



October 10, 2024

WEERO Co.,Ltd.  
Moon Young Han  
Regulatory Affairs  
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Suwon, Gyeonggi 16648  
South Korea

Re: K240992

Trade/Device Name: eMVFit (MVF-10M)  
Regulation Number: 21 CFR 890.5850  
Regulation Name: Powered muscle stimulator  
Regulatory Class: Class II  
Product Code: IPF  
Dated: April 2, 2024  
Received: April 11, 2024

Dear Moon Young Han:

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](mailto: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

## Indications for Use

Submission Number (if known)

K240992

Device Name

eMVFit (MVF-10M)

Indications for Use (Describe)

EMS is used for:

- Relaxation of muscle spasms
- Prevention or retardation of disuse atrophy
- Increasing local blood circulation
- Muscle re-education
- Maintaining or increasing range of motion
- Immediate postsurgical 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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**1. Submitter and US Official Correspondent**

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**2. Device Information**

Trade/Device Name: eMVFit / MVF-10M  
Regulation Name: - Powered Muscle Stimulator  
Classification Name: - Stimulator, Muscle, Powered  
Product Code: IPF  
Device Class: Class II (Regulation 21CFR890.5850)

**3. Predicate Device(Equivalent Legally Marketed Device)**

Manufacturer	Device	510(k) No.
<b>Main Predicate</b>		
INMODE LTD.	Evolve System with the T3 Applicator	K201285
<b>Reference Predicate</b>		
INMODE LTD.	Evolve System with the Tone Applicator	K201285
TimeWaver Production GmbH	TimeWaver Frequency	K212832

**4. Description of the Device**

eMVFit has MULTI handpiece, EMS handpiece, patient switch, cradle, distilled water injection hose & funnel, key switch and power cable.

eMVFit has a user interface including an LCD touch screen and has MULTI mode and EMS mode.

MULTI mode has RF and EMS functions that use the MULTI handpiece.

In the case of RF, the target temperature can be set and a vacuum can be used together, and a cooling function can be used as a safety system to prevent burns on the skin surface.

In addition, the MULTI handpiece has a temperature sensor, so the output is automatically turned off when the skin surface temperature exceeds 43 °C.

EMS mode has an EMS function that uses the EMS handpiece.

**5. Indications for use (intended use)**

EMS is used for:

- Relaxation of muscle spasms
- Prevention or retardation of disuse atrophy
- Increasing local blood circulation
- Muscle re-education
- Maintaining or increasing range of motion
- Immediate postsurgical stimulation of calf muscles to prevent venous thrombosis

**6. Substantial Equivalence Discussion**

**1) Comparison Information**

Name	Subject device	Main Predicate device	Reference Predicate device	Reference Predicate device	<b>Comparison</b>
Device Name	eMVFit(MVF-10M)	Evolve System with the T3 Applicator	Evolve System with the Tone Applicator	TimeWaver Frequency	
Manufacturer	WEERO Co.,Ltd.	INMODE LTD.	INMODE LTD.	TimeWaver Production GmbH	
510(k) No.	-	K210877	K201285	K212832	
Product Code, Class	IPF Class II	IPF, GZJ, PBX Class II	IPF, GZJ Class II	IPF, GZJ Class II	<p>The eMVFit device follows the same Product codes(IPF) as the predicate device and eMVFit does not use the code GZJ: Transcutaneous electrical nerve stimulator for pain relief. Therefore, eMVFit does not have the indications for use of the GZJ Product Code.</p> <p>This does not raise new questions of safety and effectiveness.</p>
Indications for use	<ul style="list-style-type: none"> <li>• Relaxation of muscle spasms</li> <li>• Prevention or retardation of disuse atrophy</li> <li>• Increasing local blood circulation</li> <li>• Muscle re-education</li> <li>• Maintaining or increasing range of motion</li> <li>• Immediate postsurgical stimulation of calf muscles to prevent venous thrombosis</li> </ul>	<ul style="list-style-type: none"> <li>• Relaxation of muscle spasms</li> <li>• Prevention or retardation of disuse atrophy</li> <li>• Increasing local blood circulation</li> <li>• Muscle re-education</li> <li>• Maintaining or increasing range of motion</li> <li>• Immediate postsurgical stimulation of calf muscles to prevent venous thrombosis</li> </ul>	<ul style="list-style-type: none"> <li>• Relaxation of muscle spasms</li> <li>• Prevention or retardation of disuse atrophy</li> <li>• Increasing local blood circulation</li> <li>• Muscle re-education</li> <li>• Maintaining or increasing range of motion</li> <li>• Immediate postsurgical stimulation of calf muscles to prevent venous thrombosis</li> </ul>	<ul style="list-style-type: none"> <li>-Relaxation of muscle spasms</li> <li>-Retardation or prevention of disuse atrophy</li> <li>-Increased local blood circulation</li> <li>-Re-Educating muscles</li> <li>-Maintaining or increasing range of motion.</li> <li>-Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis</li> </ul>	Same

