October 6, 2023

Mettler Electronics Corporation
An Le
QS/RA Manager
1333 South Claudina Street
Anaheim, California 92805

Re: K223802
Trade/Device Name: accufit
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered Muscle Stimulator
Regulatory Class: Class II
Product Code: IPF
Dated: October 5, 2023
Received: October 5, 2023

Dear An Le:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jitendra V. Virani -S

CDR Jitendra Virani, MS, MBA
Assistant Director
DHT5B: Division of Neuromodulation
and Rehabilitation Devices
OHT5: Office of Neurological
and Physical Medicine Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K223802

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

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 – accufit (510k number K223802)

Mettler Electronics Corporation
accufit 510k Summary

I. Submitter

Mettler Electronics, Corporation 1333 South Claudina Street Anaheim, CA USA 92805

Contact Person Timothy Duggins Phone: 602-200-4981
Email: timd@horizonphoenix.biz Date Revised: March 27, 2023

II. Device

Trade Name:	accufit
Usual Name:	powered muscle stimulator
Regulation Number:	21 CFR 890.5850
Regulation Name:	Powered Muscle Stimulator
Regulatory Class:	Class II
Product Code:	IPF

III. Predicate Device

Primary Predicate Device (for the accufit):

Trade Name:	Mettler Sys*Stim ME 240, K113017
Common or Usual Name:	powered muscle stimulator
Regulation Number:	21 CFR 890.5850
Regulation Name:	Powered Muscle Stimulator
Regulatory Class:	Class II
Product Code:	IPF, GZJ, ILY, LIH

Premarket Notification: Mettler Electronics K113017 (06/22/2012)

Secondary Predicate Device: Self-adhesive Electrode, K222252 for the IntelliSTIM and IntelliGEL

Trade Name:	Self-adhesive Electrode
Common or Usual Name:	Cutaneous electrode
Regulation Number:	21 CFR 882.1320
Regulation Name:	cutaneous electrode
Regulatory Class:	Class II
Product Code:	GXY

Premarket Notification: Shenzhen Roundwhale Technology Co., Ltd, K222252, (01/19/2023)

IV. Device Description

accufit (subject device) when using the Biphasic/Interferential (4P) waveforms is a non-invasive powered muscle stimulator used to provide an electrical stimulation of muscles for muscle re-education. The accufit is used on an outpatient basis under the supervision of a clinician.

The accufit is the result of a close collaboration between Lutronic Corporation and Mettler Electronics, Corporation. Mettler is the manufacturer of both the subject and predicate device. Using the Mettler Sys*Stim ME240 (K113017) as a starting point, the accufit utilizes two of the original and unchanged waveforms for muscle reeducation.

There are four preprogrammed treatment regimens that enable users to mimic common physical exercises. Each treatment regimen has recommended treatment electrode placement depicted in both the accufit operator's manual and on the accufit graphic user interface (GUI). The IntelliSTIM treatment electrodes have been designed to support the accufit and are controlled by an intelligent real-time impedance feedback Mettler System. The IntelliSTIM are held in place with hydrogel adhesive strips and Velcro body wraps. The user may select the treatment duration of either 15, 30 or 45 minutes. The size, type of electrode and technical/performance characteristics.

V. Indications for Use

As the accufit (subject device) and the Mettler Sys*Stim ME240 (predicate device K113017) have nearly identical technical and performance specifications. The two devices share the same indications for use considering the accufit uses only 2 of the Mettler Sys*Stim ME240 9 outputs/waveforms as indicated:

Waveform	Indication for Use
Biphasic, Interferential (4P)	• 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

VI. Comparison of the technology characteristics with the predicate device

Mettler Electronics, Corporation believes that the accufit described herein and for use under the conditions of the proposed labeling is substantially equivalent to the Mettler Sys*Stim ME240, predicate device (K113017). Owing to the close collaboration between Lutronic Corporation and Mettler Electronics the subject and predicate device have nearly identical Technical Characteristics.

Mettler Electronics, Corporation **29 September 2023**
Traditional 510k Submission
accufit
Powered Muscle Stimulator **21 CFR §890.5850**

Utilizing FDA's Guidance for Industry and FDA Staff "Format for traditional and Abbreviated 510(k)s", the accufit (subject device) is substantially equivalent to the Mettler Sys*Stim ME 240 (predicate device K113017).

