March 21, 2024

Electronic Pulse Stimulator
% Salon Chen
System Engineer
IMD Medical & Drug Technology Services Institutions
Room 308, Building 11, No. 23 Jinqu Road
Wanjiang District, Dongguan City
ShenZhen City, Guangdong Province 518117
China

Re: K232439
Trade/Device Name: Electrical Stimulator System
Regulation Number: 21 CFR 882.5890; 21 CFR 890.5850
Regulation Name: Transcutaneous Electrical Nerve Stimulator For Pain Relief
Regulatory Class: Class II
Product Code: NUH, NGX
Dated: February 20, 2024
Received: February 20, 2024

Dear Salon Chen:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Robert Kang -S

for 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K232439

Device Name
Electrical Stimulator System

Indications for Use *(Describe)*

TENS (TENS 1 and TENS 2)

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.

PMS (STIM1 STIM2 STIM3 and STIM4)

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.

510(k) Summary- K232439

1. Submitter's Identification:

- Company Name: Gymmax Technology Shenzhen Co., Ltd.
- Establishment Registration Number: 3007689716
- Address:5F 4th Bldg., Heping Complex (4th Bldg. Huimingsheng Technology Park) Fuhai Subdistrict, Baoan District Shenzhen City, Guangdong Province 518103 P.R.C.
- Phone: +86-755-2912-4050
- Fax: +86-755-2912-4050
- Contact Person (Title): Benson Wang (General Manager)
- E-mail：benson_gmx@qq.com
- Date of Preparation: Feb.19, 2024

2. Name of the Device:

- Electrical Stimulator System
- Models: GMX-007 and GMX-006

3. Common Name and Classification:

- Stimulator, Nerve, Transcutaneous, Over-The-Counter

- Classification Product Code: NUH, NGX
- Regulation Number:21 CFR 882.5890
- Class: II

4. Predicate Device Information1:

- 510(k) Number: K171803
- Predicate Device Name: HIVOX OTC Electrical Stimulators Model SEM44 and Model SEM44-1
- Manufacturer: HivoxBiotek Inc.
- This predicate has not been subject to a design-related recall
- No reference devices were used in this submission.

5. Predicate Device Information2:

- 510(k) Number: K133929
- Predicate Device Name: Health Expert Electronic Stimulator, Model AST300Cand AST-300D
- Manufacturer: Shenzhen OSTO Technology Company Limited
- This predicate has not been subject to a design-related recall
- No reference devices were used in this submission.

6. Predicate Device Information3:

- 510(k) Number: K130802
- Predicate Device Name: OTC ELECTRICAL STIMULATOR (MT9001), OTC TENS DEVICE (LT3060)
- Manufacturer: SHENZHEN DONGDIXIN TECHNOLOGY CO, LTD
- This predicate has not been subject to a design-related recall
- No reference devices were used in this submission.

7. Application Correspondent

- Company Name: IMD Medical & Drug technology service institutions
- Phone: +86-18613190779
- Fax: +86-755-62809168
- Contact Person (Title): Salon Chen (System engineer)
- E-mail：33999439@qq.com
- Address: Room 308, Building 11, No. 23 Jinqu Road, Wanjiang District, Dongguan City, Guangdong Province, China

8. Device Description

The Electrical Stimulator System delivers electric pulses to the user's body areas such as aching muscles in shoulder, waist, back, arm, and leg. The portable and compact device has multiple modes of different pulse frequencies, including transcutaneous electrical nerve stimulation (TENS) and power muscle stimulation (PMS) that is also called Electrical Muscle Stimulation (EMS). It includes the operating elements of an M button, intensity increase

button, intensity decrease button, and can be attached and detached to electrodes.

The electrodes cleared include accessory electrodes, which may be packaged separately and/or together with the subject device.

The associated accessories include:

Belt * 1

Control Unit * 1

USB Charging Cable * 1

Belt Extension Kit * 1

Storage pouch * 1

9. Indications for Use

TENS (TENS 1 and TENS 2)

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.

PMS (STIM1、STIM2、STIM3 and STIM4)

To stimulate healthy muscles in order to improve and facilitate muscle performance.

