May 16, 2024

Edan Instruments, Inc.
Tracy Yue
Regulatory Affairs Engineer
#15 Jinhui Road, Pingshan District
Shenzhen, Shenzhen 518122
China

Re: K232786
Trade/Device Name: Stimulation System (PA series, PR series, S series and Q series)
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered Muscle Stimulator
Regulatory Class: Class II
Product Code: IPF, GZJ
Dated: September 08, 2023
Received: September 11, 2023

Dear Tracy Yue:

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,

Jitendra V. Virani -S

CDR Jitendra Virani, MS, MBA
Assistant Director
DHT5B: Division of Neuromodulation
and Rehabilitation 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)*
K232786

Device Name
Stimulation System
Model: PA4 Pro; PA4; PA36; PA38; PR4 Pro; PR4; PR36; PR38; Q3; Q9; Q10; Q12; S6; S9; S10; S12;

Indications for Use *(Describe)*

PA&PR series:
The PA&PR series are a neuromuscular electrical stimulator indicated for use under medical supervision for adjunctive therapy in the treatment of medical diseases and conditions.
As a powered muscle stimulator, PA&PR series are indicated for the following conditions:
• Relaxation of muscle spasms,
• Prevention or retardation of disuse atrophy,
• Increasing local blood circulation,
• Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis,
• Maintaining or increasing range of motion,
• Muscle re-education.

Environments of Use: Clinics, hospital.
Patient population: Adults

S&Q series:
The S&Q series are a neuromuscular electrical stimulator indicated for use under medical supervision for adjunctive therapy in the treatment of medical diseases and conditions.
As a powered muscle stimulator, S&Q series are indicated for the following conditions:
• Relaxation of muscle spasms,
• Prevention or retardation of disuse atrophy,
• Increasing local blood circulation,
• Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis,
• Maintaining or increasing range of motion,
• Muscle re-education.
As a transcutaneous electrical nerve stimulator for pain relief, S&Q series are indicated for the following conditions:
• Symptomatic relief and management of chronic (long-term), intractable pain,
• Adjunctive treatment in the management of post-surgical pain and post traumatic acute pain.

Environments of Use: Clinics, hospital and home environments.
Patient population: Adults

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
Prepared in accordance with the content and format regulatory Requirements of 21 CFR Part 807.92

1. Submitter:

Edan Instruments, Inc.
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Kengzi Sub-District, Pingshan District,
Shenzhen, 518122 P.R.China.
Tel: +86(0755) 26858736
Fax: +86(0755) 26882223

Contact person: Liu Yongying
Preparing date: April 29, 2024

2. Device name and classification:

Trade Name: Stimulation System
Common/Usual Name: PA series, PR series, Q series, S series
Model:
PA series: PA4 Pro; PA4; PA36; PA38;
PR series: PR4 Pro; PR4; PR36; PR38;
Q series: Q3; Q9; Q10; Q12;
S series: S6; S9; S10; S12;

Classification Name	**Product code**
21 CFR 890.5850 Physical Medicine	IPF
21 CFR 882.5890 Neurological	GZJ

Regulatory Class: Class II

3. Predicate Device(s):

1) Otto Bock Healthcare Product GmbH, STIWELL med4, cleared under K080950 (Predicate device).

4. Device Description:

Subject device have four series, which are PA series, PR series, Q series and S series. These four series are all electrical stimulating devices.

5. Indication for Use

PA&PR series：
The PA&PR series are a neuromuscular electrical stimulator indicated for use under medical supervision for adjunctive therapy in the treatment of medical diseases and conditions.
As a powered muscle stimulator, PA&PR series are indicated for the following conditions:

- Relaxation of muscle spasms,
- Prevention or retardation of disuse atrophy,
- Increasing local blood circulation,
- Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis,
- Maintaining or increasing range of motion,
- Muscle re-education.

Environments of Use: Clinics, hospital.
Patient population：Adults

S&Q series：
The S&Q series are a neuromuscular electrical stimulator indicated for use under medical supervision for adjunctive therapy in the treatment of medical diseases and conditions.
As a powered muscle stimulator, S&Q series are indicated for the following conditions:

- Relaxation of muscle spasms,
- Prevention or retardation of disuse atrophy,
- Increasing local blood circulation,
- Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis,
- Maintaining or increasing range of motion,
- Muscle re-education.

As a transcutaneous electrical nerve stimulator for pain relief, S&Q series are indicated for the following conditions:

- Symptomatic relief and management of chronic (long-term), intractable pain,
- Adjunctive treatment in the management of post-surgical pain and post traumatic acute pain.

