October 29, 2020

g.tec medical engineering GmbH
Christoph Guger
CEO
Siemingerstrasse 14
Schiedlberg, 4521
Austria

Re: K200088
Trade/Device Name: g.Estim FES
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered Muscle Stimulator
Regulatory Class: Class II
Product Code: IPF, GZI
Dated: July 29, 2020
Received: July 31, 2020

Dear Dr. Guger:

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,

Amber Ballard, PhD
Assistant Director
DHT5B: Division of Neuromodulation
and Physical Medicine Devices
OHT5: Office of Neurological
and Physical Medicine Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200088

Device Name
g.Estim FES

Indications for Use *(Describe)*
Neuromuscular electronic stimulator indicated for use under medical supervision for adjunctive therapy in the treatment of medical diseases and conditions.

As powered muscle stimulator:
- Temporary Relaxation of muscle spasms
- Prevention or retardation of disuse atrophy
- Increasing local blood flow in the treatment area
- Muscle re-education
- Prevention of post-surgical phlebo-thrombosis through immediate stimulation of calf muscles
- Maintaining or increasing range of motion

As external functional neuromuscular stimulator:
- Helps to relearn voluntary motor functions of the extremities

The device must be used by trained and qualified personnel.

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 510(k) summary has been prepared pursuant to requirements specified in 21CFR 807.92(a).

807.92(a)(1)

Submitter Information

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Contact Person: Christoph Guger

Date: 28.10.2020

807.92(a)(2)

Trade Name: g.Estim FES

Common Name: Electrical muscle stimulator

Classification Names(s): Powered muscle stimulator
(per 21 CFR section 21 CFR 890.5850)
External functional neuromuscular stimulator
(per 21 CFR section 21 CFR 882.5810)

Product Code: IPF, GZI

807.92(a)(3)

Predicate Devices/ Reference Devices

	Secondary Predicate	**Reference**	**Primary Predicate**
Manufacturer:	Mettler Electronics Corp	Thought Technology Ltd	Otto Bock Healthcare Product GmbH
Trade Name	SYS*STIM 208/208A	MyoTRac Infiniti	STIWELL med 4
510(k) document control number	K031017	K053266	K080950

807.92(a)(4)

Device Description

The g.Estim FES is a constant-current powered muscle stimulator that can deliver rectangular electrical pulses with alternating polarities, lengths and amplitudes, or trains of such pulses. The device is battery supplied and can be connected via USB to a computer. It can be triggered via software or with a hand or foot switch.

The programmable parameters of the stimulator are: frequency, current, pulse width, ramp up and down and session length. The phase width and the stimulation current can be changed during stimulation; the other parameters can only be changed when the stimulator is stopped. Stimulation can be started and stopped using a configurable ramp for smooth on- and offsets. A LED shows the stimulus onset.

The system consists of the stimulator, a USB connector cable to connect the device to a host computer, patient cables for electrode connection and a software package including the driver and a graphical user interface. Optional trigger out cables and trigger in cables as well as a hand switch and foot switch to trigger the stimulator are available. The device stops stimulation if an over-load is detected or the electrodes are disconnected.

A foot switch or hand switch can be used to trigger the stimulator.

The device can perform an impedance measurement to check the electrodes impedance before the stimulation is done and can measure the actual stimulation current when a stimulation is done. The impedance measurement is done quickly so that the stimulation can rapidly be performed. If a high impedance is detected the stimulator does not stimulate.

g.Estim FES works in the same manner as the approved predicate devices.

807.92(1)(5)

Indications for Use

Neuromuscular electronic stimulator indicated for use under medical supervision for adjunctive therapy in the treatment of medical diseases and conditions.

As powered muscle stimulator:

- Temporary Relaxation of muscle spasms
- Prevention or retardation of disuse atrophy
- Increasing local blood flow in the treatment area
- Muscle re-education
- Prevention of post-surgical phlebo-thrombosis through immediate stimulation of calf muscles
- Maintaining or increasing range of motion

As external functional neuromuscular stimulator

- Helps to relearn voluntary motor functions of the extremities

The device must be used by trained and qualified personnel.

