February 5, 2025

Biomedical Devices Spa
% Juan Tezak
Consultant
Compliance 4 Devices
118 W Prive Cr.
Delray Beach, Florida 33445

Re: K241488
Trade/Device Name: TrainFES Advanced
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered Muscle Stimulator
Regulatory Class: Class II
Product Code: IPF, GZI
Dated: May 24, 2024
Received: May 24, 2024

Dear Juan Tezak:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

Heather L. Dean -S

for 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K241488

Device Name

TrainFES Advanced

Indications for Use *(Describe)*

For Prescription and Home Use by prescription from a medical professional:
The TrainFES advanced is 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, TrainFES advanced 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 an external functional neuromuscular stimulator (FES), TrainFES Advanced is indicated for the following conditions:
Helps to relearn voluntary motor functions of the extremities.

TrainFES' Advanced intended population is anybody aged 22 or over.
Environments of use: TrainFES Advanced devices can be used by both therapists and patients, in the clinic, hospitals or at home.
Platform: TrainFES is a battery-powered, wireless device, accessible through software.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary
K241488

Prepared July 03, 2024

I) Applicant

Submitter	Biomedical Devices Spa
Address	Camino El Alba 8760, of 903 Las Condes RM Chile
Contact	Mr. Matias Hosiasson
Telephone	+56 998 954326
E-mail	matias@trainfes.com

II) Device

Trade Name	TrainFES Advanced
Common Name	External functional neuromuscular stimulator
Classification Name	Stimulator, Neuromuscular, External Functional
Regulation Number	890.5850 IPF / 882.5810 GZI
Product Code	IPF, GZI

III) Predicate Device

510(k) Number	K210002
Applicant	EGZOTech Sp. Z.o.o
Trade Name	Stella BIO
Classification Name	Power Muscle Stimulator
Regulation Number	890.5850 / 882.5890 / 882.5050 / 876.5320 882.5810
Product Code	IPF, GZJ, HCC, GZI, KPI, NGX, NUH, NYN

IV) Indication For Use

For Prescription and Home Use by prescription from a medical professional: The TrainFES advanced is 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, TrainFES advanced 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 an external functional neuromuscular stimulator (FES), TrainFES Advanced is indicated for the following conditions: Helps to relearn voluntary motor functions of the extremities. TrainFES' Advanced intended population is anybody aged 22 or over.
Environments of use: TrainFES Advanced devices can be used by both therapists and patients, in the clinic, hospitals or at home.
Platform: TrainFES is a battery-powered, wireless device, accessible through software.

V) Device Description

TrainFES Advanced is a portable functional electrostimulator with 6 channels designed for use in the clinics and hospitals by the medical professionals as well as in the home environment by the patient. This device generates electrical impulses to stimulate the musculature of paralyzed segments and facilitate both the relearning of movement and neuromodulation of tone.
TrainFES Advanced is a battery-powered, wireless device, configurable from the TRAINFES App, available for Smartphone and Tablets, which allows you to adjust different parameters and follow a training plan from your smartphone.
Session settings can be retrieved from the PC or Cloud.

VI) Comparison of Technological Characteristics

Basic Device Characteristics			
Characteristics / Specification	**TrainFES Advanced**	**Stella BIO**	**DIfference**
510(k) Number	K241488	K210002	N/A
FDA product code	IPF, GZI	IPF, GZJ, HCC, GZI, KPI, NGX, NUH, NYN	N/A
Manufacturer	Biomedical Devices Spa	EGZO Tech	N/A

Classification	Class II	Class II	Same
Prescription or OTC	Prescription and Home Use	Prescription and Home Use	Same
Environment of Use	Clinics, hospitals and home environments	Clinics, hospitals and home environments	Same
Indications for use	**For Prescription and Home Use by prescription from a medical professional:** The TrainFES advanced is 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,** TrainFES advanced 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 an external functional neuromuscular stimulator (FES),** TrainFES Advanced is indicated for the following conditions: • Helps to relearn voluntary motor functions of the extremities.	The Stella BIO is 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, Stella BIO 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, Stella BIO 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, Stella BIO is indicated for: • Biofeedback, relaxation, and muscle re- education.	Similar Note 1