Environments of Use: Clinics, hospital and home environments.
Patient population：Adults

6. Predicate Device Comparison

Comparison to the predicate devices, the subject device has the same intended use, similar product design, similar performance effectiveness, the different technological characteristics of Subject device dose not raise different questions of safety and effectiveness. The summary is as following tables:

Subject device (PA&PR series)compares with predicate device

The following tabulation indicates the detailed differences between the subject device (PA&PR series) and the predicate device, we use the maximum configurations to compare with predicate device, and it can cover all other models.

Item	< **Predicate Device** > STIWELL med4	< **Subject Device** > PA&PR series	**Comparison Result**
Manufacturer /K#	K080950	Current Submission	——
Indication for use	The STIWELL med4 is a neuromuscular electronic stimulator indicated for use under medical supervision for adjunctive therapy in the treatment of medical diseases and conditions. **As a powered muscle stimulator**, STIWELL med4 is indicated for the following conditions: • Relaxation of muscle spasms, • Prevention or retardation of disuse atrophy, • Increasing local blood circulation, • Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis, • Maintaining or increasing range of motion, • Muscle re-education.	The PA&PR series are a neuromuscular electronic stimulator indicated for use under medical supervision for adjunctive therapy in the treatment of medical diseases and conditions. **As a powered muscle stimulator,** PA&PR series are indicated for the following conditions: • Relaxation of muscle spasms, • Prevention or retardation of disuse atrophy, • Increasing local blood circulation, • Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis, • Maintaining or increasing range of motion, • Muscle re-education.	Similar, The indications for use of the targeted device is within that of the predicate device

	As a transcutaneous electrical nerve stimulator for pain relief, STIWELL med4 is indicated for the following conditions: • Symptomatic relief and management of chronic (long-term), intractable pain, • Adjunctive treatment in the management of post-surgical pain and post traumatic acute pain. **As a biofeedback device**, STIWELL med4 is indicated for: • Biofeedback, relaxation, and muscle re-education. **As an external functional neuromuscular stimulator，** STIWELL med4 is indicated for the following conditions: - Helps to relearn voluntary motor functions of the extremities. **As a non-implanted electrical continence device**, STIWELL med4 is indicated for the following conditions: • Acute and ongoing treatment of stress, urge or mixed urinary incontinence and where the following results may improve urinary control: inhibition of the detrusor muscles through reflexive mechanisms and strengthening of pelvic floor muscles. • Incontinence treatment for assessing EMG activity of the pelvic floor and accessory muscles such as abdominal and the gluteus muscles.		

Product codes	IPF, GZJ, HCC, GZI, KPI	IPF	Similar
Environment of Use	Clinics, hospital and home environments	Clinics, hospital	Similar
Patient population	Adults	Adults	Same
Power Source	Battery Pack Li-Ion 11.1 V	AC or Lithium-ion Battery 14.4V	Different Note(1)
Method of Line Current Isolation	Medical Class II Power Adapter	Medical Class I Power Adapter	
Patient Leakage Current (normal condition)	<100 μ A	<100μA	Same
Patient Leakage Current (single fault condition)	<100 μ A	<100μA	
Number of Output Modes	4	3	Different Note(2)
Number of Output Channels	4	4	Same
Synchronous or Alternating	Alternating	Alternating	Same
Method of channel isolation	Transformer, inductive couplers	Transformer	Different Note(3)
Regulated Current or Regulated Voltage	Regulated Current	Regulated Current	Same
Software/Firmware/ Microprocessor Control	Yes	Yes	Same
Automatic Overload trip	Yes	Yes	Same
Automatic no-load trip	Yes	Yes	Same
Automatic Shut Off	Yes	Yes	Same
Patient override control	Yes(Stop Button)	Yes(Stop Button)	Same

method			
Indicator display -On/Off status -Low battery -Voltage/current level	Yes	Yes	Same
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; IEC 60601-2-40;	Same
Compliance with 21 CFR 898	YES	YES	Same
Dimensions	175×95×30mm	270mm*232mm*55mm	Different Note(4)
Weight	440g	≤3 kg	
Housing material and Construction	Plastic (Injection Molded ABS)	Plastic (Injection Molded ABS)	Same

Note (1):

Although the "Power Source" and "Method of Line Current Isolation" are different from predicate device, Subject device is compliant with IEC 62133 standard. Moreover, the Subject device is IEC 60601-1 compliant and has been tested for electrical safety. The difference between them does not raise different questions of safety and effectiveness of Subject device

Note (2):

The "Number of Output Modes" of Subject device are covered by predicate device，the difference between them does not raise different questions of safety and effectiveness of Subject device.

