February 13, 2025

Boston Aesthetics Inc
Hongmei Cao
General Manager
1521 Concord Pike Suite 201
Wilmington, Delaware 19803

Re: K241832
Trade/Device Name: Unicorn+ RF System (Unicorn+); Unicorn+ RF System (Unicorn+ I); Unicorn+ RF System (Unicorn+ II); Unicorn+ RF System (Unicorn+ III)
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: GEI, PBX
Dated: November 20, 2024
Received: January 17, 2025

Dear Hongmei Cao:

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,

James H. Jang -S

Digitally signed by James H. Jang -S
Date: 2025.02.13 17:23:19 -05'00'

For
Long Chen, Ph.D.
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K241832

Device Name

Unicorn+ RF System (Unicorn+);
Unicorn+ RF System (Unicorn+ I);
Unicorn+ RF System (Unicorn+ II);
Unicorn+ RF System (Unicorn+ III)

Indications for Use *(Describe)*

The Unicorn+ RF System is intended for use in dermatologic and general surgical procedures for electrocoagulation and hemostasis. The RF System is used for the relief of minor muscle aches and pain, 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.

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510(k) Summary

This 510(k) Summary is being submitted in accordance with requirements of Title 21, CFR Section 807.92.

1. General Information

Submitter: Boston Aesthetics INC
1521 Concord Pike Suite 201 Wilmington DE 19803.US
Contact Person: Hongmei Cao
General Manager
Tel: 001 949-792-816
Email: bsnaesthetics@gmail.com
Summary Preparation Date: June 14,2024

2. Device Name and Code

Trade/Common Name: Unicorn+ RF System
Classification Name: Electrosurgical, Cutting & Coagulation & Accessories
Classification: Class II
Product Code: GEI, PBX
Regulation Number: 21 CFR 878.4400
Review Panel: General & Plastic Surgery

3. Predicate Device

Predicate Device 1:Potenza, cleared under Traditional 510(k) K192545
Predicate Device 2: AGNES, cleared under Traditional 510(k) K160469
Predicate Device 2: Capenergy C Equipment RF System, cleared under Traditional 510(k) K222260

4. Device Description

Unicorn+ RF System is consist of a host, a trolley, a footswitch, a power cord, three kinds of handpieces and matched electrodes.

5. Indications for Use

The Unicorn＋ RF System is intended for use in dermatologic and general surgical procedures for electrocoagulation and hemostasis. The RF System is used for the relief of minor muscle aches and pain, muscle spasm, and temporary improvement of local blood circulation.

6. Technological Characteristics in Comparison to the Predicate Device

Although this subject device has three Predicate devices, they have same fundamental technology theory. Operators control host through touch screen, outputs different amounts of RF energy to handpieces and matched electrodes. These three kinds of electrodes(including invasive or non-invasive electrodes) act on different skin depth to achieve different treatment modes.

The subject device has the same intended use and indications for use and the same fundamental scientific technology as the Predicate devices. The subject device design, technology, and the

principles of operation are the same as the predicate devices. Although subject device output has minor differences with some predicate devices, and RF Energy= RF Output power × On Time, subject device conducts treatment duration to achieve same treatment with predicates devices. Therefore, the minor differences do not raise any new safety and effectiveness results because the parameters of the Subject device are similar to those of the predicate device.

7. Substantial Equivalence Table

A comparison of the intended use and technological characteristics of the subject device and predicate device is provided in the table below:

Items	**Subject device**	**Predicate device (K192545)**	**Predicate device (K160469)**	**Predicate device (K222260)**
Description	Unicorn+ RF System	POTENZA	AGNES	Capenergy C Equipment RF System - C25, C50, C100, C200, C300, C400, C500
Manufacturer	Boston Aesthetics INC	Jeisys Medical Incorporated	Gowoonsesang Cosmetics Co., Ltd	Capenergy Medical S.L.
Classification Product Code	GEI,PBX	GEI	GEI,KCW	PBX
Indication for Use	The Unicorn＋ RF System is intended for use in dermatologic and general surgical procedures for electrocoagulation and hemostasis. The RF System is used for the relief of minor muscle aches and pain, muscle spasm, and temporary improvement of local blood circulation	The POTENZA is intended for use in dermatologic and general surgical procedures for electrocoagulation and hemostasis.	AGNES is indicated for use in dermatological and general surgical procedures for electrocoagulation and hemostasis.	Capenergy C equipments RF System - C25, C50, C100, C200, C300, C400, C500 are intended to provide topical heating for the purpose of elevating tissue temperature for treatment of selected medical conditions such as: relief of pain, muscle spasms, increase in local circulation, and dermatological procedures. The massage device provided is intended to provide a temporary reduction in the appearance of cellulite.

				Capenergy C equipments RF System - C25, C50, C100, C200, C300, C400, C500 are indicated for use in dermatological and general surgical procedures for electrocoagulation and hemostasis.
Prescription/Over-the Counter Use	Prescription	Prescription	Prescription	Prescription
System Type	Bipolar RF (Radiofrequency) and Monopolar RF (Radiofrequency)	Bipolar RF (Radiofrequency) and Monopolar RF(Radiofrequency)	Monopolar RF (Radiofrequency)	Monopolar RF (Radiofrequency)
Frequency	1MHz	1MHz, 2Mhz	1MHz	1MHz
Max Output Power	50W	50W	46W	45W
Treatment Duration(Time)	MicroRF:10-600 ms Artisit: 50ms-5000ms Pure+B1:1-30min	5-500ms	Min 50ms / Max 1,000ms	15-660 sec
Tips	single electrode： ArtistD2.0, 2.0mm ArtistD3.5, 3.5mm ArtistD4.5, 4.5mm ArtistD6.0, 6.0mm Pure+B1, 3cm^2 dual electrodes: MicroRF 49, 0.5-3.5mm MicroRF 25, 0.5-3.5mm	Depth: Maximum of 4.0mm Thickness : 0.25mm	Needle length : 0.8/1.25/1.5/ 2.0 mm Thickness : 0.2mm	N.A.

