June 4, 2025

WEERO Co.,Ltd.
Moon Young Han
Regulatory Affairs
A-605, Venture Valley II, 142-10, Saneop-Ro 156 Beon-Gil,
Gwonseon-Gu Suwon-Si,Gyeonggi-Do
Suwon, Gyeonggi 16648
Korea, South

Re: K241433
Trade/Device Name: EVE Synergy (EVE-20M)
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered Muscle Stimulator
Regulatory Class: Class II
Product Code: IPF, GZJ
Dated: May 17, 2024
Received: May 21, 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) 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
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)*

K241433

Device Name

EVE Synergy (EVE-20M)

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

TENS is used for:
- Symptomatic relief and management of chronic, intractable pain
- Post-surgical acute pain
- Post-trauma acute pain

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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1. Submitter and US Official Correspondent

Submitter : WEERO Co.,Ltd.
Address: A205 VentureValley II, 142-10, Saneop-ro 156beon-gil, Gwonseon-gu, Suwon-si, Gyeonggi-do, Republic of Korea
Telephone No.: +82-31-427-0787

Official Correspondent: Moon-young Han
Correspondent: WEERO Co.,Ltd.
Address: A205 VentureValley II, 142-10, Saneop-ro 156beon-gil, Gwonseon-gu, Suwon-si, Gyeonggi-do, Republic of Korea
Telephone No.: +82-31-427-0787
Email: ra@weeroweero.com

Date prepared: May 26, 2025

2. Device Information

Trade/Device Name: EVE Synergy / EVE-20M

Regulation Name: - Powered Muscle Stimulator
- Transcutaneous electrical nerve stimulator for pain relief

Classification Name: - Stimulator, Muscle, Powered
- Stimulator, Nerve, Transcutaneous, For Pain Relief

Product Code: IPF, GZJ

Regulatory Class: Class II

Regulation Number: 21CFR890.5850, and 21CFR882.5890

3. Predicate Device(Equivalent Legally Marketed Device)

Manufacturer	Device	510(k) No.
Primary Predicate Device		
INMODE LTD.	EVOLVE System with the T3 Applicator	K210877
Secondary Predicate Device		
INMODE LTD.	EVOLVE System with the Tone Applicator	K201285

4. Description of the Device

EVE Synergy has Synergy handpiece(1EA), Pro handpiece(2EA), Micro cable, Tip(Ball type, T type, COMB type) and Power adaptor & cable.

EVE Synergy has Synergy mode and Pro mode.
Synergy mode has radio frequency and low frequency functions using a synergy handpiece. The Synergy handpiece has a temperature sensor, so the output is automatically turned off when the skin surface temperature exceeds 43℃.
Pro mode has low frequency function that uses the Pro handpiece with tip.

It should be noted that the device has radio frequency (RF Mode) indicated for relief of minor muscle aches and pain, relief of muscle spasm, temporary improvement of local blood circulation. This RF mode was previously reviewed by the FDA under K212253 and

was cleared under regulation 21 CFR 878.4400 (Product code PBX). In the subject submission, there are no changes being proposed related to the RF Mode, and, hence, the review of the RF Mode is not within the scope of the subject 510(k) submission.

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

TENS is used for:
- Symptomatic relief and management of chronic, intractable pain
- Post-surgical acute pain
- Post-trauma acute pain

6. Substantial Equivalence Discussion

1) Comparison Information

Name	Subject device	Primary Predicate Device	Secondary Predicate device	Comparison
Device Name	EVE Synergy(EVE-20M)	EVOLVE System with the T3 Applicator	EVOLVE System with the Tone Applicator	
Manufacturer	WEERO Co.,Ltd.	InMode Ltd.	InMode Ltd.	
510(k) No.	K241433	K210877	K201285	
Product Code, Class	IPF, GZJ Class II	IPF, GZJ Class II	IPF, GZJ Class II	Identical
Indications for 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 post-surgical stimulation of calf muscles to prevent venous thrombosis TENS is used for: · Symptomatic relief and management of chronic, intractable pain · Post-surgical acute pain · Post-trauma acute pain	EMS mode is intended 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 post-surgical stimulation of calf muscles to prevent venous thrombosis TENS mode is intended for: · Symptomatic relief and management of chronic, intractable pain · Post-surgical acute pain · Post-trauma acute pain	The EVOLVE System with the Tone Applicator is an electro-muscle and transcutaneous nerve stimulation device for the treatment of different body areas. The EVOLVE System with Tone Applicator is designed to operate in two modes – EMS and TENS. In EMS mode it 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 post-surgical stimulation of calf muscles to prevent venous thrombosis And in TENS mode is intended for · Symptomatic relief and management of chronic, intractable pain · Post-surgical acute pain · Post-trauma acute pain	Identical

