10/21/2022

EMSI, Inc.
% Cherita James
Regulatory Consultant
M Squared Associates,Inc.
127 West 30th Street, 9th Floor
New York, New York 10001

Re: K221958
Trade/Device Name: Flex-MI
Regulation Number: 21 CFR 890.5850, 21 CFR 882.5890
Regulation Name: Powered muscle stimulator
Regulatory Class: Class II
Product Code: IPF, LIH
Dated: October 10, 2022
Received: October 11, 2022

Dear Cherita James:

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:

CDR Jitendra Virani,
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)*
K221958

Device Name
Flex-MI

Indications for Use *(Describe)*

Interferential Stimulation
> Symptomatic relief of chronic intractable pain
> Adjunctive treatment for the management of post-traumatic or post-surgical pain

EMS (Electrical Muscle Stimulation)
> Relaxation of muscle spasm
> Increasing local blood circulation
> Muscle re-education
> Prevention or retardation of disuse atrophy
> Prevention of venous thrombosis of the calf muscles immediately after surgery
> Maintaining or increase range of motion

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

The following information is provided as required by 21 CFR § 807.87 for the Flex-MI 510(k) premarket notification. In response to the Safe Medical Devices Act of 1990, the following is a summary of the information upon which the substantial equivalence determination is based.

Sponsor: EMSI, Inc
3504 Cragmont Dr. Suite#100
Tampa, Florida 33619
Telephone: 813-471-0129
Fax: 813-471-0130
Registration Number: 3003573572

Contact: Cherita James
M Squared Associates, Inc.
127 West 30th St, 9th Floor
New York, New York 10001
Ph. 347-954-0624
Fax. 703-562-9797
Email: Cjames@MSquaredAssociates.com

Date of Submission: October 10, 2022

Proprietary Name: Flex- MI

Common Name: Combination EMS/Interferential stimulator

Regulatory Class: II

Regulation: 21 CFR 890.5850, 21 CFR 882.5890

Product Codes: IPF Powered Muscle Stimulator, LIH Interferential Current Therapy

Predicate Device(s): K112348 RS-4I Plus

Reference devices: K140467 Flex MT Plus, K071869 Flex IT (TENS/IF 14)

Device Description: The Flex-MI is a combination EMS and interferential stimulation device which delivers nerve or muscle stimulation by applying an electrical current to electrodes, which are attached on the patient's skin. The output and waveform is adjustable according to the intended treatment of patient. The stimulator has 2 output channels, accessed through jacks at the top of the housing, so that it may stimulate either 2 or 4 patient electrodes. The device is powered by 4.8V Ni- MH rechargeable battery pack. A patient compliance timer can memorize 60 sets of operation records; the total recordable time is

999 hours. Flex-MI is compatible and recommended for use with Everlife self-adhesive electrodes (K012463).

Indications for Use

Interferential Stimulation

> Symptomatic relief of chronic intractable pain

> Adjunctive treatment for the management of post-traumatic or post-surgical pain

EMS

> Relaxation of muscle spasm

> Increasing local blood circulation

> Muscle re-education

> Prevention or retardation of disuse atrophy

> Prevention of venous thrombosis of the calf muscles immediately after surgery

> Maintaining or increase range of motion

Substantial Equivalence and Comparison to Predicate Devices

The claim of substantial equivalence of the Flex-MI combination EMS and interferential (IF) stimulator to the like modes of the products identified above is based on the comparison of the indications and intended use, product technical characteristics, performance characteristics and product handling. All devices are for prescription use.

Both the subject device, predicate device and the reference devices have the same indications and intended use for the IF and EMS modes. The primary predicate includes a more broad statement for IF, however the IF indications for the subject device are in-line with most IF devices cleared by the Agency as well as the reference IF device i.e. relief of acute and chronic pain. All devices are prescription devices and the appropriate treatment modality is the responsibility of the prescribing clinician. Based on the comparison in the following table the Flex-MI is substantial equivalent to the predicate device.

