July 29, 2022

Aerin Medical Inc.
Shannon Scott
Sr. Director RA/QA
2565 Leghorn St.
Mountain View, California 91043

Re: K221907
Trade/Device Name: RhinAer® Stylus (FG1393)
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: June 28, 2022
Received: June 30, 2022

Dear Shannon Scott:

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,

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

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)*
K221907

Device Name

RhinAer® Stylus

Indications for Use *(Describe)*

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.

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
PRAStaff@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

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

General Information

Submitter Information	
Company:	Aerin Medical Inc.
Submitter's Address:	2565 Leghorn St. Mountain View, CA 94043
Contact Person:	Shannon Scott Sr Director, Regulatory Affairs & Quality Assurance Phone: 512-221-9956
Establishment Registration Number	3011625895
Date Prepared:	07/25/2022
Name of the Device	
Proprietary Name:	RhinAer® Stylus, Model FG1393
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 Section:	21 CFR 878.4400
Predicate Device:	RHIN1 Stylus (K192471)
Device Description	
The RhinAer Stylus is functionally unchanged from the predicate in design and intended use to generate and deliver bipolar RF energy to treat tissue in ENT procedures. The design of the Stylus shaft has been changed to improve physician visualization and access during the procedure. The Stylus shaft diameter has been reduced and is more malleable. The treatment tip shape has been re-designed to change its position relative to the shaft to facilitate tissue apposition. The subject and predicate devices have the same material composition. The device and packaging system has been tested and validated with shelf-life studies out to 6 months. The optional custom treatment parameters (power, temperature, time) have been removed.	

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 the technological characteristics of the device compared to the predicate device		
The RhinAer Stylus was found to be equivalent to the predicate device in design and intended use to generate and deliver bipolar RF energy to treat tissue in ENT procedures.		
Characteristic	**RhinAer Stylus (Model FG1393) Subject Device**	**RHIN1 Stylus (Model FG815) Predicate Device K192471**
Design configuration	Same	Integrated cable, handle and electrode
Energy type	Same	Bipolar radiofrequency
Tissue temperature	60°C	50 – 70 °C (temperature controlled)
Power	4 W	3-5 W
RF generator compatibility	Same	Aerin Console, Model FG226
Shaft shape	Straight with diameter step down	Straight
Shaft Diameter, proximal Shaft Diameter, distal *(Dimension without shrink tube)*	0.120 inches 0.083 inches	0.148 inches* *same diameter throughout proximal and distal shaft
Treatment Tip	10° tilt 	No tilt 
Sterilization	Same	EtO
Packaging System	Same	Tray
Use limit feature	Yes	Yes
Stylus validation feature	Yes	Yes
Summary of non-clinical tests		
Device performance testing included bench functional testing and usability testing. Force load testing was conducted to verify adequate stylus strength. The efficacy of the subject device is supported by thermocouple accuracy and response time testing. The subject devices met all the performance testing requirements. The usability of the RhinAer Stylus, the Instructions for Use, and the Physician Training Materials were all evaluated to validate and confirm that there were no		

new use errors that could cause serious harm to the user or patient, that no further improvement to the device and its user interface is necessary, and the device is safe to use. All study objectives were met. After reviewing the differences between the RhinAer and RHIN1 Styluses (changes to the shaft diameter and malleability, and treatment tip design), it was determined that the RHIN1 Stylus design verification testing is applicable to the RhinAer Stylus for biocompatibility, electrical safety, and sterility validation. The packaging and devices passed all aging and transit testing acceptance criteria, thereby allowing all styluses to be labeled with a 6-month shelf life.
Summary of clinical tests
No clinical testing was deemed necessary for this device.
Conclusion
Verification testing demonstrates that the modified device RhinAer Stylus does not raise new questions of safety or effectiveness. Therefore, the subject device is substantially equivalent to the predicate device.