Name	Subject device	Primary Predicate Device	Secondary Predicate device	Comparison
Device Name	EVE Synergy(EVE-20M)	EVOLVE System with the T3 Applicator	EVOLVE System with the Tone Applicator	
Manufacturer	WEERO Co.,Ltd.	InMode Ltd.	InMode Ltd.	
510(k) No.	K241433	K210877	K201285	
Design	The EVE Synergy 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. The System supports the following components: ▪ LCD display touch screen ▪ Audio loudspeaker ▪ 24V AC/DC power supply ▪ Controller	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. The System supports the following components: · LCD display touch Screen · Audio loudspeaker · 48V AC/DC power Supply · Controller	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. The System supports the following components: ▪ LCD display touch screen ▪ Audio loudspeaker ▪ 48V AC/DC power supply ▪ Controller	Not identical. The subject device was tested and is compliant with IEC60601-1 and IEC 60601-2-10. Therefore the difference doesn't impact essential performance, basic safety or substantial equivalence.
- Components Console	The EVE Synergy consists of the following components: ▪ Power supply unit, Console, including controller and user interface including an LCD touch screen. ▪ Handpieces with up to 3 units connected to the console via 3 designated cables and 3 designated connection ports.	The EVOLVE System consists of the following components: • Console, including a power supply unit, controller and user interface including an LCD touch screen. • T3 Applicator with up to 6 units connected to the console via 6 designated cables and 6 designated connection ports.	The EVOLVE System consists of the following components: ▪ Console, including a power supply unit, controller and user interface including an LCD touch screen. ▪ Tone applicator with up to 4 units connected to the console via 4 designated cables and 4 designated connection ports.	Not identical. Although the number of connection ports is different from the predicate device, both the subject and predicate devices comply with IEC 60601-1 and IEC 60601-2-10 requirements and the difference doesn't impact essential performance, basic safety or substantial equivalence.
Dimension Console [W x H x D] Applicator unit [L x D]	22.4cm W x 41.8cm D x 32.5cm H [8.8'' W x 16.5'' D x 12.8'' H] Synergy handpiece: 167.5mm L x 43 mm D [6.6'' L x 1.7'' D] Pro handpiece: 136mm L x 27.5mm D [5.4'' L x 1.1'' D] Ball type tip: 86mm L x 18mm D [3.4'' L x 0.7'' D] T type tip: 80mm L x 50mm D [3.1'' L x 2.0'' D] COMB type tip: 88mm L x 30mm D [3.5'' L x 1.2'' D]	46cm W x 46cm D x 100cm H [18.2'' W x 18.2'' D x 44'' H] T3 Applicator unit: 67.3mm L x 54.3mm D [2.7'' L x2.2'' D]	46cm W x 46cm D x 100cm H [18.2'' W x 18.2'' D x 44'' H] Tone Applicator: 12cm L x 10cm D [4.7'' L x 4'' D]	Not identical. Although the dimension of the subject device is different from the predicate device, both the subject and predicate devices comply with IEC 60601-1 and IEC 60601-2-10 requirements, which ensures that they meet the necessary safety and performance standards. The difference in dimension does not affect essential performance, basic safety, or substantial equivalence.

Name	Subject device	Primary Predicate Device	Secondary Predicate device	Comparison
Device Name	EVE Synergy(EVE-20M)	EVOLVE System with the T3 Applicator	EVOLVE System with the Tone Applicator	
Manufacturer	WEERO Co.,Ltd.	InMode Ltd.	InMode Ltd.	
510(k) No.	K241433	K210877	K201285	
Weight Console Weight applicator	7 kg [15.4 lbs.] Synergy handpiece: 0.12 kg [0.26 lbs.] Pro handpiece: 0.06 kg [0.13 lbs.] Ball type tip: 0.04 kg [0.08 lbs.] T type tip: 0.02 kg [0.04 lbs.] COMB type tip: 0.02 kg [0.04 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.]	Not identical. Although the weight of the subject device is different from the predicate device, both the subject and predicate devices comply with IEC 60601-1 and IEC 60601-2-10 requirements, which ensures that they meet the necessary safety and performance standards. The difference in weight does not affect essential performance, basic safety, or substantial equivalence.
Applicator unit treatment area	Synergy handpiece electrode(2ea): 6 cm^2 Ball type tip: 10.17 cm^2 T type tip: 7.85 cm^2 COMB type tip: 28.83 cm^2	6.46 cm^2	12 cm^2	Not identical. However, the difference doesn't raise new questions of safety and effectiveness.
Power Source(s)	Power Supply Adapter - Input: 100-240Vac, 50/60Hz, 1.4-0.7A - Output: 24Vdc, 5A	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	Not identical. The subject device was tested and is compliant with IEC60601-1 and IEC 60601-2-10. Therefore the difference doesn’t impact essential performance, basic safety or substantial equivalence.
Method of Line Current Isolation	Independent transformer isolated	Independent transformer isolated	Independent transformer isolated	Identical
Electrical Type	Type BF	Type BF	Type BF	Identical
Patient Leakage Current – Normal Condition (μA)	<100uA patient leakage	<100uA patient leakage	<100uA patient leakage	Identical
Patient Leakage Current – Single Fault Condition (μA)	<300uA line leakage	<300uA line leakage	<300uA line leakage	Identical
Number of Output Modes	2	Unknown	2	Identical
Number of Output Channels	3	6	2	Not identical. However, the difference doesn't raise new questions of safety and effectiveness.

