March 13, 2026

WEERO Co., Ltd.
Han Moon Young
Regulatory Affairs
A-205, Venture Valley II, 142-10, Saneop-Ro 156 Beon-Gil
Gwonseon-Gu Suwon-Si,Gyeonggi-Do
Suwon, Gyeonggi 16648
Republic Of Korea

Re: K253261
Trade/Device Name: Apollo Quattro (APQ-10M)
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: PBX, QPZ
Dated: February 9, 2026
Received: February 9, 2026

Dear Han Moon Young:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 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 Management System Regulation (QMSR) (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,

Colin K. Chen -S

Digitally signed by Colin K. Chen -S
Date: 2026.03.13 07:29:43 -04'00'

Colin Kejing 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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K253261

Please provide the device trade name(s).

Apollo Quattro (APQ-10M)

Please provide your Indications for Use below.

Q-LF handpiece, Q-FX handpiece, Q-SC handpiece, and Q-BT handpiece in RF mode are intended for:
• Relief of minor muscle aches and pain, relief of muscle spasm, and temporary improvement of local blood circulation.

Q-EP handpiece in cooling mode is intended for:
• Use in dermatologic procedures for the removal of benign lesions of the skin and for the temporary reduction of pain, swelling, inflammation, and hematoma from minor surgical procedures.

Please select the types of uses (select one or both, as applicable).

- [x] Prescription Use (Part 21 CFR 801 Subpart D)
- [ ] Over-The-Counter Use (21 CFR 801 Subpart C)

Apollo Quattro
510(k) Summary

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

2. Device Information

Trade/Device Name: Apollo Quattro / APQ-10M

Regulation Name:
- Electrosurgical cutting and coagulation device and accessories.
- Contact cooling system for aesthetic use.

Classification Name:
- Massager, Vacuum, Radio Frequency Induced Heat
- Contact Cooling For Skin Lesion Pain Relief

Product Code: PBX, QPZ

Regulatory Class: Class II

Regulation Number: 21CFR878.4400, and 21CFR878.4340

3. Predicate Device(Equivalent Legally Marketed Device)

Manufacturer	Device	510(k) No.
Primary Predicate Device		
WEERO Co.,Ltd.	Apollo Duet (Model : APD-4000)	K212253
Secondary Predicate Device		
R2 Technologies, Inc.	Dermal Cooling System	K213294

4. Description of the Device

Apollo Quattro is a combination stimulator used to relieve pain by applying radio frequency, low frequency, heating, and cooling energy to the affected area.
Apollo Quattro has a Q-EP handpiece, Q-LF handpiece, Q-FX handpiece, Q-SC handpiece, Q-BT handpiece, patch (cleared under K042301), patch cable, funnel hose, and power cable.
The Q-LF, Q-FX, Q-SC, and Q-BT handpieces are used for radio frequency or low frequency output, while the Q-EP handpiece is used for heating or cooling output, or for low frequency when used with the patch and patch cable.

The cooling function of Apollo Quattro is substantially equivalent to the device cleared in K213294. The Apollo Quattro is a cryosurgical device used to cool the skin, without the

use of cryogenic gases or liquids, for the removal of benign skin lesions and for use when cooling is intended for the temporary reduction of pain, swelling, inflammation, and hematoma from minor surgical procedures. Surface contact cooling is achieved using a thermoelectric cooler (TEC), with an integrated aluminum plate, to lower the temperature of the skin.

5. Indications for use (intended use)

Q-LF handpiece, Q-FX handpiece, Q-SC handpiece, and Q-BT handpiece in RF mode are intended for:

- Relief of minor muscle aches and pain, relief of muscle spasm, and temporary improvement of local blood circulation.

Q-EP handpiece in cooling mode is intended for:

- Use in dermatologic procedures for the removal of benign lesions of the skin and for the temporary reduction of pain, swelling, inflammation, and hematoma from minor surgical procedures.