Indications for Use

The accufit (subject device) and the Mettler Sys*Stim ME240 (predicate device K113017) have the following identical indications for use considering the two common waveforms (Biphasic and Interferential (4P) bolded).

Waveform	accufit	ME240 (K113017)	Comment
Biphasic Interferential (4P)	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	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	Identical
Microcurrent, Interferential (4P), Premodulated (2P3), Biphasic and TENS waveforms	Not applicable.	Symptomatic relief and management of chronic, intractable pain, Post-traumatic acute pain, Post-surgical acute pain	See Note below.
DC (Direct Current) Mode	Not applicable.	Relaxation of muscle spasm	See Note below.
Laser and cluster applicators of the Sys*Stim 240emit infrared energy	Not applicable.	Temporary increase in blood circulation, Temporary relief of minor muscles and joint aches, pains and stiffness, relaxation of muscles, temporary relief of muscle spasms, temporary relief of minor pain and stiffness associated with arthritis.	See Note below.

NOTE: The ME 240 (predicate device K113017) has other modes (Microcurrent, Premodulated (2P3), TENS, DC (direct current), and laser/cluster applicators which are NOT present in the accufit (subject device). There is no claim of substantial equivalency with these modes and their indications for use.

Mettler Electronics, Corporation **29 September 2023**
Traditional 510k Submission
accufit
Powered Muscle Stimulator **21 CFR §890.5850**

Characteristic	**accufit**510k –K223802 (subject device)	**Mettler Sys*Stim ME240**, K113017 (predicate device)	**Substantial equivalence discussion**
Manufacturer	Mettler Electronics Corporation	Mettler Electronics Corporation	Identical
Classification	Class II- 890-5850 - IPF	Class II- 890-5850 - IPF, GZJ, ILY, LIH	Identical
Power Source	100-240VAC, 50/60Hz, 1.0A (Fuse: 250V / 6.3A)	100-240VAC, 50/60Hz, 1.0A (Fuse: 250V / 6.3A)	Identical
Therapeutic Modality	Electrical muscle stimulator	Electrical muscle stimulator	Identical
Treatment Output Mode	Electrode	Electrode	Identical
Method of Line Current Isolation	Double Insulated Wire Non- Conductive Enclosure	Double Insulated Wire Non- Conductive Enclosure	Identical
Measured Patient Leakage:			
Normal Condition (µ A)	Less than 100µA	Less than 100µA	Identical
Single Fault Condition (µA)	Less than 500µA	Less than 500µA	Identical
Number of Output Modes	2	9	See Note #7.
Number of Output Channels	2	2	Identical
Regulated Current or Voltage?	Current = 100mA maximum	Current = 100mA maximum	Identical
Synchronous or Alternating	Synchronous Channel 1&2	Synchronous Channel 1&2	Identical
Constant Current	NA	Optional	See Note #5.
Constant Voltage	NA	Optional	See Note #5.
Method of Channel Isolation	Line current isolation	Line current isolation	Identical
Pulse Intensities	Adjustable, 0-100 mA peak into 500ohm load each Electrode channel	Not known	See Note #6.
Software/Firmware/Microprocessor Control?	Yes	Yes	Substantially Equivalent see Note #1
Automatic Overload Trip?	Yes	Yes	Identical
Automatic No Load Trip?	Yes	Yes	Identical
Automatic Shut Off?	Yes	Yes	Identical
Patient Override Control?	Patient Interrupt (Stop) Switch	Patient interrupt Switch	Identical
Indicator Display:	Yes	Yes	Substantially Equivalent see Note #1
On/ Off Status?	Yes	Yes	Substantially Equivalent see Note #1
Low Battery?	NA	Yes	NA See Note #3.
Voltage/ Current Level?	Yes	Yes	Substantially Equivalent see Note #1
Timer range	15, 30, 45 mins	0 – 60 minutes	Substantially Equivalent see Note #2
Compliance: Voluntary Standards	IEC 60601-1; 60601-1-2; 60601-2-10, ISO 14971, UL 60601, CSA C22.2 No 606.1, MDD 93/42/EEC, Annex II	IEC 60601-1; 60601-1-2; 60601-2-10, ISO 14971, UL 60601, CSA C22.2 No 606.1, MDD 93/42/EEC, Annex II	Identical
Compliance: 21 CFR 898	Yes	Yes	Yes
Weight	27 Kg	4.5 lbs. , 5.5 lbs. with battery	See Notes #3 and #4.
Dimensions (mm) W x L x H	452 x 582 x 1101	8 inches (H) x 8 inches (W) x 13 inches (L)	See Note #4
Housing, Materials and Construction	ABS plastic	ABS plastic	Identical
Medical Equipment Classification	Type BF	Type BF	Identical

NOTE 1: In each device the software operates the GUI. In the case of the accufit the software only activates the 2 waveforms described, the Biphasic and the Interferential (4P). The difference does not raise any new safety or effectiveness questions and each device has identical safety and performance characteristics.