	MicroRF 9N, 0.5-3.5mm MicroRF 25N, 0.5-3.5mm			
Single Use or Reusable	Single Use/Resusable	Single Use/Resusable	Single Use	Reusable
Sterilization	EO gas	EO gas	EO gas	N.A.

Unicorn+ RF System belongs Product Code GEI and PBX in Classification,and does not own Needle-type epilator,so that not belong to KCW. Therefore, Unicorn+ RF System Classification code are all same as three predicate devices code. The Unicorn＋ RF System is intended for use in dermatologic and general surgical procedures for electrocoagulation and hemostasis. This description is same as POTENZA and AGNES. The RF System is used for the relief of minor muscle aches and pain, muscle spasm, and temporary improvement of local blood circulation. This description is same as Capenergy C Equipment RF System statement,which Capenergy C equipments RF System - C25, C50, C100, C200, C300, C400, C500 are intended to provide topical heating for the purpose of elevating tissue temperature for treatment of selected medical conditions such as: relief of pain, muscle spasms, increase in local circulation, and dermatological procedures. The Unicorn+RF system owns 3 modes matched 3 different types of tips. MicroRF, is Bipolar RF (Radiofrequency) ,which is same as POTENZA Bipolar tips in 1Mhz mode, Moreover, Artist&Pure+ tips are Monopolar RF (Radiofrequency) same as others. Treatment depends on device supplied energy , the energy is affected by treatment duration and power supply. Micro RF tips treatment duration is minimal different from POTENZA ones. Artist tips treatment is 50ms-5000ms, much longer than AGNES treatment duration, however, Artist tips max output power is designed 20W, and AGNES is 46W, thus the influence on energy with tissue is also minimal. Finally on Pure+ tips is not a point of use, this tip is effect on skin area, thus the treatment duration depends on treatment area size. MicroRF tips length is no more than POTENZA tips maximum length; Some of Artist tips lengths are longer than AGNES, but tips lengths is effect on treatment target tissue area under the skin, because all tips divided into non-insulated and insulated part, only non-insulated release energy to target tissue.

Conclusion, Unicorn+RF system is designed similar with predicate devices, they are same indications for use, and the operating principle and technological characteristics. Although there are some differences as output power, treatment duration and tip physical dimensions. the thermal damage tests which is compare with the predicate devices and performance test reports are supported to the safety and effectiveness of the subject device.

8. Performance Date

The following performance data were provided in support of the substantial equivalence determination:

Biocompatibility

The biocompatibility evaluation for electrode was conducted in accordance with the International Standard ISO 10993-1 Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing

within a Risk Management Process, as recognized by FDA. The subject device is contacted with patient during the treatment for duration of less than 24 hours. The biocompatibility testing includes the following:

• In Vitro Cytotoxicity Test: ISO 10993-5: 2009
• Skin Sensitization Test: ISO 10993-10:2021
• Intracutaneous Reactivity Test: ISO 10993-23:2021
• Acute Systemic Toxicity Test: ISO 10993-11:2017
• Pyrogen Test: ISO 10993-11:2017

Sterilization Validation Sterilization validation of the electrode has been conducted per the standard ISO 10993-7:2008 for Ethylene Oxide(standard ISO 11135:2014).

Shelf-life Validation

The shelf-life validation of the device has been conducted using the accelerated aging method in accordance to ASTM F1980-16.

Electrical safety and electromagnetic compatibility (EMC)

Electrical safety testing and EMC testing were conducted on the Radio frequency System complying with the IEC 60601-1 standard, the IEC 60601-2-2 standard ,the IEC 60601-1-6 standard for safety and the IEC 60601-1-2 standard for EMC.

Software Verification and Validation Testing

Software Verification and Validation Testing were conducted and documentation was provided as recommended by FDA relevant Guidance for Industry and FDA Staff Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices.' The software for this device was considered as a 'moderate' level of concern, since a failure or latent flaw in the software could indirectly result in minor injury to the patient or operator.

Ex Vivo testing

Ex Vivo testing conducted on four types of tissue-Live, Kidney, Skin and Muscle under GLP
Thermal testing in accordance with FDA's "Guidance for Industry and FDA Staff: Premarket Notification (510(k)) Submissions for Electrosurgical Devices for General Surgery", August 15, 2014

Summary discussion Non-clinical tests data

Based on bench test, the device demonstrated ability to reach and maintain therapeutic temperature 40-45℃ on the surface of skin, and the actual skin temperature test was conducted.
No preclinical and clinical data was provided in this submission

9. Conclusion

In comparing between the subject device and the predicate devices, there are the same indications for use, the operating principle and technological characteristics .Although there are some differences as output power, treatment duration and tip physical dimensions. the thermal damage test which is compare with the predicate devices and performance test reports are supported to the safety and effectiveness of the subject device.

In this regard, we conclude that the subject device is substantially equivalent to the predicate devices.