6. Substantial Equivalence Discussion

1) Comparison Information

(1) Main Product Code: PBX

Name	Subject device	Predicate device	Comparison
Device Name	Apollo Quattro (APQ-10M)	Apollo Duet (APD-4000)	
Manufacturer	WEERO Co.,Ltd.	WEERO Co.,Ltd.	
510(k) No.	-	K212253	
Product Code, Class	PBX Class II	PBX Class II	Identical
Indications for use	Relief of minor muscle aches and pain, relief of muscle spasm, and temporary improvement of local blood circulation.	Relief of minor muscle aches and pain, relief of muscle spasm, and temporary improvement of local blood circulation.	Identical
Energy Used	(Non-invasive) Bipolar RF	(Non-invasive) Bipolar RF	Identical
Physical specification: Dimensions	Main unit: 15.9(W) x 15.4(D) x 41(H) in / 405(W) x 391(D) x 1041(H) mm Q-LF handpiece: 1.5(W) x 6.8(D) x 1.5(H) in / 37.3(W) x 172.8(D) x 37.6(H) mm Q-FX handpiece: 1.1(W) x 5.8(D) x 1.1(H) in / 28.8(W) x 147.1(D) x 28.8(H) mm Q-SC handpiece: 2.8(W) x 6.8(D) x 2.1(H) in / 71.5(W) x 172.5(D) x 53.1(H) mm Q-BT handpiece: 2.8(W) x 6.6(D) x 2.8(H) in / 70.8(W) x 168.4(D) x 70.8(H) mm	Main unit: 13.1(W) x 13.1(D) x 7.2(H) in / 334(W) x 334(D) x 183.6(H) mm RF Handpiece 1.7(W) x 6.4(D) in / 43.2(W) x 162.5(D) mm	Not identical Although "Dimensions" and "Weight" of subject device are different from the predicate device, they all comply with IEC 60601-1, IEC 60601-2-2 requirements, thus the differences of the function specifications does not raise any safety or effectiveness issue.
Weight	Main unit: 20 kg / 44.1 lb Q-LF handpiece: 78.5 g [0.2 lb] Q-FX handpiece: 48.5 g [0.1 lb] Q-SC handpiece: 181.5 g [0.4 lb] Q-BT handpiece: 138 g [0.3 lb]	Main unit: 5 Kg / 11 lb RF Handpiece: 200 g [0.44 lb]	
Input power	100-240 VAC, 50/60 Hz	100-240 VAC, 50/60 Hz	Identical
RF Frequency	1 MHz	1 MHz	Identical
Max. RF Output Power	42 [W]	40 [W]	Not identical Although the "Max. RF Output 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.
Patient contact material	Electrode: SUS 304 LED display part: PC	Electrode: SUS 304 LED display part: PC	Identical
Standards Met	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-2	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-2	Identical

(2) Subsequent Product Code : QPZ

The "Apollo Quattro (subject device)" and "Dermal Cooling System (predicate device, K213294)" have the same indications for use as follows,

"Use in dermatologic procedures for the removal of benign lesions of the skin and for the temporary reduction of pain, swelling, inflammation, and hematoma from minor surgical procedures."

The subject device and predicate device (K213294) also have the same fundamental scientific technological elements.

- comprised of a cooling unit (chiller) with a cold plate/probe applicator used to cool the skin in the area intended for treatment
- same cooling mechanism - thermoelectric cooling
- controlled contact surface cooling at a targeted treatment site on the skin
- metal cooling interface within an applicator
- the lowest treatment temperature (-16 ℃)

The key differences that exist between the "Apollo Quattro" and the "Dermal Cooling System" are:

- size and shape of cold plate/probe applicator

The differences do not raise new questions of safety and effectiveness with respect to the proposed indication.

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.
All the performance specifications of the subject device 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 high frequency surgical equipment and high frequency surgical accessories testing according to IEC 60601-2-2 standard. These performance tests demonstrated that the device specifications meet the system requirements and do not raise new safety or effectiveness concerns.

3) Conclusion

"Apollo Duet (Model : APD-4000)" and "Dermal Cooling System" 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 device 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 Apollo Quattro are as safe and effective as legally marketed predicate devices.
Therefore, it is concluded that the Apollo Quattro is substantially equivalent to the legally marketed predicate devices.

7. Non-Clinical (Bench) Performance Data:

As part of demonstrating safety and effectiveness of the Apollo Quattro 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 Apollo Quattro 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 IEC60601-2-2:2017/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.
- 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 Apollo Quattro 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 Apollo Quattro meets all design specifications and performance requirements, and to measure the accuracy of the output parameters of Apollo Quattro 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, and Class II Special Controls Guidance Document: Contact Cooling System for Aesthetic Use.
The testing results support that the requirements for performance and electrical safety were met for the acceptance of the device. The Apollo Quattro passed all testing and supports the claims of substantial equivalence to the predicate device.

Regarding the cooling function, performance data is provided in support of the substantial equivalence determination.
Bench testing was completed to demonstrate the ability of the Apollo Quattro to meet performance specifications.
No other performance testing was performed for the subject device for this Traditional 510(k) since there was no change to the device design or methods for use required for the range of treatment parameters previously cleared for the Dermal Cooling System (K213294) allows the same cooling characteristics at the skin surface.
No pre-clinical or clinical testing was performed.

8. Sterilization/Disinfection/Cleaning/Shelf Life

The Apollo Quattro 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 Apollo Quattro is as safe and effective as the predicate devices, it can be concluded that the Apollo Quattro is substantially equivalent to the legally marketed predicate devices.