Note 2: The accufit uses identical levels of intensity however for a shorter duration. The difference does not raise any new safety or effectiveness questions and each device has identical safety and performance characteristics.

Note 3: The accufit does not have a battery. The difference does not raise any new safety or effectiveness questions and each device has identical safety and performance characteristics.

Note 4: The accufit is enclosed in an upright, wheeled configuration which is merely a branding initiative. The difference does not raise any new safety or effectiveness questions and each device has identical safety and performance characteristics.

Note 5: The accufit does have these options. The difference does not raise any new safety or effectiveness questions and each device has identical safety and performance characteristics.

Note 6: The accufit (subject device) and ME 240 (predicate device K113017) have identical electronic characteristics, therefore the difference in pulse intensities (if any) do not raise any new safety or effectiveness questions and each device has identical safety and performance characteristics.

Note 7: The accufit (subject device) and ME240 (predicate device K113017) generate identical Biphasic and Interferential (4P) waveforms. The ME240 (predicate device K113017) generates six additional waveforms and one additional mode which are not found in the accufit (subject device). Substantially equivalency claim is limited only to the Biphasic and Interferential (4P) waveforms. The difference does not raise any new safety or effectiveness questions and each device has identical safety and performance characteristics.

VII. Comparison of the output specifications with the predicate device (K113017)

Powered Muscle Stimulator Device	**accufit** 510k – K223802 (subject device)	**Mettler Sys*Stim ME240 -** K113017 (predicate device)	**Substantial Equivalence Discussion**
Waveforms	2 (Biphasic and Interferential (4P))	Medium Frequency (Russian), Biphasic, High Volt Pulsed Current (HVPC), Interferential (4P), Premodulated (2P), Microcurrent, TENS and DC (Direct Current) Mode	Different See Note #2
Shape	Square (Biphasic) Sinusoidal (Interferential (4P))	Square (Biphasic) Sinusoidal (Interferential (4P))	Identical
Maximum Output Voltage (Biphasic) (Volts, peak to peak)	104 @ 500Ω; 197 @ 2kΩ; 178 @ 10kΩ	104 @ 500Ω; 197 @ 2kΩ; 178 @ 10kΩ	Identical
Maximum Output Voltage (Interferential (4P)) (Volts, peak to peak)	106 @ 500Ω; 144 @ 2kΩ; 122 @ 10kΩ	106 @ 500Ω; 144 @ 2kΩ; 122 @ 10kΩ	Identical
Maximum Output Current (Biphasic) (mA, ±20%)	106 @ 500Ω; 49 @ 2kΩ; 9 @ 10kΩ	106 @ 500Ω; 49 @ 2kΩ; 9 @ 10kΩ	Identical
Maximum Output Current (Interferential (4P)) (mA, ±20%)	106 @ 500Ω; 35 @ 2kΩ; 6.3 @ 10kΩ	106 @ 500Ω; 35 @ 2kΩ; 6.3 @ 10kΩ	Identical
Pulse Width (Biphasic)	40-800 µSec	40-800 µSec	Identical
Pulse Width (Interferential (4P))	200-400 µSec	200-400 µSec	Identical
Frequency (Biphasic)	1-200 Hz	1-200 Hz	Identical
Frequency (Interferential (4P))	2.5 kHz, 4 kHz, 5 kHz	2.5 kHz, 4 kHz, 5 kHz	Identical
For Interferential (4P) modes only: Best Frequency (Hz)	1-250 Hz	1-250 Hz	Identical
For Multiphasic waveforms only: Symmetrical phases?	Yes	Yes	Identical
Phase duration (Biphasic) – (µSec)	~35 µSec	Not known	See Note #1.
Phase duration (Interferential (4P)) – (µSec)	100, 125, 200 µSec	100, 125, 200 µSec	Identical
Net Charge (µC micro Coulombs per pulse). If zero, method of achieving	Net Charge = 0 µC (Biphasic & Interferential (4P) pulses are symmetrical about 0V)	Net Charge = 0 µC (Biphasic & Interferential (4P) pulses are symmetrical about 0V)	Identical
Duration of Primary (depolarizing) Phase	~35 µSec	Not known	See Note #1.