	Subject Device Flex-MI K221958	**Primary RS-4I Plus K112348**	**Reference K140467 Flex MT Plus (EMS function)**	**Reference K071869 Flex IT (IF function)**
Product code	IPF, LIH	IPF, LIH	IPF	LIH
Indication for Use	IF- •Symptomatic relief of chronic intractable pain •Post traumatic and post surgical pain relief EMS- Electrical Muscle Stimulation •Relaxation of muscle spasm •Increasing local blood circulation •Muscle re-education •Prevention or retardation of disuse atrophy •Prevention of venous thrombosis of the calf muscles immediately after surgery •Maintaining or increase range of motion	IF- -Relieve acute pain -Relieve and manage chronic pain EMS- Electrical Muscle Stimulation •Relaxation of muscle spasm •Increasing local blood circulation •Muscle re-education •Prevention or retardation of disuse atrophy •Prevention of venous thrombosis of the calf muscles immediately after surgery •Maintaining or increase range of motion	EMS- Electrical Muscle Stimulation •Relaxation of muscle spasm •Increasing local blood circulation •Muscle re-education •Prevention or retardation of disuse atrophy •Prevention of venous thrombosis of the calf muscles immediately after surgery •Maintaining or increase range of motion	IF- •Symptomatic relief of chronic intractable pain • Post traumatic and post surgical pain relief

Both the subject device and the predicate devices are battery powered, handheld devices with similar unit characteristics. Based on the comparison in the following table the Flex-MI is substantial equivalent to the predicate devices.

	Subject Device Flex-MI K221958	**Primary RS-4I Plus**	**Reference Flex MT Plus (EMS function)**	**Reference Flex IT (IF function)**
1. 510(k) Number	Not assigned	K112348	K140467	K071869
2. Device Name, Model	Flex-MI	RS-4I Plus	Flex MT Plus	Flex IT
3. Manufacturer	EMSI/Everlife	RS Medical	EMSI/Everlife	EMSI/Apex Medical

	Subject Device Flex-MI **K221958**	**Primary** **RS-4I Plus**	**Reference** **Flex MT Plus (EMS function)**	**Reference** **Flex IT (IF function)**
4. Power Source	500 mAh 4.8V Ni-MH, rechargeable battery pack and charger	Lithium Ion battery with charger	700 mAh 4.8V Ni-MH, rechargeable battery pack and charger	four batteries, size AA, alkaline; or adapter 6VDC
5. Number of Output Modes	2	2	2	2
6. Number of Output Channels	2	4	2	2
– Synchronous or Alternating	Synchronous or Alternating	Synchronous or Alternating	Synchronous or Alternating	Synchronous
– Method of Channel Isolation	Transformer	unknown	Transformer	Transformer
7. Regulated Current or Regulated Voltage?	Regulated Voltage	Regulated Voltage	Regulated voltage	Regulated voltage
8. Software/Firmware/ Microprocessor Control?	Yes	yes	Yes	Yes
9. Automatic Overload Trip?	Yes	unknown	Yes	No
11. Automatic Shut Off?	Yes	Yes	Yes	Yes
12. Patient Override Control?	Yes	Yes	Yes	Yes
13. Indicator Display: On/Off Status? Low Battery? Voltage/Current Level?	 Yes Yes Yes (1-10 bars displayed)	Yes Yes Yes 1-4 bars	Yes Yes Yes (1-10 bars displayed)	Yes Yes Yes (1-10 bars displayed)
4. Timer Range (minutes)	5-90 minutes, or continuous	0-60 minutes	5-90 minutes, or continuous	5-90 minutes, or continuous
15. Compliance with Voluntary Standards?	IEC 60601-1-2 as applicable	unknown	IEC 60601-1-2 as applicable	IEC 60601-1-2 as applicable
16. Compliance with 21 CFR 898?	Yes	unknown	Yes	Yes
17. Weight	159g (including battery)	471g including battery	156 g (including battery)	140g
18. Dimensions [W x H x D]	12cm x 5.4cm x 3.3cm	3.2”x 8” x1.8”	12 cm x 5.4cm x 2.5cm	12 cm x 5.5cm x 2.5cm

	Subject Device Flex-MI K221958	Primary RS-4I Plus	Reference Flex MT Plus (EMS function)	Reference Flex IT (IF function)
19. Housing Materials and Construction	plastic	unknown	plastic	plastic

Output Specifications

Both the subject device, predicate and the reference devices have similar output specifications and are within the range of currently marketed devices for the proposed intended uses.

Flex-MI and RS-4I Plus– Primary Predicate

Output Characteristics EMS mode	Subject Device- Flex MI K221958		Primary - RS-4I Plus K112348	
Waveform	Asymmetrical biphasic	Biphasic symmetrical	Asymmetrical biphasic	Biphasic symmetrical
Shape	Rectangular		Rectangular	
Maximum Output Voltage	43.0V @ 500Ω	43.0V @ 500Ω	50V @ 500Ω	50V @ 500Ω
Maximum Output Current	86.0mA @ 500Ω	86.0mA @ 500Ω	100mA @ 500Ω	100mA @ 500Ω
Pulse Width per phase	Positive 50-400µsec		Positive 50-400µsec	
Max Phase Duration (Positive Phase)	400µs =0.4ms	400µs =0.4ms	unknown	unknown
Max Phase Duration (Negative Phase)	2900µs =2.9ms	400µs =0.4ms	2.6ms	400µs =0.4ms
Pulse Frequency Max Duty factor	2~150.2Hz 400µs/(1/150.2Hz) =0.4ms/6.66ms = 0.060	2~150.2Hz (400µs+400µs)/(1/150.2Hz) =0.8ms/6.66ms = 0.120	71Hz	71Hz
Multi-phasic waveforms	Yes	Yes	Yes	Yes
Phase duration	Positive 50-400µsec	Positive 50-400µsec	421µs =0.421ms	421µs =0.421ms

