March 21, 2024

Mettler Electronics Corporation
Kevin O'Connell
VP Global Regulatory Affairs
Lutronic Corporation
Lutronic Center
219, Sowon-Ro
Deogyang-Gu, Goyang-Si 410220
South Korea

Re: K233926
Trade/Device Name: accufit
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered Muscle Stimulator
Regulatory Class: Class II
Product Code: IPF, NGX
Dated: March 7, 2024
Received: March 7, 2024

Dear Kevin O'Connell:

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,

Heather L. Dean -S

Heather Dean, PhD
Assistant Director, Acute Injury Devices Team
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)*
K233926

Device Name
accufit

Indications for Use *(Describe)*
- Relaxation of muscle spasms
- Prevention or retardation of disuse atrophy
- Increase local blood circulation
- Muscle re-education
- Maintaining or increasing range of motion
- Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis
- Improvement of abdominal tone, for strengthening of the abdominal muscles, for development of firmer abdomen.
- Improvement of muscle tone and firmness, for strengthening muscles in arms, thighs and buttocks areas.

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

K233926

A summary of 510(k) safety and effectiveness information in accordance with the requirements of 21 CFR 807.92.

807.92(a)(1) - Submitter Information	
Name	Mettler Electronics Corporation
Address	1333 South Claudina Street Anaheim, CA USA 92805
Phone number	978-888-1426
Fax number	N/A
Name of contact person	An Le QS/RA Manager, Mettler Electronics Corporation 1333 South Claudina Street Anaheim, CA 92805
Date prepared	March 19, 2024
807.92(a)(2) - Name of device	
Trade or proprietary name	accufit
Common or usual name	Powered Muscle Stimulator
Classification name	Stimulator, Muscle, Powered, For Muscle Conditioning
Classification panel	Physical Medicine
Regulation	21 CFR 890.5850
Product Code(s)	IPF, NGX
807.92(a)(3) - Legally marketed device(s) to which equivalence is claimed	
	Mettler Electronics Corporation K223802 (10/06/2023) Predicate Johari Digital Healthcare Limited K192039 (03/29/2020) Reference Sport- Elec K092476 (05/07/2010) Reference
807.92(a)(4) - Device description	
	The principle of operation of the accufit device is to provide direct electrical stimulation of muscles which produces muscle contractions in and around the area of the treatment electrodes. The accufit generates electrical stimulation to contract the muscles to achieve the desired intended use using unique IntelliPhase waveforms and IntelliSTIM electrodes. It offers two unique IntelliPhase waveforms, Biphasic and Interferential (4P), that are designed to optimize muscle re-education and activation for patients. The four IntelliPhase waveform protocols are twist, hold, grip, and tap. Each

	protocol may be used for 15, 30, or 45 minutes. Not only are there four IntelliPhase protocols, but there is also a fully automated protocol (IntelliCycle) that integrates all the above listed waveforms in a comprehensive, interlaced series. This engages all the targeted muscles in a continuous program to maximize muscle effects with the touch of a button. accufit is both the proprietary-trade name and generic name. accufit is a supplement to existing treatments and does not replace any traditional treatment or therapy. The system console is the heart of the accufit and contains the Touch LCD/GUI, electrodes, and power supply module. The main console also includes a key switch used to turn the power on and off, and an emergency stop push button that quickly de-energizes the system in emergency situations. There are 4 casters in the console base that can be used when moving the system.
807.92(a)(5) Intended use of the device	
Indications for use	The accufit is indicated for use for Relaxation of muscle spasms, Prevention or retardation of disuse atrophy, Increase local blood circulation, Muscle re-education, Maintaining or increasing range of motion, Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis, Improvement of abdominal tone, for strengthening of the abdominal muscles, for development of firmer abdomen, and Improvement of muscle tone and firmness, for strengthening muscles in arms, thighs and buttocks areas.

807.92(a)(6) Summary of the technological characteristics of the device compared to the predicate					
Model Name	accufit	accufit	Torc Body	Body Control System "4M"	Notes
510(k) #	Subject device	K223802	K192039	K092476	
Manufacturer	Mettler	Mettler	Johari Digital Healthcare Limited	Sport-Elec S.A	
Indications for Use	• Relaxation of muscle spasms • Prevention or retardation of disuse atrophy • Increase local blood circulation • Muscle re-education • Maintaining or increasing range of motion • Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis • Improvement of abdominal tone, for strengthening of the abdominal muscles, for development of firmer abdomen. Improvement of muscle tone and firmness, for strengthening muscles in arms, thighs and buttocks areas.	• Relaxation of muscle spasms • Prevention or retardation of disuse atrophy • Increase local blood circulation • Muscle re-education • Maintaining or increasing range of motion • Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis	• Improvement of abdominal tone, for strengthening of the abdominal muscles, for development of firmer abdomen. • Strengthening, toning and firming of buttocks & thighs.	Improvement of muscle tone and firmness, for strengthening muscles in arms, abdomen, thighs and buttocks areas.	Identical to predicate plus reference devices