Pulse Duration	360 µSec	Not known	See Note #1.
Maximum Phase Charge(µC) (Biphasic)	42.4 µC, 500 Ω	42.4 µC, 500 Ω	Identical
Maximum Phase Charge (Interferential (4P))	14.9 µC, 500 Ω	14.9 µC, 500 Ω	Identical
Maximum Power Density (Biphasic) (using smallest electrode conductive surface area)	0.043 W/cm², 500 Ω	0.043 W/cm², 500 Ω	Identical
Maximum Power Density (Interferential (4P)) (using smallest electrode conductive surface area)	0.176 W/cm², 500 Ω	0.176 W/cm², 500 Ω	Identical
Maximum Current Density (Biphasic)	5.13 mA/cm², 500 Ω	5.13 mA/cm², 500 Ω	Identical
Maximum Current Density (Interferential (4P))	5.196 mA/cm², 500 Ω	5.196 mA/cm², 500 Ω	Identical
Burst Mode (pulse trains)	NA (no bursts)	NA (no bursts)	Identical
ON Time (seconds)	Biphasic 1 – 240 Interferential (4P) NA	Not known	See Note #1.
OFF Time (seconds)	Biphasic 1 – 240 Interferential (4P) NA	Not known	See Note #1.

Note 1: The accufit (subject device) and ME 240 (predicate device K113017) have identical electronic characteristics, therefore the difference in these characteristics (if any) do not raise any new safety or effectiveness questions and each device has identical safety and performance characteristics.

Note 2: The accufit (subject device) and ME240 (predicate device K113017) generate identical Biphasic and Interferential (4P) waveforms. The ME240 (predicate device K113017) generates six additional waveforms and one additional mode which are not found in the accufit (subject device). Substantially equivalency claim is limited only to the Biphasic and Interferential (4P) waveforms. The difference does not raise any new safety or effectiveness questions and each device has identical safety and performance characteristics.

The IntelliSTIM and IntelliGEL are substantially equivalent to the Self Adhesive Electrode predicate device (K222252) as shown in the following table:

Characteristic See Note 1	**IntelliSTIM IntelliGEL K223802 Subject Device**	**Self-adhesive Electrode Predicate Device K222252**	**Discussion**
Regulation	21 CFR 882.1320	21 CFR 882.1320	Identical
Product Code	GXY	GXY	Identical
Manufacturer	Mettler Electronics Corporation	Shenzhan Roundwhale Technology Co. Limited	NA
Classification Name	Cutaneous electrode	Cutaneous Electrode	Identical
Model Name	IntelliSTIM (electrodes) IntelliGEL (hydrogel adhesive)	Self-adhesive Electrode with lead wire	See Note #1.
Common Name	Reusable Neurostimulation Electrode	Reusable Neurostimulation Electrode	
OTC/Prescription	Prescription	OTC and Prescription	See Note #5.

Target Population	General (Adult)	General (Adult)	Identical
Electrical Connection	Lead wire	Lead wire, snap button, Magnetic Button	Identical See Note #2.
Size and Shape	Rectangular 60*70mm	Round 50±0.5cm), Rectangular (50* 30±0.5mm), Square 50*50±0.5mm, Square 40*40±0.5mm, Oval 40*80±0.5mm	Substantially Equivalent See Note #2.
Protective Cover/Liner	ABS	PET	Substantially Equivalent See Note #3.
Conductive Component	Copper coated carbon film	Silver coated carbon film	Substantially Equivalent See Note #4.
Color	Red and Black	White	See Note #5.
Lead Wire Connector	.080.0.1" female socket or pin connector	.080/0.1" female socket or pin connector	Identical
Design Features	(1) Protective film lining of the applied part consisting of Polyethylene terephthalate and Silicon; (2) the hydrogel with silver chloride substrate and (3) a liner protecting the hydrogel and the electrode consisting of Polyethylene terephthalate and Silicon.	Six layers: 1.Insulation backing material: Fabric/Foam/ Tan fabric 2.Conductive film: Aluminum foil film /Carbon film/Carbon film coated with silver/ 3.Conductive hydrogel 4.Connection 5.double sides adhesive tape 6.Release liner	See Note #1.
Reusable	Reusable	Reusable	See Note #1.
Single Patient Use	Yes	Yes	Identical
Biocompatibility	ISO 10993 compliant	ISO 10993 compliant	Identical
Sterile	Nonsterile only	Nonsterile only	Identical
Adhesive Type	Self-adhesive (biocompatible self-adhesive conductive hydrogel)	Self-adhesive	Identical See Note #1.
Electrical Safety	ANSI AAMI ES60601-1:2005/(R)2012 & A1:2012, C1:2009/(R)2012 & A2:2010/(R)2012 (Cons. Text) [Incl. AMD2:2021] , Medical electrical equipment – Part 1: General requirements for basic safety and essential performance	ANSI AAMI ES60601-1:2005/(R)2012 & A1:2012, C1:2009/(R)2012 & A2:2010/(R)2012 (Cons. Text) [Incl. AMD2:2021] , Medical electrical equipment – Part 1: General requirements for basic safety and essential performance	Identical See Note 5.