807.92(a)(6)

Technological Characteristics

	Item	g.tec medical engineering GmbH g.Estim FES this Submission	Mettler Electronics Corp. SYS*STIM 208/208A K031017 for IPF (secondary)	Thought Technology Ltd MyoTrac Infiniti K053266 for IPF (reference)	Otto Bock Healthcare Product GmbH STIWELL med4 K080950 for IPF and GZI (primary)	Comments
1.	Intended use	Neuromuscular electronic stimulator indicated for use under medical supervision for adjunctive therapy in the treatment of medical diseases and conditions.	Powered Muscle Stimulation	Muscle Stimulation and EMG Biofeedback	Neuromuscular electronic stimulator indicated for use under medical supervision for adjunctive therapy in the treatment of medical diseases and conditions	Equivalent with predicate K080950, which covers all indications claimed also by this submission (including the indications of the other predicate devices).
2.	Indication for use	As powered muscle stimulator: • Temporary Relaxation of muscle spasms • Prevention or retardation of disuse atrophy • Increasing local blood flow in the treatment area • Muscle re-education • Prevention of post-surgical phlebo-thrombosis through immediate stimulation of calf muscles • Maintaining or increasing range of motion As external functional neuromuscular stimulator: • Helps to relearn voluntary motor functions of the extremities The device must be used by trained and qualified personnel.	• Temporary Relaxation of muscle spasms • Prevention or retardation of disuse atrophy • Increasing local blood flow in the treatment area • Muscle re-education • Prevention of post-surgical phlebo-thrombosis through immediate stimulation of calf muscles • Maintaining or increasing range of motion • Symptomatic relief of chronic intractable pain, acute post traumatic pain or acute post surgical pain	• 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 • Biofeedback, Relaxation • & Muscle Re-Education	As powered muscle stimulator: • Relaxation of muscle spasm • 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 As external functional neuromuscular stimulator: • Helps to relearn voluntary motor functions of the extremities As a transcutaneous electrical nerve stimulator for pain relief: • Symptomatic relief and management of chronic (long-term), intractable pain	Indications for product code IPF (green) are equivalent in safety and effectiveness. Indications for product code GZI (blue) are identical. Additional product codes of the predicate devices not claimed by the current submission (orange) are: • reduction of pain (GZJ), • biofeedback (HCC) • incontinence treatments (KPI)

	Item	g.tec medical engineering GmbH g.Estim FES this Submission	Mettler Electronics Corp. SYS*STIM 208/208A K031017 for IPF	Thought Technology Ltd MyoTrac Infiniti K053266 for IPF	Otto Bock Healthcare Product GmbH STIWELL med4 K080950 for IPF and GZI	Comments
					• Adjunctive treatment in the management of post-surgical pain and post traumatic acute pain As a biofeedback device: • Biofeedback, relaxation and muscle re-education purposes As a nonimplanted electrical continence device: • Acute and ongoing treatment of stress, urge or mixed urinary incontinence and where the following results may improve urinary control: Inhibition of the detruser 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 the abdominal and the gluteus muscles	