eMVFit  
510(k) Summary

Name	Subject device	Main Predicate device	Reference Predicate device	Reference Predicate device	Comparison
Device Name	eMVFit(MVF-10M)	Evolve System with the T3 Applicator	Evolve System with the Tone Applicator	TimeWaver Frequency	
Manufacturer	WEERO Co.,Ltd.	INMODE LTD.	INMODE LTD.	TimeWaver Production GmbH	
510(k) No.	-	K210877	K201285	K212832	
Design	<p>The eMVFit with handpiece consists of an AC/DC power supply unit, controller and user interface including an LCD touch screen. The delivery of the electrical energy is controlled by a Start/Stop button positioned on the front panel.</p> <p>The System supports the following components:</p> <ul style="list-style-type: none"> <li>• LCD display touch Screen</li> <li>• Audio loudspeaker</li> <li>• 24V AC/DC power Supply</li> <li>• Controller</li> <li>• The System operates while connected to the handpiece.</li> </ul>	<p>The EVOLVE System with T3 Applicator consists of an AC/DC power supply unit, Controller and user interface including an LCD touch screen. The delivery of the RF/electrical energy is controlled by a Start/Stop button positioned on the front panel.</p> <p>The System supports the following components:</p> <ul style="list-style-type: none"> <li>• LCD display touch Screen</li> <li>• Audio loudspeaker</li> <li>• 48V AC/DC power Supply</li> <li>• Controller</li> </ul> <p>The System operates while connected to the T3 Applicator in RF mode or in EMS/TENS mode.</p>	<p>The EVOLVE System with Tone Applicator consists of an AC/DC power supply unit, controller and user interface including an LCD touch screen. The delivery of the electrical energy is controlled by a Start/Stop button positioned on the front panel.</p> <p>The System supports the following components:</p> <ul style="list-style-type: none"> <li>• LCD display touch Screen</li> <li>• Audio loudspeaker</li> <li>• 48V AC/DC power Supply</li> <li>• Controller</li> <li>• The System operates while connected to the Tone Applicator.</li> </ul>	-	Different <u>*Note 1</u>
Components console	<p>The eMVFit consists of the following components:</p> <p>Console, including a power supply unit, controller and user interface including an LCD touch screen.</p> <p>Handpiece with up to 8 units connected to the console via 8 designated cables and 8 designated connection ports.</p>	<p>The EVOLVE System consists of the following components:</p> <ul style="list-style-type: none"> <li>• Console, including a power supply unit, controller and user interface including an LCD touch screen.</li> <li>• T3 Applicator with up to 6 units connected to the console via 6 designated cables and 6 designated connection ports.</li> </ul>	<p>The EVOLVE System consists of the following components:</p> <p>Console, including a power supply unit, controller and user interface including an LCD touch screen.</p> <p>Tone applicator with up to 4 units connected to the console via 4 designated cables and 4 designated connection ports.</p>	-	Different <u>*Note 3</u>
Dimension Console [W x H x D]	44cm W x 70cm D x 120cm H [17.3'' W x 27.5'' D x 47'' H]	46cm W x 46cm D x 100cm H [18.2'' W x 18.2'' D x 44'' H]	46cm W x 46cm D x 100cm H [18.2'' W x 18.2'' D x 44'' H]	-	Different <u>*Note 2</u>
Applicator [L X D]	<p>MULTI handpiece 8cm L x 11.5cm D [3'' L x 4.5'' D]</p> <p>EMS handpiece 10cm L x 13cm D [4'' L x 5'' D]</p>	<p>T3 Applicator unit: 67.3mm L x 54.3mm D [2.7'' L x 2.2'' D]</p>	<p>Tone Applicator 12cm L x 10cm D [4.7'' L x 4'' D]</p>		