10. Comparison to the predicate device

Electrical stimulation is the technological principle for both the subject and predicate device. In the EMS modes, electronic pulses are sent through electrode pads to passively exercise the affected muscle. When your muscle receives this signal, it contracts and flexes naturally, as it would during physical

exercise. And like with physical exercise, when the pulse ceases, the muscle relaxes and the cycle can start over again. In the TENS modes, the gentle electrical pulses were sent through electrode pads and into skin to block or shut out the pain message from ever reaching the brain from the source of the pain.

Table 1: Technological Characteristics

Elements of Comparison	Proposed Device	Predicate Device1 （K171803）	Predicate Device2 (K133929)	Predicate Device3 (K130802)	Judgment
Company Name	Gymmax Technology Shenzhen Co., Ltd.	HIVOX BIOTEK INC.	Shenzhen OSTO Technology Company Limited	SHENZHEN DONGDIXIN TECHNOLOGY CO, LTD	/
Device Name	Electrical Stimulator System	HIVOX OTC Electrical Stimulator/SEM44	Health Expert Electronic Stimulator, Model AST300C and AST-300D	OTC ELECTRICAL STIMULATOR (MT9001), OTC TENS DEVICE (LT3060)	/
Classification Product Code	NUH	NUH	NUH	NUH	SE
Subsequent Product Codes	NGX	NGX	NGX	NGX	SE
Regulation	21 CFR 882.5890	21 CFR 882.5890	21 CFR 882.5890	21 CFR 882.5890	SE
Classification Name	Transcutaneous electrical nerve stimulator for pain relief	Transcutaneous electrical nerve stimulator for pain relief	Transcutaneous electrical nerve stimulator for pain relief	Transcutaneous electrical nerve stimulator for pain relief	SE
Class	2	2	2	2	SE

Prescription or OTC		OTC	OTC	OTC	OTC	SE
Functions and design		Electrical stimulation	Electrical stimulation	Electrical stimulation	Electrical stimulation	SE
Power Source(s)		Rechargeable battery	4.5V (batteries, 3×1.5V AAA)	Adaptor Input: 100- 240Vac, 50-60Hz, 0.1A Output: 5Vdc, 1A Unit Input: 5Vdc, 1A	9V batteries	SE
Method of Line Current Isolation		Type BF Applied Part	N/A	Type BF Applied Part	N/A	SE
Patient Leakage Current	**Normal condition**	N/A	N/A	AC: 54.5μA, DC: 0.5μA	0.61μA	SE
	Single fault condition	N/A	N/A	AC:120.0μA, DC: 0.6μA	0.68μA	SE
Number of Output Modes		TENS: 2 EMS: 4	EMS: 35 TENS:15	EMS: 8 TENS:17	TENS: 1 EMS: 1	SE Note 3
Number of Output Channels		1	2	2	N/A	SE Note 3
Synchronous or Alternating		N/A	Synchronous	Synchronous	Alternating	SE

Method of Channel Isolation		By electrical circuit and software	By electrical circuit and software	Voltage Transform Isolation “BODY▼” and “ BODY▼” buttons for body channel, “ SOLE▲” and “SOLE▼” buttons for feet channel	By electrical circuit and software	SE
Regulated Current or Regulated Voltage?		Current control	Regulated voltage	Current control	Current control	SE
Software/Firmware/Microprocessor Control		Yes	Yes	Yes	Yes	SE
Automatic Overload Trip?		No	Yes	No	Yes	SE
Automatic No-Load Trip?		Yes	Yes	No	Yes	SE
Automatic Shut Off?		Yes	Yes	Yes	Yes	SE
Patient Override Control?		Yes	Yes	Yes	Yes	SE
Indicator Display	**On/Off Status?**	Yes	Yes	Yes	Yes	SE
	Low Battery?	Yes	Yes	Yes	Yes	SE
	Voltage/Current Level?	Yes	Yes	Yes	Yes	SE

