August 25, 2022

Weero Co.
Eunice Cho
Quality Management Representative
A605 VentureValley II, 142-10, Saneop-ro 156beon-gil,
Gwonseon-gu,
Suwon-si, Gyeonggi-do,
Republic of Korea

Re: K212253
Trade/Device Name: Apollo Duet (Model : APD-4000)
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: PBX, GEI
Dated: July 15, 2021
Received: July 19, 2021

Dear Eunice Cho:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

for

Colin K. Chen, Ph.D.
Acting Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical
and Infection Control 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)*
K212253

Device Name
Apollo Duet
(Model name: APD-4000)

Indications for Use *(Describe)*
Apollo duet(RF Mode) is intended for relief of minor muscle aches and pain, relief of muscle spasm, and temporary improvement of local blood circulation.

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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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Exhibit 5 K212253

Date of Summary Preparation: August. 23, 2022

1. Submitter and US Official Correspondent

Submitter : WEERO Co.
Address: A605 VentureValley II, 142-10, Saneop-ro 156beon-gil, Gwonseon-gu, Suwon-si, Gyeonggi-do, Republic of Korea
Telephone No.: +82-31-5182-8588

Official Correspondent: Eunice cho
Correspondent: WEERO Co.
Address: A605 VentureValley II, 142-10, Saneop-ro 156beon-gil, Gwonseon-gu, Suwon-si, Gyeonggi-do, Republic of Korea
Telephone No.: +82-31-5182-8588
Email: eunice@weeroweero.com

2. Device Information

Trade/Device Name:	Apollo Duet
Regulation Name:	Electrosurgical cutting and coagulation device and accessories
Classification Name:	Electrosurgical, Cutting & Coagulation & Accessories
Product Code:	GEI, PBX
Device Class:	Class II per regulation 21CFR878.4400

3. Predicate Device(Equivalent Legally Marketed Device)

Manufacturer:	InMode Ltd.
Device Name:	InMode RF Pro System
510(k) Number:	K210492
Classification:	Electrosurgical, Cutting & Coagulation & Accessories : GEI,, Massager, Vacuum, Radio Frequency Induced Heat: PBX Massager, Therapeutic, Electric: ISA, Massager, Vacuum, Light Induced Heating: NUV Class II per regulation 21CFR878.4400.

5. Description of the Device

Apollo Duet has RF handpiece attached to the main body, and consists of an electrode cable and a power adapter.

This equipment has RF mode, which is the main function,
RF mode is a mode in which Radio-frequency is output in a bipolar method. An RF handpiece is used, and a high frequency is output through 4ea RF handpiece electrodes.
In addition, the RF handpiece has a temperature sensor, so the output is automatically turned off when the skin surface temperature exceeds 45℃

6. Indications for use (intended use)

Apollo duet (RF Mode) is intended for relief of minor muscle aches and pain, relief of muscle spasm, and temporary improvement of local blood circulation.

7. Substantial equivalence chart

Name	Proposed device	Predicate device
Device Name	Apollo Duet (RF Mode)	InMode RF Pro System (Applicator: Forma)
Product Code Class	GEI Class II	GEI Class II
Manufacturer	WEERO Co.	InMode Ltd.
510(k) No.	K212253	K210492
Indications for use	Apollo duet(RF Mode) is intended for relief of minor muscle aches and pain, relief of muscle spasm, and temporary improvement of local blood circulation.	The InMode RF Pro System with the Non-invasive RF Applicators employs RF energy for various applications: i-Forma, Forma (Plus), Plus (Plus Plus) and Plus90 for relief of minor muscle aches and pain, relief of muscle spasm, and temporary improvement of local blood circulation.
Target Population	Adults requiring treatment as specified in the indication for use	Adults requiring treatment as specified in the indication for use
Environment Used	Hospital or Clinic setting	Hospital or Clinic setting
Input Power	100-240V~, 50/60Hz	100-240V~, 50/60Hz
Energy Used	(Non-invasive) Bipolar RF	(Non-invasive) Bipolar RF
Maximal RF output power	40[W]	Forma: 50[W]
RF Frequency	1MHz	1MHz
Biocompatibility	Materials are biocompatible.	Materials are biocompatible.
Sterility	NA	NA
Reprocessing	Applicator to be reprocessed in accordance with user manual instructions.	Applicator to be reprocessed in accordance with user manual instructions.

The proposed device uses similar or identical technology as the predicate devices and has same intended uses. Based upon the predicted overall performance characteristics for the Apollo Duet, WEERO Co. believes that no significant differences in usage of its underlying technological principles between Apollo Duet and the predicate devices.

8. Software / Cybersecurity

The Apollo Duet software design and development follows FDA Guidance "Guidance for the Content of Premarket Submissions for Software Contained in Medical Device".

The Apollo Duet cybersecurity follows FDA Guidance "Content of Premarket Submissions for Management of Cybersecurity in Medical Device:.

9. Electrical Safety, Electromagnetic Compatibility Testing & Performance Data

Bench tests were conducted to verify that the proposed device met all design specifications.

Ex-vivo testing was performed to compare RF ablation thermal effects of subject device and predicate device on porcine abdominal skin tissue.

Skin temperature was measured when using the subject device on 6 healthy volunteers, including 3 people of light skin and 3 people of dark skin, with a thermographic camera at the irradiated areas on the skin.

Safety testing results demonstrated that the proposed device complies with the following standards:

- Basic safety and essential performance of the Apollo Duet is tested and evaluated according to the IEC 60601-1:2005, AMD1:2012.
- Effect to the device by electromagnetic disturbances were tested and evaluated according to the FDA-recognized consensus standard IEC 60601-1-2:2014.
- Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories is tested and evaluated according to the IEC 60601-2-2:2017.
- Particular requirements for the basic safety and essential performance of nerve and muscle stimulators is tested and evaluated according to the IEC 60601-2-10:2012/A1:2016.
- Risk management was recorded by referring to ISO 14971:2019.
- Usability was documented by referring to IEC 60601-1-6:2010(Third Edition) + A1:2013.

10. Biocompatibility

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

11. Conclusion

Based on the information provided in this Summary, WEERO Co. the Apollo Duet is as safe and effective as the predicate device as indicated for use.