eMVFit  
510(k) Summary

Name	Subject device	Main Predicate device	Reference Predicate device	Reference Predicate device	Comparison
Device Name	eMVFit(MVF-10M)	Evolve System with the T3 Applicator	Evolve System with the Tone Applicator	TimeWaver Frequency	
Manufacturer	WEERO Co.,Ltd.	INMODE LTD.	INMODE LTD.	TimeWaver Production GmbH	
510(k) No.	-	K210877	K201285	K212832	
Weight Console Weight applicator	48.0 kg [106 lbs.] MULTI handpiece: 0.52 kg [1.1 lbs.] EMS handpiece: 0.42 kg [0.9 lbs.]	33.0 Kg [73 lbs.] T3: 0.16 Kg [0.4 lbs.]	33.0 Kg [73 lbs.] Tone: 0.22 Kg [0.5 lbs.]	-	Different <u>*Note 2</u>
Power Source(s)	Main Line Frequency (nominal) 50-60Hz Input Voltage (nominal) 100-240VAC Input Current (rms) 4A	Main Line Frequency (nominal) 50-60Hz Input Voltage (nominal) 100-240VAC Input Current (rms) 4A	Main Line Frequency (nominal) 50-60Hz Input Voltage (nominal) 100-240VAC Input Current (rms) 4A	-	Same
Method of Line Current Isolation	Independent transformer isolated	Independent transformer isolated	Independent transformer isolated	-	Same
Electrical Type	Type BF	Type BF	Type BF	-	Same
Patient Leakage Current - Normal Condition ( $\mu$ A)	<100uA patient leakage	<100uA patient leakage	<100uA patient leakage	<100uA patient leakage	Same
Patient Leakage Current - Single Fault Condition( $\mu$ A)	<300uA line leakage	<300uA line leakage	<300uA line leakage	<100uA patient leakage	Same
Number of Output Modes	2	Unknown	2	2	Same
Number of Output Channels	8	6	2	2	Different <u>*Note 3</u>

eMVFit  
510(k) Summary

Name	Subject device	Main Predicate device	Reference Predicate device	Reference Predicate device	Comparison
Device Name	eMVFit(MVF-10M)	Evolve System with the T3 Applicator	Evolve System with the Tone Applicator	TimeWaver Frequency	
Manufacturer	WEERO Co.,Ltd.	INMODE LTD.	INMODE LTD.	TimeWaver Production GmbH	
510(k) No.	-	K210877	K201285	K212832	
Synchronous or Alternating	See Output Specifications Below	See Output Specifications Below	See Output Specifications Below	-	Same
Method of Channel Isolation	Through transformers and isolators	Through transformers and isolators	Through transformers and isolators	-	Same
Regulated Current or Regulated Voltage (output signals only)	Regulated voltage	Regulated voltage on all channels With current limit	Regulated voltage on all channels With current limit	both	Same
Software/Firmware/ Microprocessor Control	Yes	Yes	Yes	Yes	Same
Automatic Overload Trip	Yes	Yes	Yes	Yes	Same
Automatic No-Load Trip	Yes	Yes	Yes	Yes	Same
Automatic Shut Off	Yes	Yes, On/off switch	Yes, On/off switch	Yes, PC-software	Same
Patient Override Control	Yes	Yes	Yes	Yes, PC-software	Same
Indicator Display	Yes	Yes	Yes	Yes	Same