Powered muscle stimulator comparison table

	Item	g.tec medical engineering GmbH g.Estim FES This Submission	Mettler Electronics Corp. SYS*STIM 208/208A K031017 (secondary predicate)	Thought Technology Ltd MyoTrac Infiniti K053266 (reference)	Otto Bock Healthcare Product GmbH STIWELL med4 K080950 (primary predicate)	Comments
3.	Power sources	USB and battery, 2 x 9 V	110V AC, 60Hz +-10%	not publicly available	Battery Pack Li-ion 11,1 V	g.Estim FES is powered by a combination of batteries and USB power. The applied part is powered by conventional batteries and fulfills IEC 60601-1, therefore it is equivalent in safety and effectiveness.
4.	Line current isolation	The applied part is powered by conventional batteries. The applied part is isolated from the rest of the circuit by 2 MOP according to IEC 60601-1.	AC power supply is converted to DC power supply through transformer. Hence there is an insulation of mains from circuitry. From circuitry to output again, there is insulation through the transformer, there by double separation between mains and the human body.	not publicly available	Medical Class II Power Adapter- Mascot (12,6 VDC-15,1W))	State of the art isolation strategy - equivalent in safety and effectiveness.
5.	Patient leakage current	Type BF according to IEC 60601-1 NC max: < 1 µA (IEC level NC <100 µA) SFC max: 2.6 µA (IEC level SFC <500 µA)	NC <100 µA SFC<300 µA	not publicly available	NC NA (Battery) SFC NA (Battery)	Below IEC standard thresholds and therefore equivalent in safety and effectiveness.
6.	Number of output modes	1	3: Tetanize Surge Pulse	not publicly available	1	g.Estim FES allows a similar parameter range as MyoTrac Infinity and STIWELL med 4 and is equivalent in safety and effectiveness.
7.	Number of output channels	1	1	not publicly available	4	g.Estim FES provides one channel but is equivalent in safety and effectiveness.
8.	Number of EMG (input) Channels	NA	NA	not publicly available	2	g.Estim FES provides no EMG channel and does not claim product category HCC, so equivalent in safety and effectiveness for claimed product codes.

	Item	g.tec medical engineering GmbH g.Estim FES This Submission	Mettler Electronics Corp. SYS*STIM 208/208A K031017	Thought Technology Ltd MyoTrac Infiniti K053266	Otto Bock Healthcare Product GmbH STIWELL med4 K080950	Comments
9.	EMG sensitivity	NA	NA	not publicly available	1µV	g.Estim FES provides no EMG channel and does not claim product category HCC, so equivalent in safety and effectiveness for claimed product codes.
10.	EMG sampling Rate	NA	NA	not publicly available	3 kHz	g.Estim FES provides no EMG channel and does not claim product category HCC, so equivalent in safety and effectiveness for claimed product codes.
11.	EMG detection (bipolar/monopolar)	NA	NA	Bipolar	Bipolar	g.Estim FES provides no EMG channel and does not claim product category HCC, so equivalent in safety and effectiveness for claimed product codes.
12.	EMG range(µV)	NA	NA	0-2000µV	1-2000µV	g.Estim FES provides no EMG channel and does not claim product category HCC, so equivalent in safety and effectiveness for claimed product codes.
13.	EMG bandwidth	NA	NA	20-500Hz	70-480Hz	g.Estim FES provides no EMG channel and does not claim product category HCC, so equivalent in safety and effectiveness for claimed product codes.
14.	EMG signal processing (eg. RMS)	NA	NA	RMS (root mean square)	AVR (average reached value)	g.Estim FES provides no EMG channel and does not claim product category HCC, so equivalent in safety and effectiveness for claimed product codes.
15.	Synchronous or alternating channels	NA	NA	not publicly available	Alternating	g.Estim FES provides one channel but equivalent in safety and effectiveness.

	Item	g.tec medical engineering GmbH g.Estim FES This Submission	Mettler Electronics Corp. SYS*STIM 208/208A K031017	Thought Technology Ltd MyoTrac Infiniti K053266	Otto Bock Healthcare Product GmbH STIWELL med4 K080950	Comments
16.	Method of channel isolation	The applied part is isolated from the rest of the circuit by 2 MOP according to IEC 60601-1.	In this system, all the outputs are isolated from each other, they have their own amplifiers which are independent from neighboring channels or outputs. The only common thing between the outputs is the microprocessor and the power supply.	not publicly available	Transformer inductive couplers	State of the art isolation strategy – provides equivalent safety and effectiveness.
17.	Regulated current or regulated voltage	Regulated voltage, constant current	Regulated current, constant voltage	Regulated voltage, constant current	Regulated Current	Constant current regulated but equivalent in safety and effectiveness.
18.	Software/Firmware/Microprocessor Control	• Microprocessor control • Firmware • Software	• Microprocessor control • Firmware	• Microprocessor control • Firmware	YES • Microprocessor control • Firmware • Software	g.Estim FES uses a software on a host computer for interfacing the device via USB and stops stimulation when communication loss is detected. Thus, equivalent in safety and effectiveness is given
19.	Automatic overload trip	Yes	No	not publicly available	YES	g.Estim FES provides equal safety and effectiveness as it stops when the required power cannot be delivered.
20.	Automatic no-load trip	Yes	No	not publicly available	YES	g.Estim FES provides equal safety and effectiveness as it stops when the required power cannot be delivered.
21.	Automatic shut off (timer range)	Yes	Yes	not publicly available	YES (10 min.)	Same as predicate
22.	Patient override control	No	Yes, remote stop	not publicly available	YES (Stop Button)	g.Estim has no remote stop for patient override control but is equivalent in safety and effectiveness.
23.	Indicator display • On/off Status • Low battery	 Yes Yes Yes	 Yes NA Yes	not publicly available	 YES YES YES	g.Estim FES displays the required information so it is equivalent in safety and effectiveness.