Classification	890-5850 - IPF, NGX	890-5850 - IPF	890-5850 - NGX	890-5850 - NGX	Identical to predicate plus reference devices
Power Source	100-240VAC , 50/60Hz, 1.0A (Fuse: 250V / 6.3A)	100-240VAC , 50/60Hz, 1.0A (Fuse: 250V / 6.3A)	100-240AC, 50/60Hz, 75VA	Battery powered	Identical
Therapeutic Modality	Electrical muscle stimulator	Electrical muscle stimulator	Electrical muscle stimulator	Electrical muscle stimulator	Identical
Treatment Output Mode	Electrode	Electrode	Electrode	Electrode	Identical
Method of Line Current Isolation	Double Insulated Wire Non- Conductive Enclosure	Double Insulated Wire Non-Conductive Enclosure	(a) AC Power supply is converted to DC Power supply through a medical grade PSU. (b) Isolation thru transformer in between device and patient	Not available	Same as predicate
Measured Patient Leakage:					
Normal Condition (µ A)	Less than 100µA	Less than 100µA	Less than 100µA	Not available	Identical
Single Fault Condition (µA)	Less than 100µA	Less than 100µA	Less than 300µA	Not available	Similar
Number of Output Modes	4	4	3	Not available	1 additional mode
Number of Output Channels	2	2	2	2	Identical
Regulated Current or Voltage	Current = 100mA maximum	Current = 100mA maximum	103.2 mA pp @ 500 Ohm 31.2 mA pp @ 2K Ohm 6.6 mA pp @ 10K Ohm	Not available	Identical when compared at 500 Ohm

Pulse Intensities	Adjustable, 0-100 mA peak into 500ohm load each Electrode channel	Adjustable, 0-100 mA peak into 500ohm load each Electrode channel	Not available	Not available	Same as predicate
Software/Firmware/ Microprocessor Control	yes	yes	yes	Not available	Identical
Automatic Over Current Trip?	yes	yes	yes	Not available	Identical
Automatic No Load Trip?	yes	yes	no	Not available	Same as predicate
Automatic Shut Off?	yes	yes	yes	Not available	Identical
User Override control?	Patient Interrupt (Stop) Switch	Patient Interrupt (Stop) Switch	yes	Not available	Identical
Indicator Display:	yes	yes	yes	Not available	Identical
On/ Off Status?	yes	yes	yes	Not available	Identical
Voltage/ Current Level?	yes	yes	yes	Not available	Identical
Timer range	15, 30, 45 mins	15, 30, 45 mins	1 – 60 Minutes In step of 1 minute	Not available	Similar
Compliance: Voluntary Standards	IEC 60601-1; 60601-1-2; 60601-2-10, ISO 14971, UL 60601, CSA C22.2 No 606.1	IEC 60601-1; 60601-1-2; 60601-2-10, ISO 14971, UL 60601, CSA C22.2 No 606.1	YES IEC 60601-1, IEC 60601-1-2,IEC60601-2-10, and ISO14971	Not available	Similar
Compliance: 21 CFR 898	yes	yes	yes	Not available	Identical
Weight	27 Kg	27 Kg	32.66 Kgs	Not available	Similar
Dimensions (mm) W x L x H	452 x 582 x 1101	452 x 582 x 1101	444 X 356 X 1016	84x126x30	Similar
Housing, Materials and Construction	ABS plastic	ABS plastic	ABS Plastic Body	Not available	Identical

Medical Equipment Classification	Type BF	Type BF	Not available	Not available	Identical

807.92(b)(1) NON CLINICAL TESTS SUBMITTED

- IEC 60101-1, an International Standard on Medical electrical equipment general requirements for safety (FDA Recognition List Number 19-4);
- IEC 60601-1-2, an International Standard on Medical electrical equipment, electro- magnetic compatibility (FDA Recognition List Number 19-8);
- IEC 60601-1-6, an International Standard on Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability (FDA Recognition List Number 5-132),
- IEC 60601-2-10 an International Standard on Medical electrical equipment - Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators (FDA Recognition List Number 17-16), and
- IEC TR 60601-4-2 Medical electrical equipment - Part 4-2: Guidance and interpretation - Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems (FDA Recognition List Number 19-19).
- IEC 62304 Medical device software - Software life cycle processes (FDA Recognition List Number 13-79)
- Cytotoxicity per ISO 10993-5:2009
- Skin sensitization per ISO 10993-10:2021
- Skin Irritation per ISO 10993-23:2021

807.92(b)(2) CLINICAL TESTS SUBMITTED

A clinical study was performed to assess the effect of the device on the strengthening and appearance of arms. 45 subjects were enrolled in the study and treated with this bioelectric muscle activation (BMA) device. Strength was measured with a dynamometer device at baseline, at the final treatment session, and at the posttreatment 30- and 90-day assessment. The device was tolerated, and most patients saw improvement in muscle strength from the initial to final treatment, as measured by the dynamometer. There were no significant adverse events noted in the duration of the study.

807.92(b)(3) Conclusion

Based on the comparison of the technological characteristics, the specifications for the accufit are the same or a subset of the Torc Body specifications. The options of two sized electrodes allow the users more options in how the same energy is shaped during delivery. The new indication of strengthening arms is supported by clinical testing. Also, the indication is the same as the reference device, SPORT-ELEC BODY CONTROL SYSTEM, MODEL 4M. Therefore, we believe that the subject device is substantially equivalent to the predicate devices.