	TrainFES' Advanced intended population is anybody aged 22 or over. **Environments of use:** TrainFES Advanced devices can be used by both therapists and patients, in the clinic, hospitals or at home. **Platform:** TrainFES is a battery-powered, wireless device, accessible through software.	As an external functional neuromuscular stimulator, Stella BIO is indicated for the following conditions: • Helps to relearn voluntary motor functions of the extremities. As a non-implanted electrical continence device, Stella BIO 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. **Patient population:** Stella BIO Prescription and Home Use by prescription from a medical professional can be used on adults aged 22 yrs and older. **Environments of Use:** Clinics, hospital and home environments. **Platform:** Stella BIO is a battery-powered, wireless device, accessible through software.	
Power Source	Battery: Li-Ion 3,7V (4000mAh)	Battery pack Li-Ion 7,4V	Different Note 2
Method of Line Current Isolation	N/A (Battery)	N/A (Battery)	Same

Patient leakage current (Normal condition, µA)	N/A Battery Operated Device (<100µA patient leakage)	N/A Battery Operated Device (<100µA patient leakage)	Same
Patient leakage current (Single fault condition, µA)	N/A Battery Operated Device (<100µA patient leakage)	N/A Battery Operated Device (<100µA patient leakage)	Same
Number of Output Modes	2	4	Different Note 3
Software/ 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 (Button)	Yes	Same
Indicator Display On/Off Status	Yes (Led)	Yes	Same
Indicator Display Low Battery	Yes	Yes	Same
Indicator Display Voltage/Current Level	Yes	Yes	Same
Standards	ISO 13485:2016 Bluetooth: Complies with FCC 15.2473 (for U.S.) regulations IEC 60601-1 IEC 60601-1-2 IEC 60601-2-10 IEC 60601-1-11 IEC 62133 Compliance IEC 62304:2015 IEC 62366	 IEC 60601-1 IEC 60601-1-2 IEC 60601-2-10 IEC 60601-1-11 IEC 62304 IEC 62366 IEC 62133 ANSI/AAMI NS4	Different Note 4
Compliance with 21 CFR 898	Yes	Yes	Same
Weight	218 g	112 g	Similar Note 5
Dimension	130 x 79 x 33mm 5.11 in x 3.12 in x 1.3 in	91.5 x 68.4 x 24 mm	Similar Note 5

Housing material and Construction	ABS Plastic	Plastic (Injection Molded ABS)	Same
Apply Part	BF		

Substantial Equivalence discussion and Differences analysis for Basic Device Characteristics:

Note 1: Indication for Use
Although the predicates are not exactly the same, the difference is that the predicate device has more functions than the subject device, but the functions of powered muscle stimulator and the external functional neuromuscular stimulator are exactly the same.

Note 2: Power Source
The predicate device as well as the subject device are battery powered. Although the battery provided by the new device is different from the battery of the predicate device, it is compliant with IEC 62133 standard. Moreover, the new device is IEC 60601-1 compliant and has been tested for electrical safety with a positive result. Therefore, differences in power source doesn't influence essential performance or basic safety, as well as doesn't impact substantial equivalence to the predicate device.

Note 3: Number of Output Modes
Although the "Number of Output Channels" are different from the predicate device they all comply with IEC 60601-1 and IEC 60601-2-10 requirements and the difference doesn't impact essential performance, basic safety or substantial equivalence.

Note 4: Voluntary Standards
The new device complies with the same voluntary standards as the predicate device except standard ANSI/AAMI NS4. All voluntary standards are recognized FDA standards and this change difference doesn't impact essential performance, basic safety or substantial equivalence.

Note 5: Weight and Dimensions
Although Weight and Dimensions of subject device are different from the predicate device, they all comply with IEC 60601-1, IEC 60601-2-10 and IEC 60601-1-11 requirements, thus the differences of the function specifications do not raise any safety or effectiveness issue.

Powered muscle stimulator designation comparison of proposed new device and predicate device

Powered Muscle Stimulator			
Characteristics / Specification	**TrainFES Advanced**	**Stella BIO**	**DIfference**
510(k) Number	K241488	K210002	N/A
Manufacturer	Biomedical Devices Spa	EGZO Tech	N/A
Number of channels	6 Channels	8 Channels	Different Note 1 PMS
Synchronous or alternating	Alternating	Synchronous	Different Note 2 PMS
Method of channel isolation	Multiplexer	Multiplexer	Same
Regulated Current or regulated voltage	Regulated Current	Regulated Current	Same
Time Range	1 – 60 min	1 – 60 min	Same
Output Specifications			
Waveform (Monophasic or biphasic)	Biphasic	Biphasic	Same
Shape	Rectangular	Rectangular, triangular, trapezoidal, sinusoidal	Different Note 3 PMS
Symmetrical or asymmetrical	Symmetrical	Symmetrical	Same
Maximum voltage output	50V @500Ω 164V @2kΩ 170V @10kΩ	50V @500Ω 60V @2kΩ N/A @10kΩ	Different Note 4 PMS
Maximum output Current	100mA @500Ω 82 mA @2kΩ 17 mA @10kΩ	100mA @500Ω 30mA @2kΩ N/A @10kΩ	Different Note 4 PMS
Current output channel	0 - 100 mA (steps 1mA)	0 - 100 mA	Same
Pulse Width	50 µs - 400 µs	50 µs - 400 µs	Same
Frequency	1 - 140 Hz	1 - 140 Hz	Same
Beat Frequency	N/A	N/A	N/A
Net charge (µC per pulse)	0µC (Balanced pulses)	0µC Same positive and negative impulse	Same
Max phase charge @500Ω	40 µC	40 µC	Same
Maximum current density (mA/cm) @500Ω	0.224 mA/cm2 (25 cm2 electrode area)	0.22 mA/cm2	Different Note 5 PMS