emc/emi	ANSI AAMI ES60601-1:2005/(R)2012 & A1:2012, C1:2009/(R)2012 & A2:2010/(R)2012 (Cons. Text) [Incl. AMD2:2021], Cl.8.5.2.3	ANSI AAMI ES60601-1:2005/(R)2012 & A1:2012, C1:2009/(R)2012 & A2:2010/(R)2012 (Cons. Text) [Incl. AMD2:2021], Cl.8.5.2.3	Identical See Note 5.
Biocompatibility	Complies with ISO 10933	Complies with ISO 10933	Identical
Force required to remove wire from electrode	More than six pounds of force	More than six pounds of force	Identical
AC Impedance	<200Ω	<300Ω	Substantially Equivalent – See Note 2.
Adhesive strength	>185g/in	≥7N	See Note 6.
Indications for use	The IntelliSTIM and IntelliGel when used according to the accufit operator's manual forms a conductive adhesive interface between the accufit and the patient's skin.	Self-Adhesive Electrode are intended for use as a reusable, conductive adhesive interface between the patient's skin and the marketed electrical stimulators (i.e. TENS (Transcutaneous Electrical Nerve Stimulation), EMS (Electrical Muscular Stimulation), IF or IFC (Interferential) or PGF (Pulsed Galvanic Stimulation) for transmitting electrical current. The electrode is for OTC (Over-The-Counter) or Prescription use.	Substantially Equivalent – See Note #1.

Note 1 – In each device the electrode floats above the patient through the use of a hydrogel pad. The accufit IntelliStim electrode and IntelliGel self-adhesive hydrogel pad forms an identical combination to the predicate device (K222252) however the IntelliStim electrode being separate is reusable. The IntelliGel pad is disposable. The Self Adhesive Electrodes [Predicate Device, K222252] is a substantially equivalent combination of electrode and hydrogel pad however as the electrode and hydrogel pad are a single unit, therefore entire accessory is single use. The IntelliSTIM and IntelliGEL are for use only with the accufit and no claims are made for use on any other device. The difference does not raise any new safety or effectiveness questions and each device has identical biocompatible safety and performance characteristics

Note 2 – The electrode's size is directly related to the area being treated. Its AC impedance, size and shape evenly distributes the electrical stimulation preventing burns or similar injuries. The IntelliSTIM electrode was purpose-developed for use the accufit and for no other device, therefore there is no snap button or magnetic button required. There is no substantial equivalence claimed for any size of the Predicate's (K222252) Square 50*50±0.5mm electrode. The difference does not raise any new safety or effectiveness questions and each device has identical safety and performance characteristics.

Note 3 – Both materials are thermoplastics with identical performance characteristics. The difference does not raise any new safety or effectiveness questions and each device has identical safety and performance characteristics.

Note 4 - Both copper and silver are highly conductive materials. Copper is used in the IntelliSTIM because the metal is stronger and therefore more suited for a reusable accessory. Both the subject and predicate device (K222252) were tested according to the ISO 10993 series of Standard and were found to have zero toxic, irritating or sensitization risks. The difference does not raise any new safety or effectiveness questions and each device has identical safety and performance characteristics.