Name	Subject device	Primary Predicate Device	Secondary Predicate device	Comparison
Device Name	EVE Synergy(EVE-20M)	EVOLVE System with the T3 Applicator	EVOLVE System with the Tone Applicator	
Manufacturer	WEERO Co.,Ltd.	InMode Ltd.	InMode Ltd.	
510(k) No.	K241433	K210877	K201285	
Synchronous or Alternating	See Output Specifications Below	See Output Specifications Below	See Output Specifications Below	Identical
Method of Channel Isolation	Through transformers and isolators	Through transformers and isolators	Through transformers and isolators	Identical
Regulated Current or Regulated Voltage (output signals only)	Regulated voltage on all channels With current limit	Regulated voltage on all channels With current limit	Regulated voltage on all channels With current limit	Identical
Software/Firmware / Microprocessor Control	Yes	Yes	Yes	Identical
Automatic Overload Trip	Yes	Yes	Yes	Identical
Automatic No-Load Trip	Yes	Yes	Yes	Identical
Automatic Shut Off	Yes	Yes	Yes	Identical
Patient Override Control	No	Yes	Yes	Not identical. However, the difference doesn't raise new questions of safety and effectiveness.
- On/Off Status	Yes	Yes	Yes	Identical
- Battery	No battery	No battery	No battery	Identical
-Voltage/Current level	Yes	Yes	Yes	Identical
Timer Range	0-60 [minutes]	0-60 [minutes]	0-60 [minutes]	Identical
Compliance with 21 CFR 890.5850 (IPF)	Yes	Yes	Yes	Identical
Compliance with 21 CFR 882.5890 (GZJ)	Yes	Yes	Yes	Identical

Name	Subject device	Primary Predicate Device	Secondary Predicate device	Comparison
Device Name	EVE Synergy(EVE-20M)	EVOLVE System with the T3 Applicator	EVOLVE System with the Tone Applicator	
Manufacturer	WEERO Co.,Ltd.	InMode Ltd.	InMode Ltd.	
510(k) No.	K241433	K210877	K201285	
EMS Output				
Output Specifications: Waveform	Symmetrical Biphasic Waveform	Symmetrical Biphasic Waveform	Symmetrical Biphasic Waveform	Identical
Pulse Shape	Rectangular	Rectangular	Rectangular	Identical
Maximum Output Voltage (± 20%)	34 V @500Ω 48 V @2kΩ 48 V @10kΩ	30 V @500Ω 54 V @2kΩ 54 V @10kΩ	56 V @500Ω 56 V @2kΩ 56 V @10kΩ	Not identical. Since the maximum output voltage & current of the subject device are similar to the predicate devices, they do not raise new questions about safety and effectiveness.
Maximum Output Current (± 20%)	68 mA @500Ω 24 mA @2kΩ 4.8 mA @10kΩ	60 mA @500Ω 27 mA@2kΩ 5.4 mA @10kΩ	92.86 mA @500Ω 26.7 mA@2kΩ 5.4 mA @10kΩ	
Pulse Width(μsec.) – The output active positive pulse width	100 to 155 [μs]	20 to 400 [μs]	20 to 400 [μs]	Not identical. Since the pulse width of the subject device is within the range of the predicate devices, it does not raise new questions about safety and effectiveness.
Frequency (Hz)	3 to 200 [Hz]	3 to 200 [Hz]	3 to 200 [Hz]	Identical
Net Charge @ 500 Ohms [μC/pulse]	0 [μC] @ 500Ω	0 [μC] @ 500Ω	0 [μC] @ 500Ω	Identical
Maximum Phase Charge [μC]	10.54 [μC] @500Ω	24 [μC] @500Ω	43.2 [μC] @ 500Ω	Not identical. 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 primary predicate device, the phase charge ranges from 1.2 μC to 24 μC. 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.