	Item	g.tec medical engineering GmbH g.Estim FES This Submission	Mettler Electronics Corp. SYS*STIM 208/208A K031017	Thought Technology Ltd MyoTrac Infiniti K053266	Otto Bock Healthcare Product GmbH STIWELL med4 K080950	Comments
	• Voltage / Current level					
24.	Timer range	0-120 minutes	0-60 minutes	1-120 minutes	2-120 min.	Higher range but equivalent in safety and effectiveness.
25.	Standards	IEC60601-1 IEC60601-1-2 IEC60601-2-10 ISO14971 IEC62304 IEC62366	none	not publicly available	IEC60601-1 IEC60601-1-2 IEC60601-2-10	More standards applied.
26.	Compliance with 21 CFR 898	Yes	Yes	not publicly available	YES	g.Estim FES is compliant to the CFR regulation and therefore equivalent in safety and effectiveness.
27.	Weight	0.85 kg	2.25 lbs	not publicly available	0,44 kg	Equivalent in safety and effectiveness because weight is within the range of predicates.
28.	Dimensions	240 x 137 x 80 mm	2.5 x 6 x 8 in	not publicly available	175 x 95 x 30 mm	Biggest device but equivalent in safety and effectiveness
29.	Housing material and construction	ABS Plastic injection molded	ABS Plastic injection molded	not publicly available	Plastic	Same as predicate
30.	Waveform	Symmetrical biphasic	Asymmetrical biphasic	Asymmetric biphasic	Symmetrical biphasic	Symmetrical biphasic, equivalent in safety and effectiveness by providing a zero-net charge.
31.	Shape	rectangular	rectangular	not publicly available	rectangular	Same as predicate
32.	Maximum output voltage	30 V @ 500 Ω 80 V @ 2 kΩ 80 V @10 kΩ	92 V @ 500 Ω 144 V @ 2 kΩ 166 V @10 kΩ	not publicly available	50 V @ 500 Ω 115 V @ 2 kΩ NA @ 10 kΩ	Lower voltage but equivalent in safety and effectiveness.
33.	Maximum output current	0-60 mA @ 500 Ω 0-40 mA @ 2 kΩ 0-8 mA @10 kΩ	184 mA @ 500 Ω 72 mA @ 2 kΩ 17mA @ 10 kΩ	0-100mA @ 500 Ω	100 mA @ 500 Ω 58 mA @ 2 kΩ NA @10 kΩ	Lower current but equivalent in safety and effectiveness.
34.	Pulse width	50-400 µs	182 µs	50-400 µs	50-400 µs	Equivalent range and therefore equivalent in safety and effectiveness.

