October 9, 2024

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

Re: K240991
Trade/Device Name: eMVFit (MVF-10M)
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: PBX, GEI
Dated: September 13, 2024
Received: September 13, 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,

Long H. Chen -S

Digitally signed by Long H. Chen -S
Date: 2024.10.09 09:18:09 -04'00'

Long Chen, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
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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)*

K240991

Device Name

eMVFit (MVF-10M)

Indications for Use *(Describe)*

The eMVFit (MVF-10M) Radio frequency is used for:
• Relief of minor muscle aches and pain, relief of muscle spasm, temporary improvement of local blood circulation.
• Temporary reduction in the appearance of cellulite.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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1. Submitter and US Official Correspondent

Submitter : WEERO Co.,Ltd.
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Official Correspondent: Moon-young Han
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2. Device Information

Trade/Device Name: eMVFit / MVF-10M
Regulation Name: - Electrosurgical cutting and coagulation device and accessories
Classification Name: - Massager, Vacuum, Radio Frequency Induced Heat
Product Code: PBX
Device Class: Class II (Regulation 21CFR878.4400)

3. Predicate Device(Equivalent Legally Marketed Device)

Manufacturer	Device	510(k) No.
Main Predicate		
INMODE LTD.	Embody System	K183450

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

5. Indications for use (intended use)

The eMVFit (MVF-10M) Radio frequency is used for:

- Relief of minor muscle aches and pain, relief of muscle spasm, temporary improvement of local blood circulation.
- Temporary reduction in the appearance of cellulite.

6. Substantial Equivalence Discussion

1) Comparison Information

- Main Predicate : PBX

Name	Subject device	Predicate device	Comparison
Device Name	eMVFit(MVF-10M)	EmBody System	
Manufacturer	WEERO Co.,Ltd.	INMODE LTD.	
510(k) No.	-	K183450	
Product Code, Class	PBX, IPF Class II	PBX, ISA Class II	N/A
Indications for use	Radio frequency is used for: • Relief of minor muscle aches and pain, relief of muscle spasm, temporary improvement of local blood circulation. • Temporary reduction in the appearance of cellulite.	The InMode EmBody System with its designated hand pieces is intended for the treatment of the following medical conditions; The EmBodyPlus hand piece is intended for the temporary relief of minor muscle aches and pain, temporary relief of muscle spasm, and temporary improvement of local blood circulation The EmBodyFX hand piece is intended for the treatment of the following medical conditions using RF combined with massage: • Relief of' minor muscle aches and pain, relief of muscle spasm, temporary improvement of local blood circulation. • Temporary reduction in the appearance of cellulite.	The eMVFit device shares the same intended for use as EmBody System for the RF technology (PBX code). Also, the eMVFit device has less indications for use than EmBody System. Therefore, the eMVFit device does not have new indications for use compared to the predicate device for RF technologies. This does not raise new questions of safety and effectiveness.
Energy Used / Delivered	RF energy	RF energy	Same
Physical specification: Dimensions	Dimensions: W*D*H 17.3 x 27.5 x 47 in / 44 x 70 x 120 cm	Dimensions: W*D*H 18.2 x 18.2 x 40 in / 46 x 46 x 100 cm	Different *Note 1
Weight Console Weight Handpieces	Weight: 48 kg / 106 lbs MULTI handpiece 0.52kg [1.1lb] EMS handpiece 0.42kg [0.9lb]	Weight: 20 Kg / 44 lbs EmBodyPLUS Handpiece 0.17kg [0.375lb] EmBodyFX Handpiece 0.90kg [2.00lb]	Different *Note 1
Performance Specifications: Main Line Frequency (nominal)	50-60Hz	50-60Hz	Same
Input Voltage (nominal)	100-240VAC	100-240VAC	Same
Input Current(rms)	4A	4A	Same

Name	Subject device	Predicate device	Comparison
Device Name	eMVFit(MVF-10M)	EmBody System	
Manufacturer	WEERO Co.,Ltd.	INMODE LTD.	
510(k) No.	-	K183450	
RF Frequency	1 MHz	1 MHz	Same
Vacuum	50-350 mbar	200-500 mbar	Different *Note 2
RF electrical power	Up to 25 watts	Up to 50 watts	Different *Note 2
Cut off Temperature	32~43℃	35-43℃	Different *Note 2
Standards Met	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-2	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-2	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: "Weight" and "Dimensions"

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

Note 2:

"Vacuum"

The "Vacuum" of the subject device is within the predicate device's vacuum output range or lower than the predicate device's output. Therefore the difference doesn't impact essential performance, basic safety or substantial equivalence.

"RF electrical power"

Although the "RF electrical power" of the subject device is different than in the predicate device, it was all tested and is compliant with IEC 60601-2-2. Therefore the difference doesn't impact essential performance, basic safety or substantial equivalence.

"Cut off Temperature"

The "Cut off Temperature" of the subject device is within the predicate device's cut off temperature range or lower than the predicate device. Therefore the difference doesn't impact essential performance, basic safety or substantial equivalence.

3) Conclusion

"Embody System" was chosen as predicate 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 high frequency surgical equipment and high frequency surgical accessories was tested and evaluated according to the IEC 60601-2-2:2017/A1:2023.
- 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 for Premarket Notification (510(k)) Submissions for Electrosurgical Devices for General Surgery.
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. 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
External plastic material of hand-piece	PC (GN1006FL)			

10. 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.