Note (3):

The "Method of channel isolation" of Subject device is different from predicate device, but the Subject device is IEC 60601-1 compliant and has been tested for electrical safety. Thus the difference between them does not raise different questions of safety and effectiveness of Subject device.

Note (4):

Although "Weight" and "Dimensions" of Subject device are different from predicate devices, they all comply with IEC 60601-1, IEC 60601-2-10 requirements, thus the difference between them does not raise different questions of safety and effectiveness of Subject device.

As a powered muscle stimulator（PMS）			
Item	< **Predicate Device** > STIWELL med4	< **Subject Device** > PA&PR series	**Comparison Result**
Manufacturer /K#	K080950	Current Submission	/
Output specifications			
Waveform	Biphasic symmetrical	Biphasic symmetrical	Same
Shape	Rectangular	Rectangular	
Maximum output Voltage(500Ω)	50V	50V	Same
Maximum output current(500Ω)	100mA	100mA	Same
Maximum output Voltage(2kΩ)	115V	145V	Similar Note 1 PMS
Maximum output current(2kΩ)	58mA	72.5mA	
Maximum output Voltage(10kΩ)	125V	150V	
Maximum output current(10kΩ)	14mA	15mA	
Pulse duration	50-400μs	50-400μs	Same
Pulse frequency	1-140Hz	2-140Hz	Similar
For interferential modes only: -Beat Frequency (Hz)	N/A	N/A	Same
For multiphasic waveforms only: -Symmetrical phases?	N/A	N/A	Same
For multiphasic	N/A	N/A	Same

waveforms only: -Phase Duration			
Net Charge(per pulse)（500Ω）	0μC	0μC	Same
Maximum Phase Charge（500Ω）	40μC	40μC	Same
Maximum current density（500Ω）	12.5mA/cm^2	12.5mA/cm^2	Same
Maximum power density（500Ω）	7.9mW/cm^2	7.9mW/cm^2	Same
Burst Mode	N/A	N/A	Same
ON Time	1 - 20 s	1 - 20 s	Same
OFF Time	1 - 50 s	1 - 20 s	Different
Treatment Time range	2-120min	1-60min，adjustable	Note2 PMS

Note1 PMS:

At impedances of 2kΩ and 10kΩ, the Maximum output current is determined by the Maximum output Voltage of the subject device. The Maximum output Voltage of the subject device is slightly higher than that of the predicate device, and the maximum output current is also slightly higher than that of predicate device, but the maximum output current is within the range of 100mA.

Also, the working principle of the subject device is to electrically stimulate the human body through a constant current output, and performance is determined by the current density. The maximum current density of subject device and predicate device is the same.

Therefore, the different technological characteristics of Subject device do not raise any different questions of safety and effectiveness.

Note2 PMS：

The “OFF Time” and “Treatment Time range” of Subject device are covered by the predicate device, thus the different technological characteristics of Subject device do not raise different questions of safety and effectiveness.

Subject device (S&Q series) compares with predicate devices

The following tabulation indicates the detailed comparison between the subject device(S&Q series) and the predicate device, we use the Maximum configuration to compare with predicate device, and it can cover all other models.

Item	< predicate Device > STIWELL med4	< Subject Device > S&Q series	Comparison Result
Manufacturer /K#	K080950	Current Submission	——
Indication for use	The STIWELL med4 is a neuromuscular electronic stimulator indicated for use under medical supervision for adjunctive therapy in the treatment of medical diseases and conditions. As a powered muscle stimulator, STIWELL med4 is indicated for the following conditions: • Relaxation of muscle spasms, • Prevention or retardation of disuse atrophy, • Increasing local blood circulation, • Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis, • Maintaining or increasing range of motion. • Muscle re-education, As a transcutaneous electrical nerve stimulator for pain relief, STIWELL med4 is indicated for the following conditions: • Symptomatic relief and management of chronic (long-term), intractable pain,	The S&Q series are a neuromuscular electronic stimulator indicated for use under medical supervision for adjunctive therapy in the treatment of medical diseases and conditions. As a powered muscle stimulator, S&Q series are indicated for the following conditions: • Relaxation of muscle spasms, • Prevention or retardation of disuse atrophy, • Increasing local blood circulation, • Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis, • Maintaining or increasing range of motion. • Muscle re-education,	Similar, The indications for use of the targeted device is within that of the predicate device