Name	Subject device	Primary Predicate Device	Secondary Predicate device	Comparison
Device Name	EVE Synergy(EVE-20M)	EVOLVE System with the T3 Applicator	EVOLVE System with the Tone Applicator	
Manufacturer	WEERO Co.,Ltd.	InMode Ltd.	InMode Ltd.	
510(k) No.	K241433	K210877	K201285	
Maximum Current (RMS) Density [mA/cm^2]	1.31 [mA/cm^2] Surface = 6 cm²	0.74 [mA/cm2] Surface = 6.46cm²	0.72 [mA/cm^2] Surface = 12 cm²	Not identical. Although the subject device demonstrates a higher maximum current density compared to the predicate devices, this value does not exceed the safety level 2 mA/cm² specified in IEC 60601-2-10. Furthermore, the subject device demonstrates a maximum power density comparable to the predicate devices, indicating that the overall energy delivered to the tissue is similar. Therefore, this difference does not raise new questions of safety or effectiveness.
Maximum Power Density [mW/cm^2]	47 [mW/cm^2] @ 500Ω	22.2 [mW/cm2] @ 500Ω	55 [mW/cm^2] @ 500Ω	Not identical. The maximum power density of the subject device are similar to the predicate devices; therefore, they do not raise new questions about safety and effectiveness.
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	Identical
On time (sec.)	1 – 60 [sec]	1 – 60 [sec]	1 – 60 [sec]	Identical
Off time (sec.)	1 – 60 [sec]	1 – 60 [sec]	1 – 60 [sec]	Identical
Treatment Time (min) - the time limit that will put the system in STOP state Level	Up to 60 min	Up to 60 min	Up to 60 min	Identical

Name	Subject device	Primary Predicate Device	Secondary Predicate device	Comparison
Device Name	EVE Synergy(EVE-20M)	EVOLVE System with the T3 Applicator	EVOLVE System with the Tone Applicator	
Manufacturer	WEERO Co.,Ltd.	InMode Ltd.	InMode Ltd.	
510(k) No.	K241433	K210877	K201285	
TENS Output				
Output Specifications: Waveform	Symmetrical Biphasic Waveform, Pulsed Monophasic	Symmetrical Biphasic Waveform	Symmetrical Biphasic Waveform	The difference between a symmetrical biphasic waveform and a pulsed monophasic waveform is solely in whether the current flows in both positive and negative directions or in a single direction. Both waveforms are present in predicate devices cleared by the FDA for TENS applications. This difference does not raise new questions about the safety and effectiveness.
Pulse Shape	Rectangular	Rectangular	Rectangular	Identical
Maximum Output Voltage((± 20%)	10 V @500Ω 10 V @2kΩ 10 V @10kΩ	19 V @500Ω 19 V @2kΩ 19 V @10kΩ	36 V @500Ω 36 V @2kΩ 36 V @10kΩ	Not identical. The maximum output voltage and current of the subject device are similar to those of the primary predicate device. In addition, since the maximum power density of both devices is very similar, the total energy delivered to the tissue remains similar in its effect on tissue response. Therefore, these differences do not raise new questions about safety and effectiveness.
Maximum Output Current((± 20%)	20 mA @500Ω 5.0 mA @2kΩ 1.0 mA @10kΩ	38 mA @500Ω 9.5 mA@2kΩ 1.9 mA @10kΩ	67.8 mA @500Ω 17.7 mA@2kΩ 3.6 mA @10kΩ	
Pulse Width(μsec.) – The output active positive pulse width	100 to 150 [μs]	20 to 400 [μs]	20 to 400 [μs]	Not identical. Since the pulse width of the subject device is within the range of the predicate devices, it does not raise new questions about safety and effectiveness.
Frequency(Hz)	3 to 200 [Hz]	3 to 200 [Hz]	3 to 200 [Hz]	Identical