eMVFit  
510(k) Summary

Name	Subject device	Main Predicate device	Reference Predicate device	Reference Predicate device	Comparison
Device Name	eMVFit(MVF-10M)	Evolve System with the T3 Applicator	Evolve System with the Tone Applicator	TimeWaver Frequency	
Manufacturer	WEERO Co.,Ltd.	INMODE LTD.	INMODE LTD.	TimeWaver Production GmbH	
510(k) No.	-	K210877	K201285	K212832	
On/Off Status	Yes	Yes	Yes	Yes	Same
Battery	No battery	No battery	No battery	-	Same
Voltage/Current level	Yes	Yes, voltage levels	Yes, voltage levels	Yes	Same
Timer Range(Minutes)	15, 30, 45, 60 [minutes]	0-60 [minutes]	0-60 [minutes]	-	Same
Compliance with 21 CFR 890.5850 (IPF)	Yes	Yes	Yes	Yes	Same
<b>EMS Output Mode</b>					
Output Specifications: Waveform	Symmetrical Biphasic Waveform	Symmetrical Biphasic Waveform	Symmetrical Biphasic Waveform	-	Same
Pulse Shape	Rectangular	Rectangular	Rectangular	Rectangular	Same
Maximum Output Voltage( $\pm$ 10%)	34V @500 $\Omega$	30V @500 $\Omega$	56V @500 $\Omega$	0.25V @500 $\Omega$	Different * <u>Note 4</u>
	43V @2k $\Omega$	54V @2k $\Omega$	56V @2k $\Omega$	1.2V @2k $\Omega$	
	43V @10k $\Omega$	54V @10k $\Omega$	56V @10k $\Omega$	12V @10k $\Omega$	

eMVFit  
510(k) Summary

Name	Subject device	Main Predicate device	Reference Predicate device	Reference Predicate device	Comparison
Device Name	eMVFit(MVF-10M)	Evolve System with the T3 Applicator	Evolve System with the Tone Applicator	TimeWaver Frequency	
Manufacturer	WEERO Co.,Ltd.	INMODE LTD.	INMODE LTD.	TimeWaver Production GmbH	
510(k) No.	-	K210877	K201285	K212832	
Maximum Output Current( $\pm$ 10%)	68 mA @500 $\Omega$	60 mA @500 $\Omega$	92.86 mA @500 $\Omega$	0.5 mA @500 $\Omega$	Different * <a href="#">Note 4</a>
	20 mA @2k $\Omega$	27 mA @2k $\Omega$	26.7 mA @2k $\Omega$	0.5 mA @2k $\Omega$	
	5 mA @10k $\Omega$	5.4 mA @10k $\Omega$	5.4 mA @10k $\Omega$	0.5 mA @10k $\Omega$	
Pulse Width ( $\mu$ sec) – The output active positive pulse width	150 [ $\mu$ s]	20 to 400 [ $\mu$ s]	20 to 400 [ $\mu$ s]	5000 [ $\mu$ s]	Different * <a href="#">Note 5</a>
Frequency (Hz)	3 to 200 [Hz]	3 to 200 [Hz]	3 to 200 [Hz]	50 [Hz]	Same
Net Charge @ 500 ohms [ $\mu$ C/pulse]	0 [ $\mu$ C] @ 500 $\Omega$	0 [ $\mu$ C] @ 500 $\Omega$	0 [ $\mu$ C] @ 500 $\Omega$	-	Same
Maximum Phase Charge[ $\mu$ C]	10.2 [ $\mu$ C] @500 $\Omega$	24 [ $\mu$ C] @500 $\Omega$	43.2 [ $\mu$ C] @500 $\Omega$	2.5 [ $\mu$ C] @500 $\Omega$	Different * <a href="#">Note 6</a>
Maximum Current Density[mA/cm <sup>2</sup> ]	0.62 [mA/cm <sup>2</sup> ] Surface = 13cm <sup>2</sup> .	0.74 [mA/cm <sup>2</sup> ] Surface = 6.46cm <sup>2</sup>	0.72 [mA/cm <sup>2</sup> ] Surface = 12cm <sup>2</sup>	0.02 [mA/cm <sup>2</sup> ] Surface = 25cm <sup>2</sup>	Different * <a href="#">Note 7</a>
Maximum Power Density[mW/cm <sup>2</sup> ]	21.3[mW/cm <sup>2</sup> ] @ 500 $\Omega$	22.2 [mW/cm <sup>2</sup> ] @ 500 $\Omega$	55[mW/cm <sup>2</sup> ] @ 500 $\Omega$	0.005 [mW/cm <sup>2</sup> ] @ 500 $\Omega$	