Output Characteristics EMS mode	**Subject Device- Flex MI K221958**		**Primary - RS-4I Plus K112348**	
Net Charge (µC per pulse)	Positive wave 86.0mA*400µs =86.0mA*0.4ms = 34.4 @ 500Ω Negative wave (-86mA/2)*400µs+(-8mA/2)*2500µs =(-43mA)*0.4ms+(-4mA)*2.5ms = -17.2+(-10) = -27.2 @ 500Ω 34.4+ (-27.2) = 7.2 @ 500Ω	Positive wave 86.0mA*400µs =86.0mA*0.4ms = 34.4 @ 500Ω Negative wave -86.0mA*400µs =-86.0mA*0.4ms = -34.4 @ 500Ω 34.4+ (-34.4) = 0 @ 500Ω	unknown	unknown
Maximum Phase Charge (µC)	Positive wave 86.0mA*400µs =86.0mA*0.4ms = 34.4 @ 500Ω Negative wave (-86mA/2)*400µs+(-8mA/2)*2500µs =(-43mA)*0.4ms+(-4mA)*2.5ms = -17.2+(-10) = -27.2 @ 500Ω 34.4+ (-27.2) = 7.2 @ 500Ω	Positive wave 86.0mA*400µs = 34.4 @ 500Ω Negative wave -86.0mA*400µs = -34.4 @ 500Ω 34.4+ (-34.4) = 0 @ 500Ω	unknown	unknown
Surface Area of Electrode	4cm*4cm= 16cm^2		unknown	
Maximum Current Density (mA/cm²)	28.1mA/16cm^2 = 1.76 @500Ω	42.8mA/16cm^2 = 2.68 @500Ω	unknown	unknown
Maximum Power Density (W/cm²)	Average Voltage 43.0V*0.4ms/6.66ms = 2.58V @ 500Ω Average Current 86.0mA*0.4ms/6.66ms = 5.17mA @ 500Ω 2.58V*5.17mA/16cm^2 =2.58V*0.00517A/16cm^2 = 0.000834 @500Ω	Average Voltage 43.0V*0.4ms/6.66ms = 2.58V @ 500Ω Average Current 86.0mA*0.4ms/6.66ms = 5.17mA @ 500Ω 2.58V*5.17mA/16cm^2 =2.58V*0.00517A/16cm^2 = 0.000834 @500Ω	unknown	unknown

Output Characteristics EMS mode	**Subject Device- Flex MI K221958**		**Primary - RS-4I Plus K112348**	
Maximum Pulse Duration	400µs+2900µs =0.4ms+2.9ms =3.3ms	400µs+400µs =0.4ms+0.4ms =0.8ms	unknown	unknown
Additional Features (if applicable)	Patient compliance timer		Patient compliance timer	

*Flex-MI and Flex MT Plus (EMS function)**- Reference device***

Output Characteristics EMS mode	**Subject Device- Flex MI K221958**		**Flex-MT + K140467**	
Waveform	Asymmetrical biphasic	Biphasic symmetrical	Asymmetrical biphasic	Biphasic symmetrical
Shape	Rectangular		Rectangular	
Maximum Output Voltage	43.0V @ 500Ω 107V @ 2kΩ 214V @ 10kΩ	43.0V @ 500Ω 105V @ 2kΩ 214V @ 10kΩ	43.2V @ 500Ω 150V @ 2kΩ 428V @ 10kΩ	43.2V @ 500Ω 90V @ 2kΩ 344V @ 10kΩ
Maximum Output Current	86.0mA @ 500Ω 53.5mA @ 2kΩ 21.4mA @ 10kΩ	86.0mA @ 500Ω 52.5mA @ 2kΩ 21.4mA @ 10kΩ	86.4mA @ 500Ω 75.0mA @ 2kΩ 42.8mA @ 10kΩ	86.4mA @ 500Ω 45.0mA @ 2kΩ 34.4mA @ 10kΩ
Pulse Width per phase	Positive 50-400µsec		Positive 50-400µsec	
Max Phase Duration (Positive Phase)	400µs =0.4ms	400µs =0.4ms	400µs =0.4ms	400µs =0.4ms
Max Phase Duration (Negative Phase)	2900µs =2.9ms	400µs =0.4ms	2.6ms	400µs =0.4ms
Pulse Frequency Max Duty factor	2~150.2Hz 400µs/(1/150.2Hz) =0.4ms/6.66ms = 0.060	2~150.2Hz (400µs+400µs)/(1/150.2Hz) =0.8ms/6.66ms = 0.120	2-151.5Hz 400µsec/6.6ms = 0.061	2-151.5Hz 400µsec+400µsec /6.6ms = 0.121
Multi-phasic waveforms	Yes	Yes	Yes	Yes