Note 5 – The IntelliSTIM electrode set is designed to be used with the accufit and no other device. The Self-adhesive Electrode (K222252)is designed to be used with multiple devices. The IntelliSTIM electrodes was included in the accufit's electrical safety and emc/emi testing; for example IEC 60601 clause 8.5.2.3, the combination accufit and IntelliSTIM electrode was found to be in compliance with all pertinent requirements. The difference does not raise any new safety or effectiveness questions and each device has identical safety and performance characteristics.

Note 6 – 185g/in was determined using a different methodology then that used in the predicate device (K222252). The adhesive strength is stronger in the subject device owing to having two elements (IntelliSTIM and IntelliGEL) instead of one and it was designed for exclusive use with the accufit. Design did not have to consider the variety of devices that the electrode/adhesive might be used on. The difference does not raise any new safety or effectiveness questions and each device has identical safety and performance characteristics.

VIII. Indications for Use Statement Comparison

The accufit (subject device) uses only two of the Mettler Sys*Stim ME240's waveforms/outputs:

Waveform	accufit	ME240 (K113017)
Medium Frequency (Russian)	Not used	X
Biphasic	X	X
High Volt Pulsed Current (HVPC)	Not used	X
Interferential (4P)	X	X
Premodulated (2P3) waveforms	Not used	X
Microcurrent	Not used	X
Interferential (4P3)	Not used	X
Premodulated (2P)	Not used	X
DC (Direct Current)	Not used	X
Laser/cluster infrared	Not used	X

IX. Performance Data

Biocompatibility

Testing

The accufit and the IntelliSTIM treatment electrodes have no meaningful biocompatibility risk or hazard as there is no patient contact.

The IntelliGel hydrogel adhesive strips biocompatibility evaluation was conducted in accordance with the FDA's Guidance for Industry and FDA Staff "Use of International Standard ISO 10993-1, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing within a Risk Management Process" using:

a. ISO 10993-5, Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity,

b. ISO 10993-10, Biological evaluation of medical devices – Part 10: Tests for Irritation and Sensitization,

No appreciable risk or hazard was detected.

Sterilization and Shelf-Life

The accufit, IntelliSTIM and IntelliGel are not provided sterile and does not need to be sterilized by the end user. The accufit and IntelliSTIM electrodes are cleaned with a soft cloth usually moistened with isopropyl alcohol or a gentle household cleaner. The IntelliSTIM treatment electrodes must have the hydrogel removed from the electrode using a lint free cloth soaked with 90% isopropyl alcohol. The IntelliGel expected service life is 2 years and has been established by accelerated shelf life testing.

Electrical Safety and Electromagnetic Compatibility (EMC)

Electrical safety and EMC testing were conducted on the accufit and IntelliSTIM treatment electrodes (including the hospital grade power cord and patient stop switch) by a duly accredited third party test laboratory whose scope includes electromedical equipment. In every instance the accufit and the IntelliSTIM treatment electrodes were found to be in compliance with:

- IEC 60601-1, 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), and

- 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).

Software Verification and Validation Testing

Software verification and validation testing were conducted, and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" and ISO 62304 Medical device software — Software life cycle processes. The software for the accufit was considered as a "moderate" level of concern (FDA) and as a Class B (ISO 62304) since a failure of the software could result in minor injury to a patient or to a user of the device.

Performance Testing

No animal or clinical testing was required to demonstrate the accufit is safe and will perform as intended. Bench Testing was performed to ensure that the accufit performs as intended and documentation was provided. Testing included normal, single fault and multiple fault scenarios using the requirements of FDA recognized Standards for electrical safety, electromagnetic disturbances and powered muscle stimulators.

X. Conclusions

The accufit [subject device] and the ME240 (primary predicate device, K113017) emanate Biphasic/Interferential (4P) waveforms. The predicate device (K113107)has other modes and indications, but no claim of substantial equivalency is made for these. When used according to the accufit operator's manual, with only those two waveforms, the accufit has the identical intended use, identical indications for use, and the identical fundamental scientific technology and performance characteristics as the predicate device (K113017). The IntelliSTIM and IntelliGel (subject devices) have identical intended use, identical fundamental scientific technology and performance characteristics with the secondary predicate device the Self-adhesive electrode (K222252). The differences between the subject and primary (K113017) and secondary predicate device (K222252) are minor are NOT the result of any short coming or adverse event. Therefore, the accufit is as safe, as effective, and performs as well as the legally marketed predicate devices (K113017) and (K222252).