	• Adjunctive treatment in the management of post-surgical pain and post traumatic acute pain. As a biofeedback device, STIWELL med4 is indicated for: • Biofeedback, relaxation, and muscle re-education. As an external functional neuromuscular stimulator，STIWELL med4 is indicated for the following conditions: - Helps to relearn voluntary motor functions of the extremities. As a non-implanted electrical continence device, STIWELL med4 is indicated for the following conditions: • Acute and ongoing treatment of stress, urge or mixed urinary incontinence and where the following results may improve urinary control: inhibition of the detrusor muscles through reflexive mechanisms and strengthening of pelvic floor muscles. • Incontinence treatment for assessing EMG activity of the pelvic floor and accessory muscles such as abdominal and the gluteus muscles.	As a transcutaneous electrical nerve stimulator for pain relief, S&Q series are indicated for the following conditions: • Symptomatic relief and management of chronic (long-term), intractable pain, • Adjunctive treatment in the management of post-surgical pain and post traumatic acute pain.	
Product codes	IPF, GZJ, HCC, GZI, KPI	IPF, GZJ	Similar
Environment of Use	Clinics, hospital and home environments	Clinics, hospital and home environments	Same
Patient population	Adults	Adults	Same

Power Source	Battery Pack Li-Ion 11.1 V	Lithium-ion Battery 3.7V	Different Note(1)
Method of Line Current Isolation	Medical Class II Power Adapter	Internal Power Supply, Charging for class II	
Patient Leakage Current (normal condition)	<100 μ A	<100 μ A	Same
Patient Leakage Current (single fault condition)	<100 μ A	<100 μ A	
Number of Output Modes	4	3	Different Note(2)
Number of Output Channels	4	2	
Synchronous or Alternating	Alternating	Alternating	Same
Method of channel isolation	Transformer, inductive couplers	Optocoupler	Different Note(3)
Regulated Current or Regulated Voltage	Regulated Current	Regulated Current	Same
Software/Firmware/ Microprocessor Control	Yes	Yes	Same
Automatic Overload trip	Yes	Yes	Same
Automatic no-load trip	Yes	Yes	Same
Automatic Shut Off	Yes	Yes	Same
Patient override control method	Yes(Stop Button)	Yes(Stop Button)	Same
Indicator display -On/Off status -Low battery	Yes	Yes	Same

-Voltage/current level			
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; IEC 60601-2-40; IEC 60601-1-11;	Similar
Compliance with 21 CFR 898	YES	YES	Same
Dimensions	175×95×30mm	127 mm×66 mm×25mm	Different Note(4)
Weight	440g	≤220g（including the battery）	
Housing material and Construction	Plastic (Injection Molded ABS)	Plastic (Injection Molded ABS)	Same

Note (1):

Although the "Power Source" and "Method of Line Current Isolation" are different from Predicate Devices, Subject device are compliant with IEC 62133 standard. Moreover, the Subject device are IEC 60601-1 compliant and has been tested for electrical safety. The different technological characteristics of the Subject device do not raise different questions of safety and effectiveness.

Note (2):

The "Number of Output Modes" and "Number of Output Channels" of Subject device are covered by predicate devices, the different technological characteristics of the Subject device do not raise different questions of safety and effectiveness.

Note (3):

Although "Method of channel isolation" is different from the predicate devices, Subject device are IEC 60601-1 compliant and has been tested for electrical safety with a positive result and Patient Leakage Current. The different technological characteristic of the Subject device does not raise different questions of safety and effectiveness.

Note (4):

Although "Weight" and "Dimensions" of Subject device are different from the predicate devices, they all comply with IEC 60601-1, IEC 60601-2-10 requirements, thus the difference between them doesn't affect the performance and safety of the Subject device.

As a powered muscle stimulator（PMS）

Item	< predicate Device >	< Subject Device >	Comparison Result

	STIWELL med4	S&Q series	
Manufacturer /K#	K080950	Current Submission	/
Output specifications			
Waveform	Biphasic symmetrical	Biphasic symmetrical	Same
Shape	Rectangular	Rectangular	
Maximum output Voltage(500Ω)	50V	50V	Same
Maximum output current(500Ω)	100mA	100mA	Same
Maximum output Voltage(2kΩ)	115V	110V	Similar Note 1 PMS
Maximum output current(2kΩ)	58mA	55mA	
Maximum output Voltage(10kΩ)	125V	115V	
Maximum output current(10kΩ)	14mA	11mA	
Pulse duration	50-400μs	50-400μs	Same
Pulse frequency	1-140Hz	2-140Hz	Similar
For interferential modes only: -Beat Frequency (Hz)	N/A	N/A	Same
For multiphasic waveforms only: -Symmetrical phases?	N/A	N/A	Same
For multiphasic waveforms only: -Phase Duration	N/A	N/A	Same
Net Charge(per pulse)	0μC	0μC	Same