Output Characteristics EMS mode	**Subject Device- Flex MI K221958**		**Flex-MT +** **K140467**	
Phase duration	Positive 50-400µsec	Positive 50-400µsec	Positive 50-400µsec	Positive 50-400µsec
Net Charge (µC per pulse)	Positive wave 86.0mA*400µs =86.0mA*0.4ms = 34.4 @ 500Ω Negative wave (-86mA/2)*400µs+(-8mA/2)*2500µs =(-43mA)*0.4ms+(-4mA)*2.5ms = -17.2+(-10) = -27.2 @ 500Ω 34.4+ (-27.2) = 7.2 @ 500Ω	Positive wave 86.0mA*400µs =86.0mA*0.4ms = 34.4 @ 500Ω Negative wave -86.0mA*400µs =-86.0mA*0.4ms = -34.4 @ 500Ω 34.4+ (-34.4) = 0 @ 500Ω	Positive wave 86.4mA*400µsec = 34.6 @ 500Ω Negative wave = -20.0 @ 500Ω 34.6+ (-20.0) = 14.6 @ 500Ω	Positive wave 86.4mA*400µsec = 34.6 @ 500Ω Negative wave 86.4mA*400µsec = -34.6 @ 500Ω 34.6+ (-34.6) = 0 @ 500Ω (symmetrical phases result in 0)
Maximum Phase Charge (µC)	Positive wave 86.0mA*400µs =86.0mA*0.4ms = 34.4 @ 500Ω Negative wave (-86mA/2)*400µs+(-8mA/2)*2500µs =(-43mA)*0.4ms+(-4mA)*2.5ms = -17.2+(-10) = -27.2 @ 500Ω 34.4+ (-27.2) = 7.2 @ 500Ω	Positive wave 86.0mA*400µs = 34.4 @ 500Ω Negative wave -86.0mA*400µs = -34.4 @ 500Ω 34.4+ (-34.4) = 0 @ 500Ω	Positive wave 86.4mA*400µsec = 34.6 @ 500Ω Negative wave = -20.0 @ 500Ω 34.6+ (-20.0) = 14.6 @ 500Ω	Positive wave 86.4mA*400µsec = 34.6 @ 500Ω Negative wave 86.4mA*400µsec = -34.6 @ 500Ω 34.6+ (-34.6) = 0 @ 500Ω (symmetrical phases result in 0)
Surface Area of Electrode	4cm*4cm= 16cm^2		4cm*4cm (1.5in x 1.5in)= 16cm^2	
Maximum Current Density (mA/cm²)	28.1mA/16cm^2 = 1.76 @500Ω	42.8mA/16cm^2 = 2.68 @500Ω	29.2mA/4*4cm^2 = 1.83@500Ω (4cm*4cm Electrode)	45.1mA/4*4cm^2 = 2.82@500Ω (4cm*4cm Electrode)

Output Characteristics EMS mode	**Subject Device- Flex MI K221958**		**Flex-MT +** **K140467**	
Maximum Power Density (W/cm^2)	Average Voltage 43.0V*0.4ms/6.66 ms = 2.58V @ 500Ω Average Current 86.0mA*0.4ms/6.66ms = 5.17mA @ 500Ω 2.58V*5.17mA/16 cm^2 =2.58V*0.00517A/16cm^2 = 0.000834 @500Ω	Average Voltage 43.0V*0.4ms/6.66 ms = 2.58V @ 500Ω Average Current 86.0mA*0.4ms/6.66ms = 5.17mA @ 500Ω 2.58V*5.17mA/16 cm^2 =2.58V*0.00517A/16cm^2 = 0.000834 @500Ω	Average Voltage 43.2V*0.4ms/6.6ms = 2.62V @ 500Ω Average Current 86.4mA*0.4ms/6.6 ms = 5.24mA @ 500Ω 2.62V*5.24mA/4*4 cm^2 = 0.000858@500Ω (4cm*4cm electrode)	Average Voltage 43.2V*0.4ms/6.6ms = 2.62V @ 500Ω Average Current 86.4mA*0.4ms/6.6ms = 5.24mA @ 500Ω 2.62V*5.24mA/4*4cm^2 = 0.000858@500Ω (4cm*4cm electrode)
Maximum Pulse Duration	400µs+2900µs =0.4ms+2.9ms =3.3ms	400µs+400µs =0.4ms+0.4ms =0.8ms	400µs+2.6ms =0.4ms+2.6ms =3.0ms	400µs+400µs =800µs =0.8ms
Additional Features (if applicable)	Patient compliance timer		Patient compliance timer	