max. power density (W/cm2)	0.00062 W/cm2 (25 cm2 electrode area)	0.63 mW/cm2	Different Note 5 PMS
Temperature in Use	0°C to 40 ºC 32°F to 104 °F	Unknown	N/A
Temperature transporting/storing	-20°C - 60 ºC -4°F to 140 °F	Unknown	N/A
Relative humidity	In use: 10 % to 75%. In Transportation/Storage: 10% to 85%.	Unknown	N/A

Substantial Equivalence discussion and Differences Analysis. Comparison with Predicate Device - Output Specifications for Powered Muscle Stimulator

Note 1 PMS: Number of Output Channels
Although the "Number of Output Channels" are different from the predicate device they all comply with IEC 60601-1 and IEC 60601-2-10 requirements and the difference doesn't impact essential performance, basic safety or substantial equivalence.

Note 2 PMS: Alternating or Synchronous
The predicate device has a Synchronous EMG acquisition triggering. The different is that the EMG samples can be acquired and compared sample-to-sample, which in Alternating sampling is not possible. This difference doesn't impact essential performance, basic safety or substantial equivalence.
There are other devices on the market that have this same feature such as the K080950 without impacting the essential performance and basic security of the device.

Note 3 PMS: Shape of the waveforms
Predicate device provides waveforms shapes (triangular, trapezoidal and sinusoidal) in addition to rectangular waveforms. Electrical stimulation for triangular, trapezoidal and sinusoidal waveforms are considerate safer than rectangular waveforms due to lower maximal phase charge, current density and power density, but it does not mean that the rectangular waveforms is not safe, besides the predicate also uses it. Electrical stimulation for rectangular waveforms were tested and are compliant with the requirements in IEC 60601-2-10.
The difference in waveforms doesn't impact essential performance, basic safety or substantial equivalence.

Note 4 PMS: Maximum Output Voltage
Although the Maximum Output Voltage of the new device are different than in the predicate device, they were all tested and are compliant with IEC 60601-2-10. Therefore, the difference doesn't impact essential performance, basic safety or substantial equivalence.

Note 5 PMS: Maximum Current Density and Maximum Power Density
Although the Maximum Current Density and Maximum Power Density of subject device are different from the predicate device, which is related to the electrode surface that is different for both devices, they all comply with the FDA guidance requirement for Powered Muscle Stimulator 510 (k)s, so the differences of function specification will not raise any safety or effectiveness issue.

Functional electrical stimulation designation comparison of proposed new device and predicate device

Functional Electrical Stimulation (FES)			
Characteristics / Specification	**TrainFES Advanced**	**Stella BIO**	**DIfference**
510(k) Number	K241488	K210002	N/A
Manufacturer	Biomedical Devices Spa	EGZO Tech	N/A
Number of channels	6 Channels	8 Channels	Different Note 1 FES
Synchronous or alternating	Alternating	Synchronous	Different Note 2 FES
Method of channel isolation	Multiplexer	Multiplexer	Same
Regulated Current or regulated voltage	Regulated Current	Regulated Current	Same
Time Range	15 – 60 min	15 – 60 min	Same
Output Specifications			
Waveform (Monophasic or biphasic)	Biphasic	Biphasic	Same
Shape	Rectangular	Rectangular, triangular, trapezoidal, sinusoidal	Different Note 3 FES
Symmetrical or asymmetrical	Symmetrical	Symmetrical	Same
Maximum voltage output	50V @500Ω 164V @2kΩ 170V @10kΩ	50V @500Ω 60V @2kΩ N/A @10kΩ	Different Note 4 FES
Maximum output Current	100mA @500Ω 82 mA @2kΩ 17 mA @10kΩ	100mA @500Ω 30mA @2kΩ N/A @10kΩ	Different Note 4 FES
Current output channel	0 - 100 mA (steps 1mA)	0 - 100 mA	Same
Pulse Width	50 µs - 400 µs	50 µs - 400 µs	Same
Frequency	1 - 140 Hz	1 - 140 Hz	Same
Beat Frequency	N/A	N/A	N/A