Timer Range (minutes)	30minutes	5~100minutes	25 minutes	1-60 minutes	SE Note 3
Weight	40.6G [without pad]	89g (including belt clip, without batteries) 123g (including belt clip, and batteries)	2Kg (Without accessories)	128g (including batteries)	SE Note 4
Dimensions (in.) [W x H x D]	75*55*13.8 mm	132 x 63 x 29.5mm (including belt clip)	428mm x 428.8mm x 185mm	117 x 60 x 34 mm	SE Note 4
Housing Materials and Construction	ABS+PC	ABS	ABS	ABS	SE

Intended Use	TENS (TENS 1 and TENS 2) 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.	SEM44 (EMS): The device is designed to be used for stimulate healthy muscles in order to improve and facilitate muscle performance. SEM44 (TENS): The device is designed to be used for temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back, neck, upper extremities (arm), lower extremities (leg), abdomen and bottom due to strain from exercise or normal household work activities.	PMS (Mode 1~8) It is intended to stimulate healthy muscles in order to improve and facilitate muscle performance.	MT9001 - TENS: The device is designed 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. EMS: The device is designed to be used for stimulate healthy muscles in order to improve and facilitate muscle performance.	SE Note 1

Intended Use	PMS (STIM1、STIM2、STIM3 and STIM4) To stimulate healthy muscles in order to improve and facilitate muscle performance.	SEM44-1 – TENS: The device is designed to be used for temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back, neck, upper extremities (arm), lower extremities (leg), abdomen and bottom due to strain from exercise or normal household work activities.	TENS (Mode 9~25) To be used for temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back, back of the neck, arm, leg, and foot due to strain from exercise or normal household work activities by applying current to stimulate nerve.	LT3060 - TENS: The device is designed 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.	SE Note 1

Table 2: Output Specifications

Safety factor & Performance		Proposed Device	Predicate Device1	Predicate Device2	Predicate Device3		Judgment
Electrical Safety		Compliance with IEC 60601-1	Compliance with IEC 60601-1	Compliance with IEC 60601-1	Compliance with IEC 60601-1		SE
EMC		Compliance with IEC 60601-1-2	Compliance with IEC 60601-1-2	Compliance with IEC 60601-1-2	Compliance with IEC 60601-1-2		SE
Biocompatibility		Compliance with ISO 10993-1	Compliance with ISO 10993-1	Compliance with ISO 10993-1	Compliance with ISO 10993-1		SE
Performance		Compliance with IEC 60601-2-10:2012 medical electrical equipment - part 2-1	Compliance with IEC 60601-2-10:2012 medical electrical equipment - part 2-1	Compliance with IEC 60601-2-10:2012 medical electrical equipment - part 2-1	Compliance with IEC 60601-2-10:2012 medical electrical equipment - part 2-1		SE
Waveform		Biphasic, symmetrical	Biphasic, square	Pulsed, symmetric, Biphasic, Rectangular	Biphasic Square		SE
Burst Mode	**Pulses per burst**	2	3	--	7	N/A	SE
	Bursts per second	5 / 50Hz	2/60Hz	--	0.5/1/2/3/4/5 Hz	N/A	SE
	Burst duration (seconds)	20ms	36ms	--	70ms	N/A	SE

	Duty Cycle [Line(b) x Line (c)]	20ms/100ms	36ms/390ms	--	35ms/350ms	N/A	SE
ON Time (seconds)		0.25s~6.5s	2s	0.6s	N/A	1-30	SE
OFF Time (seconds)		0.25s~4.6s	2s	0.6s	N/A	1-60	SE
Maximum output voltage (volts+/-20%) at 500Ω		TENS 1:112 TENS 2: 114 STIM1:116 STIM2:116 STIM3:76 STIM4: 70	100±10 % (50±10 %(Vp))	44±10%	96±20% (48±20% (Vp))		(Note 1)
Maximum output voltage (volts+/-20%) at 2KΩ		TENS 1: 250 TENS 2: 240 STIM1: 250 STIM2: 250 STIM3: 158 STIM4: 146	180±10 % (90±10 %(Vp))	80±10%	200±20% (100±20% (Vp))	228±20% (114±20% (Vp))	(Note 2)
Maximum output voltage (volts+/-20%) at 10KΩ		TENS 1: 300 TENS 2: 286 STIM1: 310 STIM2: 308 STIM3: 278 STIM4: 276	250±10 % (125±10 %(Vp))	112±10%	210±20% (105±20% (Vp))	230±20% (115±20% (Vp))	(Note 2)