eMVFit  
510(k) Summary

Name	Subject device	Main Predicate device	Reference Predicate device	Reference Predicate device	Comparison
Device Name	eMVFit(MVF-10M)	Evolve System with the T3 Applicator	Evolve System with the Tone Applicator	TimeWaver Frequency	
Manufacturer	WEERO Co.,Ltd.	INMODE LTD.	INMODE LTD.	TimeWaver Production GmbH	
510(k) No.	-	K210877	K201285	K212832	
Burst Mode (i.e, pulse trains) a. Pulses per burst b. Bursts per second c. Burst duration (seconds) d. Duty Cycle [Line (b) x Line (c)]	Yes: a. 3 - 200 b. 1 c. 1-60 sec d. Time on / off	Yes: a. 3 - 200 b. 1 c. 1-60 sec d. Time on / off	Yes: a. 3 - 200 b. 1 c. 1-60 sec d. Time on / off	-	Same
On Time (sec.)	1 -60 [sec]	1 -60 [sec]	1 -60 [sec]	-	Same
Off Time (sec.)	1 -60 [sec]	1 -60 [sec]	1 -60 [sec]	-	Same
Treatment Time (min) – the time limit that will put the system in STOP state Level – The output intensity level	15, 30, 45, 60 [min] 1 to 50	Up to 60 min.	Up to 60 min. 1 to 50	-	Same

**2) Substantial Equivalence Discussion**

There are differences on a few things. However, these differences do not affect the significant equivalence of the device and its predicates.

**Note 1: “Power supply differences”**

The input power between the subject device and the predicate device is the same at 100-240 Vac, and there is a difference in the DC output voltage.

The subject device uses 24 Vdc and the predicate devices use 48 Vdc(K210877, K201285) or 9 Vdc(K212832).

But the power supply voltage can vary depending on the internal circuit design of the device, and the effectiveness of the device is determined by the output parameter, not the power supply voltage.

We have confirmed through performance testing that the intended performance values are output when the 24Vdc power is applied to the components, and the safety has been verified through the IEC 60601-1 test.

These differences in power supply do not raise new questions about safety and effectiveness.

**Note 2: “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 requirements, thus the differences of the function specifications does not raise any safety or effectiveness issue.

**Note 3: Number of Output Channels**

Although the “Number of Output Channels” is 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: “Maximum Output Voltage” and “Maximum Output Current”**

Since the maximum output voltage & current of the subject device are within the range of the two predicate devices(K201285, K210877), they do not raise new questions about safety and effectiveness.

In addition, there is no concern about overstimulation because the subject device has lower output compared to the predicate device (K201285), and there is no concern about under stimulation because the subject device has higher output compared to the predicate device (K212832).

The subject device was tested and is compliant with IEC 60601-2-10.

Therefore the difference doesn’t impact essential performance, basic safety or substantial equivalence.

**Note 5: “Pulse Width”**

Although the “Pulse Width“ of the subject device is different than in the predicate device, it is included in the pulse width range of the predicate device and was all tested and compliant with IEC 60601-2-10. Therefore the difference doesn’t impact essential performance, basic safety or substantial equivalence.

