For interferential modes only: -Beat Frequency (Hz)		N/A	N/A	N/A
For multiphasic waveforms only:	Symmetrical phases?	N/A	N/A	N/A
	Phase Duration† (include units), (state range, if applicable), (both phases, if asymmetrical)	N/A	N/A	N/A
Net Charge (microcoulombs (μC) per pulse) (If zero, state method of achieving zero net charge.)		8.8@500Ω 14.7@500Ω	22.5@500Ω 22.5@500Ω	11.8@500Ω
Maximum Phase Charge, (μC)		8.8@500Ω 14.7@500Ω	22.5@500Ω 22.5@500Ω	11.8@500Ω
Maximum Current Density,†† (mA/cm².)		0.66@500 Ω 0.15@500 Ω	0.52@500Ω 0.23@500Ω	1.64@500Ω
Maximum Power Density,†† (W/cm²), (using smallest electrode conductive surface area)		0.0038@500 Ω 0.0002@500 Ω	0.0034@500Ω 0.00068@500Ω	0.00101@500Ω
Burst Mode (i.e., pulse trains):	(a) Pulses per burst	N/A	N/A	NA
	(b) Bursts per second	N/A	N/A	NA
	(c) Burst duration (seconds)	N/A	N/A	NA
	(d) Duty Cycle: Line (b) x Line (c)	N/A	N/A	NA
ON Time (seconds)		Continuous	Continuous	3.4~20
OFF Time (seconds)		N/A	N/A	1~2.5

Table 03-14：

Parameter		Subject Device K193275	Predicate Device K082011: Type 281	Predicate Device K162517: PL-029K12
Mode or Program Name		P14	P9	P2
Maximum Output Voltage (volts) (+/-20%)		29.4V@500Ω	37.5V@500Ω	36.4V@500Ω
		90.6@ 2 kΩ	not publicly available	80.8V@ 2 kΩ
		125Vpp@10 kΩ	not publicly available	134V@10 kΩ
Maximum Output Current (specify units) (+/- 20%)		58.8mA@500Ω	75.0mA@500Ω	72.8mA@500Ω
		44.5mA@ 2 kΩ	not publicly available	40.4mA@ 2 kΩ
		12.5mA@10 kΩ	not publicly available	13.4mA@10 kΩ
Pulse Duration† (μsec)		100	150	100 **(Note 03)**
Frequency† (Hz) [or Rate† (pps)]		50	4~99	62.5
For interferential modes only: -Beat Frequency (Hz)		N/A	N/A	N/A
For multiphasic waveforms only:	Symmetrical phases?	N/A	N/A	N/A
	Phase Duration† (include units), (state range, if applicable), (both phases, if asymmetrical)	N/A	N/A	N/A
Net Charge (microcoulombs (μC) per pulse) (If zero, state method of achieving zero net charge.)		5.9@500Ω	11.25@500Ω	14.6@500Ω
Maximum Phase Charge, (μC)		5.9@500Ω	11.25@500Ω	14.6@500Ω
Maximum Current Density,††(mA/cm².)		0.34@500Ω	0.52@500Ω	2.02@500Ω
Maximum Power Density,†† (W/cm²), (using smallest electrode conductive surface area)		0.001@500Ω	0.0033@500Ω	0.00092@500Ω
Burst Mode (i.e., pulse trains):	(a) Pulses per burst	N/A	N/A	NA
	(b) Bursts per second	N/A	N/A	NA
	(c) Burst duration (seconds)	N/A	N/A	NA
	(d) Duty Cycle: Line (b) x Line (c)	N/A	N/A	NA
ON Time (seconds)		Continuous	Continuous	3.4~20
OFF Time (seconds)		N/A	N/A	1~2.5
Additional Features (specify, if applicable)		N/A	N/A	N/A

Table 03-15:

Parameter		Subject Device K193275	Predicate Device K082011: Type 281	Predicate Device K162517: PL-029K12
Mode or Program Name		P15	P9	P1 **(Note 05)**
Maximum Output Voltage (volts) (+/-20%)		29.7V@500Ω	37.5V@500Ω	/
		89.1V@ 2 kΩ	not publicly available	/
		125Vpp@10 kΩ	not publicly available	/
Maximum Output Current (specify units) (+/- 20%)		59.4mA@500Ω	75.0mA@500Ω	/
		44.5mA@ 2 kΩ	not publicly available	/
		12.5mA@10 kΩ	not publicly available	/
Pulse Duration† (μsec)		100~350	150	/
Frequency† (Hz) [or Rate† (pps)]		1~125	4~99	/
For interferential modes only: -Beat Frequency (Hz)		N/A	N/A	/
For multiphasic waveforms only:	Symmetrical phases?	N/A	N/A	/
	Phase Duration† (include units), (state range, if applicable), (both phases, if asymmetrical)	N/A	N/A	/
Net Charge (microcoulombs (μC) per pulse) (If zero, state method of achieving zero net charge.)		20.8@500Ω	11.25@500Ω	/
Maximum Phase Charge, (μC)		20.8@500Ω	11.25@500Ω	/
Maximum Current Density,††(mA/cm².)		1.02@500Ω	0.52@500Ω	/
Maximum Power Density,†† (W/cm²), (using smallest electrode conductive surface area)		0.0089@500Ω	0.0033@500Ω	/
Burst Mode (i.e., pulse trains):	(a) Pulses per burst	1~625	N/A	/
	(b) Bursts per second	0.2~1	N/A	/
	(c) Burst duration (seconds)	1~5	N/A	/
	(d) Duty Cycle: Line (b) x Line (c)	N/A	N/A	/
ON Time (seconds)		1~5	Continuous	/
OFF Time (seconds)		1~5	N/A	/
Additional Features (specify, if applicable)		N/A	N/A	/

Note 03: based on K 153704, pulse width is acceptable within 70~300.

Note 04: subject device's pulses per burst rate is significantly higher than the predicate device in Table 03-1 to Table 03-9 and significantly less in Table 03-10, 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.

Note 05: based on K162517, Mode P1 cycles the mode 2~8, therefore, the maximum parameters do not appear at the same time. For example, in all 8 modes, the Maximum Output Voltage is 134V@10 kΩ, which is in mode P2 (K162517), but in mode P2, the corresponding Maximum Power Density is 0.92@500Ω , which is not maximum in all 8 modes. Nevertheless, the maximum parameters will not exceed the range of mode 2~8, similarly, P15 of subject device can be customized within the parameters of its P1~P14. So, P15 of subject device is SE to P1 of K162517 when P1,P2….P14 is respectively SE to mode P2,P3…P7.

5.7 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 60601-1-11:2015 Medical Electrical Equipment - Part 1-11: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Requirements For Medical Electrical Equipment And Medical Electrical Systems Used In The Home Healthcare Environment

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.

5.8 Brief discussion of clinical tests
N/A.

5.9 Other information (such as required by FDA guidance/Test)

No.

5.10 Conclusions

The subject devices have all features of the predicate device. The few differences do not affect the safety and effectiveness of the subject devices.

Thus, the subject device is substantially equivalent to the predicate device.