（500Ω）			
Maximum Phase Charge（500Ω）	40μC	40μC	Same
Maximum current density（500Ω）	12.5mA/cm^2	12.5mA/cm^2	Same
Maximum power density（500Ω）	7.9mW/cm^2	7.9mW/cm^2	Same
Burst Mode	N/A	N/A	Same
ON Time	1 - 20 s	1 - 20 s	Same
OFF Time	1 - 50 s	1 - 20 s	Different Note 2 PMS
Treatment Time range	2-120min	≤60min	
Note1&2 PMS: These parameters of Subject device are covered by predicate device, thus the different technological characteristics of Subject device do not raise different questions of safety and effectiveness.			
As a transcutaneous electrical nerve stimulator（TENS）			
Item	< Predicate Device > STIWELL med4	< Subject Device > S&Q series	Comparison Result
Manufacturer /K#	K080950	Current Submission	/
Output specifications			
Waveform	Biphasic symmetrical	Biphasic symmetrical	Same
Shape	Rectangular	Rectangular	
Maximum output Voltage(500Ω)	50V	50V	Same
Maximum output current(500Ω)	100mA	100mA	Same
Maximum output Voltage(2kΩ)	115V	110V	Similar Note1 TENS

Maximum output current(2kΩ)	58mA	55mA	
Maximum output Voltage(10kΩ)	125V	115V	
Maximum output current(10kΩ)	14mA	11mA	
Pulse duration	150-200μs	150-200μs	Same
Pulse frequency	2-100Hz	2-100Hz	Same
For interferential modes only: -Beat Frequency (Hz)	N/A	N/A	Same
For multiphasic waveforms only: -Symmetrical phases?	N/A	N/A	Same
For multiphasic waveforms only: -Phase Duration	N/A	N/A	Same
Net Charge(per pulse)（500Ω）	0μC	0μC	Same
Maximum Phase Charge（500Ω）	20μC	20μC	Same
Maximum current density（500Ω）	12.5mA/cm^2	12.5mA/cm^2	Same
Maximum power density（500Ω）	1.0mW/cm^2	1.0mW/cm^2	Same
Burst Mode: Pulses per burst	8	8	Same
Burst Mode: Bursts per second	2	2	Same

Burst Mode: Burst duration (seconds)	100ms	100ms	Same
Burst Mode: Duty Cycle	20%	20%	Same
ON Time	Continuous or Burst	Continuous or Burst	Same
OFF Time	N/A	N/A	Same
Treatment Time range	10-120min	⩽60min	Different Note2 TENS
Note1&2 TENS: These parameters of Subject device are covered by predicate device, thus the different technological characteristics of Subject device do not raise different questions of safety and effectiveness.			

As seen in the comparison tables, the subject device and predicate device have similar design features and performance specifications. The technological differences between the subject device and predicate device do not raise different questions of safety or effectiveness.

7. Performance Data:

Non-clinical data:

Electrical safety and electromagnetic compatibility (EMC)

The subject device was assessed for conformity with the relevant requirements of the following standards and comply:

- ANSI AAMI ES 60601-1:2005/(R) 2012 and A1:2012, C1:2009/(R) 2012 and A2:2010/(R) 2012, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.
- IEC 60601-1-2 Edition 4.1 2020-09, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests

Performance testing-Bench

Edan has conducted functional and system level testing to validate the performance of the devices. The results of the bench testing show that the subject device meets its accuracy specification and meet relevant consensus standards.

- 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
- IEC 60601-2-40 Edition 2.0 2016-08, Medical electrical equipment –Part 2-40: Particular requirements for the basic safety and essential performance of electromyographs and evoked response equipment
- IEC 60601-1-11 Edition 2.1 2020-07, 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

Biocompatibility testing

This is a surface contacting device with intact skin. The biocompatibility evaluation for the proposed device was conducted in accordance with the FDA Guidance for Industry and Food and Drug Administration Staff: Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process".

Software Verification and Validation Testing

Software verification and validation testing was 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".

Clinical data: Not applicable.

Summary

The non-clinical performance testing showed that the subject devices are as safe and as effective as the predicate device.

8. Conclusion

The bench testing data and software verification and validation demonstrate that subject device is substantially equivalent to the predicate device.