	Item	g.tec medical engineering GmbH g.Estim FES This Submission	Mettler Electronics Corp. SYS*STIM 208/208A K031017	Thought Technology Ltd MyoTrac Infiniti K053266	Otto Bock Healthcare Product GmbH STIWELL med4 K080950	Comments
35.	Frequency	1-100 Hz	Pulse: 1-80 Hz Tetanize: preset of 80 Hz Surge: preset of 80 Hz	2-100 Hz	1-140 Hz	Equal range of frequency and therefore equivalent in safety and effectiveness.
36.	For interferential modes only Beat frequency	NA	NA	not publicly available	NA	Same as predicates.
37.	For multiphasic waveforms only symmectrical phases	NA	NA	not publicly available	NA	Same as predicates.
38.	For multiphasic waveforms only phase duration (including units)	NA	NA	not publicly available	NA	Same as predicates.
39.	Net charge @ 500 Ω , µC per pulse; Max. phase charge 500 Ω	Zero, (achieved with biphasic pulse), max phase charge 24 µC	Zero, (achieved with biphasic pulse), max phase charge 56µC	max phase charge 60 µC	Zero, (achieved with biphasic pulse),, max phase charge 40µC	Same zero net charge and lower max. phase charge but equivalent in safety and effectiveness.
40.	Max. current density	3.056 mA/cm² @ 500 Ω	0.132 mA/cm² @ 500 Ω	0.24 mA/cm² @ 500 Ω	12.5 mA/ cm² @ 500 Ω	g.Estim FES provides an slightliy reduced current density but is equivalent in safety and effectiveness.
41.	Max. power density@ 500 Ω using smallest electrode conductive surface area	7.33 mW/cm²	12 mW/cm²	16 mW/cm²	7.9 mW/cm²	g.Estim FES has a reduced power density but is equivalent in safety and effectiveness.
42.	Burst Mode Pulses per burst	2-2000	not publicly available	not publicly available	–N/A	g.Estim FES has a reduced range in pulses per burst but is equivalent in safety and effectiveness.
43.	Burst Mode Bursts per second	1/70 – 1/4	not publicly available	not publicly available	N/A	g.Estim FES has a comparable range in burst per second but is equivalent in safety and effectiveness.

	Item	g.tec medical engineering GmbH g.Estim FES This Submission	Mettler Electronics Corp. SYS*STIM 208/208A K031017	Thought Technology Ltd MyoTrac Infiniti K053266	Otto Bock Healthcare Product GmbH STIWELL med4 K080950	Comments
44.	Burst Mode Burst duration (seconds) *820.30C (H.36)*	2 sec. – 20 sec.	not publicly available	not publicly available	N/A	g.Estim FES has a comparable range in burst duration, but is equivalent in safety and effectiveness.
45.	Bursts Duty Cycle	2/52 – 20/22	not publicly available	not publicly available	N/A	g.Estim FES has a comparable range in burst duty cycle, but is equivalent in safety and effectiveness.
46.	Duty cycle	On: 2-20 sec. Off: 2-50 sec.	Surge Mode: On 0,375-3,75 sec. Off 0,375-3,75 sec.	On 2-20 sec. Off 2-50 sec.	On 1-20 sec. Off 1-50 sec.	g.Estim FES provides equivalent timer ranges - equivalent in safety and effectiveness.
47.	Additional features	NA	NA	NA	NA	Same as predicates.
48.	Electrodes	Pepin K070807: WWS12o, WWS22 WWS2	not publicly available	Axelgaard K874469A: # 895220; 895340	not publicly available	g.Estim FES uses Pepin electrodes but is equivalent in safety and effectiveness.
49.	Electrode conductive medium	NA	not publicly available	not publicly available	not publicly available	Same as predicate
50.	Electrode lead wires and patient cables	Cable included, part number 1163	not publicly available	not publicly available	not publicly available	defined and equivalent in safety and effectiveness
51.	Batteries	Battery, 2 x 9 V	not publicly available	not publicly available	Battery Pack Li-ion 11,1 V	g.Estim FES uses two 9 V batteries but is equivalent in safety and effectiveness.
52.	Battery charger	NA	not publicly available	not publicly available	Medical Class II Power Adapter-	g.Estim does not use a power adapter for charging but is equivalent in safety and effectiveness.