Net charge (µC per pulse)	0µC (Balanced pulses)	0µC Same positive and negative impulse	Same
Max phase charge @500Ω	40 µC	40 µC	Same
Maximum current density (mA/cm) @500Ω	0.224 mA/cm2 (25 cm2 electrode area)	0.22 mA/cm2	Different Note 5 FES
max. power density (W/cm2)	0.00062 W/cm2 (25 cm2 electrode area)	0.63 mW/cm2	Different Note 5 FES
Temperature in Use	0°C to 40 ºC 32°F to 104 °F	Unknown	N/A
Temperature transporting/storing	-20°C - 60 ºC -4°F to 140 °F	Unknown	N/A
Relative humidity	In use: 10 % to 75%. In Transportation/Storage: 10% to 85%.	Unknown	N/A

Substantial Equivalence discussion and Differences Analysis. Comparison with Predicate Device - Output Specifications for Functional Electrical Stimulation

Note 1 FES: Number of Output Channels
Although the “Number of Output Channels” are different from the predicate device they all comply with IEC 60601-1 and IEC 60601-2-10 requirements and the difference doesn’t impact essential performance, basic safety or substantial equivalence.

Note 2 FES: Alternating or Synchronous
The predicate device has a Synchronous EMG acquisition triggering. The different is that the EMG samples can be acquired and compared sample-to-sample, which in Alternating sampling is not possible. This difference doesn’t impact essential performance, basic safety or substantial equivalence.
There are other devices on the market that have this same feature such as the K080950 without impacting the essential performance and basic security of the device.

Note 3 FES: Shape of the waveforms
Predicate device provides waveforms shapes (triangular, trapezoidal and sinusoidal) in addition to rectangular waveforms. Electrical stimulation for triangular, trapezoidal and sinusoidal waveforms are considerate safer than rectangular waveforms due to lower maximal phase charge, current density and power density, but it does not mean that the rectangular waveforms is not safe, besides the predicate also uses it. Electrical stimulation for rectangular waveforms were tested and are compliant with the requirements in IEC 60601-2-10.

The difference in waveforms doesn't impact essential performance, basic safety or substantial equivalence.

Note 4 FES: Maximum Output Voltage
Although the Maximum Output Voltage of the new device are different than in the predicate device, they were all tested and are compliant with IEC 60601-2-10. Therefore, the difference doesn't impact essential performance, basic safety or substantial equivalence.

Note 5 FES: Maximum Current Density and Maximum Power Density
Although the Maximum Current Density and Maximum Power Density of subject device are different from the predicate device, which is related to the electrode surface that is different for both devices, they all comply with the FDA guidance requirement for Powered Muscle Stimulator 510 (k)s, so the differences of function specification will not raise any safety or effectiveness issue.

VII) Summary of Non-Clinical Testing

The following testing was conducted to prove safety and effectiveness as well as substantial equivalence to the predicate device:

- IEC 60601-1 Medical electrical equipment Part 1: General requirements for basic safety and essential performance.

- IEC 60601-1-2 Medical electrical equipment Part 1-2: General requirements for basic safety and essential performance. Collateral Standard: Electromagnetic
- disturbances – Requirements and tests.

- IEC 60601-2-10 Medical electrical equipment Part 2: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators.

- IEC 60601-1-11 Medical electrical equipment–Part 1-11: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment.

- IEC 62133-2 Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications.

- IEC 62304 Medical device software — Software life cycle processes.

- IEC 62366 Applying Human Factors and Usability Engineering to Medical Device.

- ISO 14971 Medical devices - Application of risk management to medical devices.

VIII) Summary of Clinical Testing

No clinical testing was performed in support of this submission.

IX) Conclusion

The intended use of the TrainFES Advanced device is equivalent to that of the predicate device K210002. The basic technological features are virtually the same for the subject and predicate devices, with minor differences that do not raise safety or efficacy issues. Comparing the hardware and software of the subject device it is equivalent to the predicate device mentioned above.The TrainFES Advanced device meets the requirements of IEC 60601-1, IEC 60601-2-10, IEC60601-1-2 and IEC 60601-1-11. The bench test and safety report documentation provided in this presentation demonstrates that possible differences in their technological characteristics do not raise new safety or effectiveness issues. Thus, the TrainFES Advanced device is substantially equivalent to the predicate device K210002.