May 18, 2026

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

Re: K260522
Trade/Device Name: RhinAer+ Stylus
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: February 15, 2026
Received: February 17, 2026

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (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 ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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,

JOYCE C. LIN -S

for Shu-Chen Peng, Ph.D.
Assistant Director
DHT1B: Division of Dental and
ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT, and Dental 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.	K260522

Please provide the device trade name(s).

RhinAer+ Stylus

Please provide your Indications for Use below.

The RhinAer+ Stylus is indicated for use in otorhinolaryngology (ENT) surgery for the destruction of soft tissue in the nasal airway, including in posterior nasal nerve regions in patients with chronic rhinitis.

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

- ☒ Prescription Use (21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) Summary

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:	18 May 2026
Name of Device	
Brand Name:	RhinAer+ Stylus
Common Name:	Radiofrequency probe
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:	RhinAer Stylus (K221907)
Device Description	
The RhinAer+ Stylus is functionally unchanged from the predicate device (K221907) in design and technological characteristics to generate and deliver bipolar RF energy for use in otorhinolaryngology (ENT) surgery for destruction of soft tissue in the nasal airway. The RhinAer+ Stylus labeling has been modified to include observational information from a clinical study conducted in patients with chronic rhinitis with comorbid migraine.	
Indications for Use	
The RhinAer+ Stylus is indicated for use in otorhinolaryngology (ENT) surgery for the destruction of soft tissue in the nasal airway, including in posterior nasal nerve regions in patients with chronic rhinitis.	

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 (K221907)
Intended Use and Indications for Use	Same	The RhinAer Stylus is indicated for use in otorhinolaryngology (ENT) surgery for the destruction of soft tissue in the nasal airway, including in posterior nasal nerve regions in patients with chronic rhinitis.
Design Configuration	Same	Integrated cable, shaft, handle and electrode
Energy Type	Same	Bipolar radiofrequency
Treatment Temperature Range	Same	60°C
Output Power	Same	4 Watts
Stylus Compatibility	Same	Aerin Console
Sterilization	Same	ETO

Summary of non-clinical test

Device performance testing was not required for this modification.

Summary of clinical test

The subject device labeling has been revised to include clinical data as observational information to inform clinicians of the results observed in a subset of chronic rhinitis patients who also have comorbid migraine.

A prospective, multi-center, non-randomized, non-significant risk clinical study was conducted to evaluate the effects of RhinAer+ Stylus use in patients with chronic rhinitis and comorbid migraine. The following outcome measures were evaluated:

- Reflective Total Nasal Symptom Score (rTNSS)
- Monthly Migraine Headache Days (MMHD)
- Migraine Disability Assessment (MIDAS)

The study showed improvements in migraine-related outcomes, including reductions in MMHD and MIDAS scores, as well as improvements in chronic rhinitis symptoms as measured by rTNSS, at 3-, 6-, and 12-month follow-up visits. The clinical study did not raise different questions of safety.

Conclusion

The subject device is substantially equivalent to the predicate device based on a comparison of the device performance and technological characteristics. Labeling language has been modified to include clinical data as observational information without changing the intended use. A risk-based assessment did not identify new risks or significantly modify existing risks. Therefore, the subject device is substantially equivalent to the predicate device.