Maximum output current (mA+/-20%) at 500Ω	TENS 1: 224 TENS 2: 228 STIM1: 232 STIM2: 232 STIM3: 152 STIM4：140	200±10 % (100±10 %(Ip))	88±10%	96±20%		(Note 2)
Maximum output current (mA+/-20%) at 2KΩ	TENS 1:125 TENS 2: 120 STIM1: 125 STIM2: 125 STIM3:79 STIM4: 73	90±10 % (45±10 %(Ip))	40±10%	50±20%	57±20%	(Note 2)
Maximum output current (mA+/-20%) at 10KΩ	TENS 1: 30 TENS 2: 28.6 STIM1: 31 STIM2:30.8 STIM3: 27.8 STIM4: 27.6	25±10 % (12.5±10 %(Ip))	11.2±10%	10.5±20%	11.5±20%	(Note2)
Pulse period (mSec)	20~200	50-450μs	120μs	50-300μS		(Note 2)
Frequency (Hz)	TENS 1: 33 TENS 2: 5 STIM1:37 STIM2:25 STIM3: 5 STIM4: 50	1-150Hz	77.3Hz	1-150Hz		(Note 2)

Maximum Phase charge(μC) at 500Ω	TENS 1: 11 TENS 2: 11 STIM1: 11.4 STIM2: 10.6 STIM3: 22.8 STIM4: 20.4	0.045	12.78μC @ 500Ω	0.0288@500Ω(mC)	(Note 2)
Maximum charge density(mA/cm²) at 500Ω	TENS 1: 0.024 TENS 2: 0.01 STIM1:0.027 STIM2: 0.021 STIM3: 0.021 STIM4: 0.059	0.667	0.235mA/cm² @ 500Ω	1.15@500Ω	(Note 2)
Maximum average power density(mw/cm²) at 500Ω	TENS 1: 1.33 TENS 2: 0.554 STIM1: 1.54 STIM2: 1.13 STIM3: 0.793 STIM4: 2.01	0.0046	1.38mW/cm² @ 500Ω	4.32@500Ω	(Note 2)

As shown in the above comparison Table, the six modes of the subject device, have the technical characteristics (such as maximum output voltage, maximum output current, maximum current density, and maximum average power density) in similarity to the predicate device. Accordingly, we are substantially equivalent to the predicate device HIVOX OTC Electrical Stimulators Model SEM44 and Model SEM44-1 (K171803) &Health Expert Electronic Stimulator, Model AST300Cand AST-300D (K133929) &OTC ELECTRICAL STIMULATOR (MT9001) &OTC TENS DEVICE (LT3060) (K130802).

Design and Technology –The basic design and technology of providing electrical stimulation is the same or similar.

Performance and Specifications – The subject device has similar electrical stimulation and specifications to the predicate device.

Indications – The indications are same.

Review of Differences：

Note 1:

The "Intended Use" of the subject device is the substantially equivalent to the predicate devices selected, all have adopted TENS (Transcutaneous Electrical Nerve Stimulation) and EMS (Electrical Muscle Stimulation) technologies to the treatment of temporary relief of pain associate with sore and aching muscles and/or the muscle performance improvement of healthy muscles respectively. Meanwhile, the" Product Code" of the subject device is the same as the predicate devices. This define does not affect the intended use or normal use of the subject device.

Note 2:

The maximum out voltage and maximum output current under 500Ω,2KΩ and 10KΩ resistance of candidate device are different from predicate device due to different design. The performance test was conducted to verify the maximum output voltage and maximum out current of candidate device under the acceptance criteria followed IEC 60601-2-10:2012 +A1:2016+A2:2023。

The candidate device has also demonstrated the electrical safety by passing 60601-1:2005+A1:2012+A2:2020, IEC 60601-1-11:2020 and IEC 60601-2-10:2012 +A1:2016+A2:2023, therefore, the different maximum out voltage will not affect the electrical safety of the candidate device.