Functional Electrical Stimulation comparison Table

	Item	**g.tec medical engineering GmbH g.Estim FES This Submission**	**Additional predicate: Otto Bock Healthcare Product GmbH STIWELL med4 K080950**	**Comments**
53.	Stimulated Muscle	Wrist flexor/extensor Finger flexors/extensors Thumb flexor/extensor	Wrist extensor Finger flexors Thumb flexor	g.Estim FES is equivalent in safety and effectiveness.
54.	Power sources	USB and battery, 2 x 9 V	Battery Pack Li-ion 11,1 V	g.Estim FES has an additional USB connection but is equivalent in safety and effectiveness.
55.	Line current isolation	The applied part is powered by conventional batteries. The applied part is isolated from the rest of the circuit by 2 MOP according to IEC 60601-1.	Medical Class II Power Adapter	g.Estim FES line current isolation is different but is equivalent in safety and effectiveness.
56.	Patient leakage current	Type BF according to IEC 60601-1 NC max: < 1 µA (IEC level NC <100 µA) SFC max: 2.6 µA (IEC level SFC <500 µA)	NC NA (Battery) SFC NA (Battery)	NC and SFC are considerd because of different power sources but are equivalent in safety and effectiveness.
57.	Number of output modes	1	1	Same as predicate
58.	Number of output channels	1	3	g.Estim FES provides one channel but is equivalent in safety and effectiveness.
59.	Number of EMG (input) Channels	NA	0	Same as predicate
60.	EMG sensitivity	NA	NA	Same as predicate
61.	EMG sampling Rate	NA	NA	Same as predicate
62.	EMG detection (bipolar/monopolar)	NA	NA	Same as predicate
63.	EMG range(µV)	NA	NA	Same as predicate
64.	EMG bandwidth	NA	NA	Same as predicate
65.	EMG signal processing (eg. RMS)	NA	NA	Same as predicate
66.	Synchronous or alternating channels	NA	Alternating	g.Estim FES provides one channel but is equivalent in safety and effectiveness.
67.	Method of channel isolation	The applied part is isolated from the rest of the circuit by 2 MOP according to IEC 60601-1.	Transformer inductive couplers	State of the art isolation strategy - equivalent in safety and effectiveness.
68.	Regulated current or regulated voltage	Regulated voltage, constant current	Regulated current	Constant current regulated but equivalent in safety and effectiveness.
69.	Software/Firmware/Microprocessor Control	• Microprocessor control • Firmware • Software	• Firmware	g.Estim FES uses a software on a host computer for interfacing the device via USB and stops stimulation when communication loss is detected. Thus, equivalent in safety and effectiveness is given

	Item	**g.tec medical engineering GmbH g.Estim FES This Submission**	**Additional predicate: Otto Bock Healthcare Product GmbH STIWELL med4 K080950**	**Comments**
70.	Automatic overload trip	Yes	YES	g.Estim FES provides equal safety and effectiveness as it stops when the required power cannot be delivered.
71.	Automatic no-load trip	Yes	YES	g.Estim FES provides equal safety and effectiveness as it stops when the required power cannot be delivered.
72.	Automatic shut off (timer range)	Yes	YES (10 min.)	Same as predicate
73.	Patient override control	No	YES (Stop Button)	g.Estim has no remote stop for patient override control but is equivalent in safety and effectiveness.
74.	Indicator display • On/off Status • Low battery • Voltage / Current level	 Yes Yes Yes	 YES YES YES	Same as predicate.
75.	Timer range	0-120min.	15-60 min.	Higher timer range of g.Estim FES but equivalent in safety and effectiveness.
76.	Standards	IEC60601-1 IEC60601-1-2 IEC60601-2-10 ISO14971 IEC62304 IEC62366	IEC60601-1 IEC60601-1-2 IEC60601-2-10	More standards applied.
77.	Compliance with 21 CFR 898	Yes	YES	g.Estim FES is compliant to the CFR regulation and therefore equivalent in safety and effectiveness.
78.	Weight	0.85 kg	0,44 kg	Heavier but equivalent in safety and effectiveness.
79.	Dimensions	240 x 137 x 80 mm	175 x 95 x 30 mm	Bigger dimensions but equivalent in safety and effectiveness.
80.	Housing material and construction	ABS Plastic injection molded	Plastic	Injection molded ABS is used but is equivalent in safety and effectiveness.
81.	Waveform	Symmetrical biphasic	Symmetrical biphasic	Same as predicate.
82.	Shape	rectangular	rectangular	Same as predicate
83.	Maximum output voltage	30 V @ 500 Ω 80 V @ 2 kΩ 80 V @10 kΩ	50 V @ 500 Ω 115 V @ 2 kΩ NA @ 10 kΩ	Lower voltage and phase charge but equivalent in safety and effectiveness.
84.	Maximum output current	0-60 mA @ 500 Ω 0-40 mA @ 2 kΩ 0-8 mA @10 kΩ	100 mA @ 500 Ω 58 mA @ 2 kΩ NA @10 kΩ	Lower current and phase charge but equivalent in safety and effectiveness.
85.	Pulse width	50-400 µs	50-400 µs	Same as predicate.
86.	Frequency	1-100 Hz	1-140 Hz Default 35Hz	Lower frequency and power but equivalent in safety and effectiveness.
87.	For interferential modes only Beat frequency	NA	NA	Same as predicates.
88.	For multiphasic waveforms only	NA	NA	Same as predicates.