*Flex-MI and Flex IT (Interferential Function)- **Reference device***

Output Characteristics- IF mode	Subject Device- Flex MI K221958	K071869 Flex IT (IF function)
Waveform	Square Wave	Square Wave
Shape	Rectangular	Rectangular
Maximum Output Voltage	16.5V@500 Ω 27V@2kΩ 54.6 V@10 kΩ	15 V @ 500 Ω 24 V @ 2 k Ω 28 V @ 10 k Ω
Maximum Output Current	33mA@500Ω 13.5mA@2kΩ 5.5mA @10kΩ	30 mA@ 500 Ω 12 mA @ 2 k Ω 2.8 mA @10 k Ω
INF: Beat Frequency	-188Hz to +387 Hz, max	-188 to + 387 Hz, max.
Pulse Width per phase	125µs	125 µs
Max Phase Duration (Positive Phase)	125µs = 0.125ms	125µs = 0.125ms
Max Phase Duration (Negative Phase)	125µs = 0.125ms	125µs = 0.125ms
Pulse Frequency Max Duty factor	4,000Hz	4,000 Hz
Multi-phasic waveforms	Yes	Yes
Phase duration	125 µs=0.125ms	125 µs
Net Charge (µC per pulse)	Positive wave 33mA*125µs =33mA*0.125ms = 4.125@ 500Ω Negative wave (-33mA)*125µs =(-33mA)*0.125ms =(-4.125)@ 500Ω 4.125+ (-4.125) = 0 @ 500Ω	0@ 500Ω Symmetrical + and – halves

Maximum Phase Charge (μC)	Positive wave 33mA*125μs =33mA*0.125ms = 4.125@ 500Ω Negative wave (-33mA)*125μsec =(-33mA)*0.125ms = (-4.125) @ 500Ω 4.125+(-4.125) = 0 @ 500Ω	3@ 500Ω
Surface Area of Electrode	4cm*4cm = 16cm^2	1.5 inches*1.5inches=2.25in^2
Maximum Current Density (mA/cm²)	33mA(@500Ω)/16cm^2 = 2.06@500Ω	2.08@ 500Ω 1.5 in electrode
Maximum Power Density (W/cm²)	Average Voltage 16.5V*125μs/(1/4000Hz) =16.5V*0.125ms/0.25ms = 8.25V@ 500Ω Average Current 33mA*125μs/(1/4000Hz) =33mA*0.125ms/0.25ms = 16.5mA@ 500Ω 8.25V*16.5mA/16cm^2 =8.25V*0.0165A/16cm^2 = 0.009 @500Ω	0.031@ 500Ω
Maximum Pulse Duration	125 μs	125 μs
Additional Features (if applicable)	Patient compliance monitor	Patient compliance monitor

Compliance with Standards

The Flex-MI was designed and tested to conform with the following FDA-recognized standards:

Standard	Recognition Number
IEC 62366-1 Edition 1.0 2015-02 Medical devices - Part 1: Application of usability engineering to medical devices [Including CORRIGENDUM 1 (2016)]	5-114
ISO 14971 Third Edition 2019-12 Medical devices - Application of risk management to medical devices	5-125
ANSI AAMI ES60601-1:2005/(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 60601-1:2005, MOD)	19-4
IEC 60601-1-11 Edition 2.0 2015-01 Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral Standard:	19-14

Standard	Recognition Number
Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment.	
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	17-16
IEC 60601-1-2, Medical Electrical Equipment, Part 1: General Requirements for Safety. Collateral Standard: Electromagnetic Compatibility- Requirements and Test.	19-8

Clinical Data: Clinical data is not required to support the substantial equivalence to the predicate devices.

Conclusion: Based on the Flex-MI and the predicate device's technical characteristics, performance, and indications for use, the subject device is substantially equivalent to the predicate device. The subject device performs as intended for the same indications as the predicate devices with regard to EMS and IF functions.