Name	Subject device	Primary Predicate Device	Secondary Predicate device	Comparison
Device Name	EVE Synergy(EVE-20M)	EVOLVE System with the T3 Applicator	EVOLVE System with the Tone Applicator	
Manufacturer	WEERO Co.,Ltd.	InMode Ltd.	InMode Ltd.	
510(k) No.	K241433	K210877	K201285	
Net Charge @ 500 Ohms [μC/pulse]	0 [μC] @500Ω	0 [μC] @ 500Ω	0 [μC] @ 500Ω	Identical
Maximum Phase Charge [μC]	3.0 [μC] @500Ω	15.2 [μC] @ 500Ω	28.8 [μC] @ 500Ω	Not identical. 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 primary predicate device, the phase charge ranges from 0.76 μC to 15.2 μC. 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.
Maximum Current Density [mA/cm^2]	0.83 [mA/cm^2] Surface = 6 cm^2	0.47 [mA/cm^2] Surface = 6.46 cm^2	0.48 [mA/cm^2] Surface = 12 cm^2	Not identical. Although the subject device demonstrates a higher maximum current density compared to the predicate devices, this value does not exceed the safety level 2 mA/cm^2 specified in IEC 60601-2-10. Furthermore, the subject device demonstrates a maximum power density comparable to the predicate devices, indicating that the overall energy delivered to the tissue is similar. Therefore, this difference does not raise new questions of safety or effectiveness.
Maximum Power Density [mW/cm^2]	8.3 [mW/cm^2] @ 500Ω	8.9 [mW/cm^2] @ 500Ω	17.3 [mW/cm^2] @ 500Ω	Not identical. The maximum power density of the subject device are similar to the primary predicate device; therefore, they do not raise new questions about safety and effectiveness.

Name	Subject device	Primary Predicate Device	Secondary Predicate device	Comparison
Device Name	EVE Synergy(EVE-20M)	EVOLVE System with the T3 Applicator	EVOLVE System with the Tone Applicator	
Manufacturer	WEERO Co.,Ltd.	InMode Ltd.	InMode Ltd.	
510(k) No.	K241433	K210877	K201285	
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	Identical
On time (sec.)	1 – 60 [sec]	1 – 60 [sec]	1 – 60 [sec]	Identical
Off time (sec.)	1 – 60 [sec]	1 – 60 [sec]	1 – 60 [sec]	Identical
Treatment Time (min) - the time limit that will put the system in STOP state Level	Up to 60 min	Up to 60 min	Up to 60 min	Identical

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.

The subject device and predicate devices utilize the same technology, for the same indication for use, and with almost identical design specifications. The device emits EMS or TENS electrical signals with similar power and current densities, pulse characteristics, and bear almost identical system components to its predicate devices such as; user interface, and hardware components. All of the subject device performance specifications are equal or similar to those of its predicate devices. The minor differences in technical specifications should not alter the device safety and effectiveness.
Furthermore, the subject device had underwent the required performance testing and validation testing and demonstrates its conformance with device design requirements and with applicable standards.

The safety features and compliance with safety standards of the subject device are similar to the safety features and compliance with safety standards of the predicate devices. For biocompatibility, all user-contacting materials (i.e., the Stainless Steel 304, and Polycarbonate) are the same as those previously cleared with K212253.

Furthermore, the design and development phases of the subject device were validated throughout a set of performance tests, including software validation testing, electrical and mechanical safety testing according to IEC 60601-1 standard, electromagnetic compatibility testing according to IEC 60601-1-2 standard, safety and essential performance of nerve and muscle stimulators testing according to IEC 60601-2-10 standard. These performance tests demonstrated that the device specifications meet the system requirements and do not raise new safety or effectiveness concerns.

3) Conclusion

"EVOLVE System with the T3 Applicator" and "EVOLVE System with the Tone Applicator" were chosen as predicate devices for the subject device in consideration of the intended use, indications, performance and principles of operation. Minor differences between the subject and the predicate devices were found and listed within the above comparison table and 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 EVE Synergy are as safe and effective as legally marketed predicate devices.
Therefore, it is concluded that the EVE Synergy is substantially equivalent to the legally marketed predicate devices.

7. Non-Clinical (Bench) Performance Data:

As part of demonstrating safety and effectiveness of the EVE Synergy 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 EVE Synergy 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.
- For biocompatibility, all user-contacting materials (i.e., Stainless Steel 304 and Polycarbonate) are the same as those previously cleared under K212253.
- Software was tested and evaluated according to IEC 62304:2015
- Content of Premarket Submissions for Device Software Functions

The EVE Synergy 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 EVE Synergy meets all design specifications and performance requirements, and to measure the accuracy of the output parameters

of EVE Synergy 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 EVE Synergy passed all testing and supports the claims of substantial equivalence to the predicate device.

8. Sterilization/Disinfection/Cleaning/Shelf_Life

The EVE Synergy 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. Biocompatibility

Part	Material	Patient Contact	Duration of Contact by ISO 10993-1	Bio-compatibility
Electrodes of handpiece	SUS 304	Intact Skin	Limited (< 24 hours)	Yes
LED Display part	PC(SR3108FM)			

10. Conclusion

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