	Item	**g.tec medical engineering GmbH g.Estim FES This Submission**	**Additional predicate: Otto Bock Healthcare Product GmbH STIWELL med4 K080950**	**Comments**
	symmectrical phases			
89.	For multiphasic wasveforms only phase duration (including units)	NA	NA	Same as predicates.
90.	Net charge (µC per pulse)	Zero, max phase charge 24 µC	Zero, same positive and negative impulse, max phase charge 40µC	Lower phase charge but equivalent in safety and effectiveness.
91.	Max. current density	3.056 mA/cm² @ 500 Ω	12.5 mA/ cm² @ 500 Ω	g.Estim FES has a reduced current density but is equivalent in safety and effectiveness.
92.	Max. power density	7.33 mW/cm²	7.9 mW/cm²	g.Estim FES has a reduced power density but is equivalent in safety and effectiveness.
93.	Burst Mode Pulses per burst	2-2000	N/A	g.Estim FES has a reduced range in pulses per burst but is equivalent in safety and effectiveness.
94.	Burst Mode Bursts per second	1/70 – 1/4	N/A	g.Estim FES has a similar range in burst per second but is equivalent in safety and effectiveness.
95.	Burst Mode Burst duration (seconds)	2 sec. – 20 sec.	N/A	g.Estim FES has a comparable range in burst duration, but is equivalent in safety and effectiveness.
96.	Bursts Duty Cycle	2/52 – 20/22	N/A	g.Estim FES has a comparable range in burst duty cycle - equivalent in safety and effectiveness.
97.	Duty cycle	On: 2-20 sec. Off: 2-50 sec.	On 1-20 sec. Off 1-30 sec.	g.Estim FES provides equivalent timer ranges - equivalent in safety and effectiveness.

Non-Clinical Testing Summary

Recogniction Number	Standard / Description
19-4	AAMI ANSI 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
19-8	IEC 60601-1-2 Edition 4.0 2014-02: Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
13-79	IEC 62304 Edition 1.1 2015-06 Medical device software – Software life cycle processes
5-40	ISO 14971 Second edition 2007-03-01 Medical devices - Application of risk management to medical devices
5-114	IEC 62366-1 Edition 1.0 2015-02 Medical devices - Part 1: Application of usability engineering to medical devices [Including CORRIGENDUM 1 (2016)]
17-16	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

807.92(b)(1)

The stimulator was tested with a data acquisition device and provides rectangular stimulation pulses with the necessary frequency and amplitude range. Furthermore digital outputs were tested to provide trigger signals and digital inputs were tested to trigger the stimulation. The impedance measurement was tested with test impedances. The tests show that the stimulator works like the predicate device.
In g.Estim FES medical safety is realized by isolating the applied part optically from the data transmission via USB and by battery supply. The current for the impedance measurement is limited with resistors.

807.92(b)(2)
Not applicable

807.92(b)(3)
The conclusion is that g.Estim FES and the predicate device provide electrical stimuli with varying pulse width, frequency and amplitude in the same way and that the g.Estim FES is substantially equivalent to the predicate device.