**Note 6: “Maximum Phase Charge”**

Maximum Phase Charge is related to the maximum output current and pulse width, and because the predicate device has various pulse widths, the range of phase charge depends on the pulse width range. For example, for the predicate device (K210877), the phase charge ranges from 1.2  $\mu\text{C}$  to 24  $\mu\text{C}$ . Because the phase charge of the subject device is within the range of the predicate device, it does not raise new questions about safety and effectiveness.

In addition, even though the Maximum Phase Charge of the predicate device (K212832) is lower than the subject device, it has the same indication for use as the subject device.

**Note 7: “Maximum Current Density” and “Maximum Power Density”**

The Maximum Current Density and Maximum Power Density of the subject device and predicate device (K210877) are very similar.

Usability and risk analysis have also been performed to support proof of safety and effectiveness of the subject device.

In addition, even though the predicate device (K212832) has much lower maximum current density and maximum power density than the subject device, it has the same indication for use as the subject device. Therefore, the difference between the subject device and the predicate devices does not raise new questions about safety and effectiveness.

The Maximum Power Density for the subject device is less than 0.25 Watts per square centimeter of electrode conductive surface area to reduce the risk of thermal burns and The Maximum Current Density for all waveforms of the new device is compliant with FDA Guidance Document for Powered Muscle Stimulator 510(k)s, thus the difference doesn't impact essential performance, basic safety or substantial equivalence.

**3) Conclusion**

“Evolve System with the T3 Applicator”, "Evolve System with the Tone Applicator" and “TimeWaver Frequency” were chosen as predicate devices for the subject device in consideration of the intended use, indications, performance and principles of operation. Minor variations between the subject and the predicate device were found and listed within the above discussion. Considerable amount of testing, including electrical safety, electromagnetic compatibility, performance, software verification and validation and usability testing were performed to support the claims of appropriately chosen predicate device. The test results show that the specifications and performance of eMVFit are as safe and effective as legally marketed predicate devices.

Therefore, it is concluded that the eMVFit is substantially equivalent to the legally marketed predicate devices.

## **7. Non-Clinical (Bench) Performance Data:**

As part of demonstrating safety and effectiveness of the eMVFit and in showing substantial equivalence to the predicate device that are subject to this 510(k) submission, we completed a number of non-clinical performance tests against applicable standards.

- Basic safety and essential performance of the eMVFit was tested and evaluated according to the IEC 60601-1:2005/A2:2020.
- Effect to the device by electromagnetic disturbances was tested and evaluated according to the FDA-recognized consensus standard IEC 60601-1-2:2014/A1:2020.
- Particular requirements for the basic safety and essential performance of nerve and muscle stimulators was tested and evaluated according to the IEC 60601-2-10:2012/A2:2023.
- Risk management was recorded by referring to ISO 14971:2019.
- Usability was documented by referring to IEC 60601-1-6:2010/A2:2020.
- Biocompatibility was tested and evaluated according to ISO 10993-5:2009, ISO 10993-10:2021, and ISO 10993-23:2021.
- Software was tested and evaluated according to IEC 62304:2015
- Content of Premarket Submissions for Device Software Functions

The eMVFit passed all the testing in accordance with internal requirements, national standards, and international standards shown above, to support substantial equivalence of the subject device.

Also, to demonstrate that the eMVFit meets all design specifications and performance requirements, and to measure the accuracy of the output parameters of eMVFit and to compare the output parameters with predicate devices, nonclinical bench testing was performed in accordance with the internal process in compliance with the recommendations of the FDA Guidance Document for Powered Muscle Stimulator 510(k)s.

The testing results support that the requirements for performance and electrical safety were met for the acceptance of the device. The eMVFit passed all testing and supports the claims of substantial equivalence to the predicate device.

## **8. Sterilization/Disinfection/Cleaning/Shelf Life**

The eMVFit is intended for multiple use and therefore must be cleaned according to the instructions provided in the device Instructions for Use. There are no sterilized parts or accessories involved with this device.

## **9. Conclusion**

Based on the comparison with the predicate devices and on the non-clinical performance testing results demonstrating that the eMVFit is as safe and effective as the predicate devices, it can be concluded that the eMVFit is substantially equivalent to the legally marketed predicate devices.