



December 10, 2024

Aerin Medical, Inc.
Teri Feeley
Regulatory Affairs Manager
2565 Leghorn St.
Mountain View, California 94043

Re: K242630

Trade/Device Name: Aerin Console
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: November 13, 2024
Received: November 13, 2024

Dear Teri Feeley:

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: 2024.12.10 13:21:08
-05'00'

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

Indications for Use

Submission Number (if known)

K242630

Device Name

Aerin Console

Indications for Use (Describe)

The Aerin Console is an electrosurgical system intended to generate radiofrequency (RF) electrical current for the use of an Aerin Medical Stylus. The Aerin Console is indicated for use in small clinic, office or hospital environments.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASStaff@fda.hhs.gov

"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."



510(k) Summary K242630

General Information

Submitter Information	
Company:	Aerin Medical Inc.
Submitter address:	2565 Leghorn St. Mountain View, CA 94043
Contact Person:	Teri Feeley Regulatory Affairs Manger Phone: 210-827-1618
Establishment Registration Number:	3011625895
Date Prepared:	30 Aug 2024
Name of Device	
Brand Name:	Aerin Console
Common Name:	Radiofrequency generator
Classification Name:	Electrosurgical cutting and coagulation device and accessories
Classification Panel	General and Plastic Surgery
Device Class:	Class II
Product Code:	GEI
CFR Regulation:	21 CFR 878.4400
Predicate Device:	Aerin Console (K162810)
Device Description	
The Aerin Console is a radio-frequency (RF) generator designed to be used with an Aerin Medical Stylus (RhinAer Stylus, K221907 and VivAer, K200300) to deliver bipolar RF energy to tissue. The Aerin Console consists of an RF generator, a power cord, and a foot switch. It incorporates user interface software to control, monitor and regulate RF power delivery to soft tissues via a cable-connected electrosurgical hand piece and electrode.	
Indications for Use	
The Aerin Console is an electrosurgical system intended to generate radiofrequency electrical current for the use of an Aerin Medical Stylus. The Aerin Console is indicated for use in small clinic, office or hospital environments.	

Summary of Technological characteristics compared to the predicate device

The subject device has the same technological characteristics as the predicate including the principle of operation, performance, and design features.

Characteristic	Subject Device	Predicate Device (K162810)
Design Configuration	Same	Generator, power cord, foot switch
Energy type	Same	Bipolar radiofrequency
Treatment temperature range	Same	50-70°C
Output Power	Same	3-5 Watts
Stylus compatibility	Same	Aerin Medical Stylus (RhinAer Stylus & VivAer Stylus)

Summary of non-clinical test

Device Performance was tested to comply to:

Electrical Safety and EMC:

- ISO 60601-1
- ISO 60601-1-2
- IEC 60601-4-2
- 47 CFR Part 15 Subpart B
- 47 CFR Part 27

Software validation

- IEC 62304

Device Security

- IEC 81001-5-1

Summary of clinical test

Clinical testing was not necessary for this device.

Conclusion

The subject device is substantially equivalent to the predicate device based on a comparison of the intended use, indications for use, and technological characteristics and the minor differences do not raise new questions of safety or effectiveness. Therefore, the subject device is substantially equivalent to the predicate device.