We have found 510(K) cleared reference deviceK171803、K133929and K130802 has difference maximum output voltage and maximum out current with the candidate device, which demonstrate that the design of candidate device doesn’t impact and effectiveness.

Pulse Width

The difference in pulse width between the subject device and the predicate device is having different sensation when delivered to human body.Different pulse width will lead to different output charge.The bigger pulse width has more energy than smaller pulse width. A large mount of charge will give more obviou

s sensation to human body, but the charge is still within the required safety performance range according to the safety calculation.

Therefore, the difference does not raise new questions of safety and effectiveness as compared to the predicate devices.

Maximum Phase Charge

The reason that the subject device's phase charge is higher than the predicate is because the allowed voltage is higher than predicate device's at 500Ω. However, the subject device's phase charge is still in the safety range. In addition, the negative phase charge and the positive phase charge are always balanced out. Therefore, the difference does not raise new questions of safety and effectiveness as compared to the predicate devices.

Frequency range

Frequency for the subject device is 5~50Hz and it falls into the subject device frequency of 1~150 Hz. So the difference doesn't raise new questions of safety and effectiveness. This difference doesn't raise new questions of safety and effectiveness. As demonstrated, the differences between the subject and predicate devices do not affect the intended use or alter the fundamental technology of the device. There are no new safety or effectiveness issues concerning the subject device, which offers substantially equivalent technical specifications, features, intended use, safety, and effectiveness as the predicate device. Bench tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

Note 3:

Although the " Number of Output Modes", "Number of Output Channels", and "Timer Range" of the subject device are a little different from the predicate devices, they are all complaint with requirement of IEC6060-1:2005+A1:2012+A2:2020、IEC 60601-1-2:2014 /AMD1:2020 and IEC 60601-2-10:2012 +A1:2016+A2:2023 standard. So these differences will not raise any safety or effectiveness issue.

Note 4:

Although the “Weight” and “Dimensions” of the subject device are different from the predicate devices, these differences are insignificant in the terms of safety or effectiveness.

1) Electrical safety

IEC6060-1:2005+A1:2012+A2:2020 Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance.

2) Electromagnetic compatibility (EMC)

IEC 60601-1-2:2014 /AMD1:2020 Medical Electrical Equipment -- Part 1-2: General Requirements For Basic Safety And Essential Performance -- Collateral Standard: Electromagnetic Disturbances -- Requirements And Tests.

3) Basic Safety and Essential Performance

IEC 60601-1-11:2020: 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 60601-2-10:2012 +A1:2016+A2:2023medical electrical equipment - part 2-10: particular requirements for the basic safety and essential performance of nerve and muscle stimulators.

IEC 60601-1-6 :2010+A1:2013+A2:2020Medical Electrical Equipment - Part 1-6: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Usability.

4) Software Verification and Validating Testing

Software verification and validation testing were conducted and documentation was provided as recommended by FDA’s Guidance for Industry and FDA

Staff, “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices.” The software for this device was considered as a “Moderate” level of concern.

5) Biocompatibility testing

ISO 10993-1:2009 Biological evaluation of medical devices-Parts 1: Evaluation and testing.

ISO 10993-10:2021 Biological evaluation of medical devices-Parts 10: Tests for skin sensitization

ISO 10993-23:2021 Biological evaluation of medical devices-Parts 10: Tests for irritation

11. Discussion of Non-clinical Tests Performed for Determination of Substantial Equivalence are as follows:

The proposed device is the same as the predicate device but the two devices are different. A series of safety and performance tests were conducted on the subject device:

Biocompatibility

Software Validation

Electromagnetic compatibility and electrical safety

Function test (Including output waveform, stimulation parameters and current distribution on the electrodes)

All the test results demonstrate Electrical Stimulator System meets the requirements of its pre-defined acceptance criteria and intended uses, and is substantially equivalent to the predicate devices.

12. Clinical Tests Performed

No clinical test data was used to support the decision of substantial equivalence.

13. Conclusion

The subject devices have all features of the predicate devices. The few differences do not affect the safety and effectiveness of the subject devices. Thus, the subject devices are substantially equivalent to the predicate devices.