December 20, 2019

Aerin Medical Inc.
Matthew Hull
Director, US Regulatory Affairs
232 E Caribbean Dr.
Sunnyvale, California 94089

Re: K192471
Trade/Device Name: RHIN1 Stylus
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: September 9, 2019
Received: September 10, 2019

Dear Matthew Hull:

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,

for Michael Ryan
Director
DHT1C: Division of ENT, Sleep Disordered Breathing, Respiratory and Anesthesia 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

Device Name
RHIN1 Stylus

Indications for Use *(Describe)*

The RHIN1 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.

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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:	232 E. Caribbean Drive Sunnyvale, CA 94089
Contact Person:	Matthew M Hull Director, Regulatory Affairs Phone: 916-642-3554
Establishment Registration Number	3011625895
Date Prepared:	09/09/2019
Name of the Device	
Proprietary Name:	RHIN1 Stylus, Model FG815
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:	InSeca ARC Stylus (K162810)
Device Description	
The RHIN1 Stylus is a handheld bipolar radiofrequency (RF) probe designed for use in otorhinolaryngology (ENT) surgery. The Stylus comprises a handle, shaft, and treatment tip. The treatment tip consists of an array of bipolar electrodes and a temperature sensor that allows for monitoring of tissue temperature during RF energy delivery. The shaft is malleable to allow the user to bend the shaft in order to more easily access the desired treatment area(s). The Stylus is designed for use with the Aerin Console. It includes features to allow compatibility with and	

authentication by the Aerin Console. The Stylus connects to the Aerin Console via a flexible cable.

The RHIN1 Stylus is used to treat patients experiencing chronic rhinitis. During a treatment procedure, the clinician inserts the shaft of the RHIN1 Stylus into a patient's nostril to position the treatment tip and deliver low power RF energy to the target tissue of the nasal airway. The low-power radiofrequency energy generates heat within the tissue, causing destruction of the unwanted soft tissue. The shaft of the RHIN1 Stylus is then removed from the nostril.

Indications for Use

The RHIN1 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 RHIN1 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	**RHIN1 Stylus (Model FG815) Subject Device**	**InSeca ARC Stylus (Model FG256) Predicate Device K162810**
Design configuration	Same	Integrated cable, handle and electrode
Energy type	Same	Bipolar radiofrequency
Tissue temperature	Same	50 – 70 °C (temperature controlled)
Power	Same	3-5 W
RF generator compatibility	Same	Aerin Console, Model FG226
Sterilization	Same	EtO
Packaging System	Tray	Pouch
Use limit feature	Yes	Yes
Stylus validation feature	Yes	Yes

Summary of non-clinical tests

Device performance testing included ex-vivo functional testing and usability testing. Force load testing was conducted to verify adequate shaft 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 RHIN1 Stylus and System, 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 RHIN1 and InSeca Styluses (change in shaft component and change in functional use to enable shaft bending for rhinitis), it was determined that the InSeca design verification testing is applicable to the RHIN1 device for biocompatibility, transit, and aging testing.

A packaging system change from pouch to lidded tray was previously documented through internal change control. The change from the originally cleared InSeca ARC Stylus packaging (polyethylene/nylon mix-Tyvek pouch) to a thermoformed polyethylene-Tyvek tray was fully validated for sterilization and evaluated for shelf-life (accelerated aging), usability, and biocompatibility risk. The results and conclusions from sterilization validation testing demonstrated the ability of Ethylene Oxide (EO) gas sterilization to effectively sterilize the ARC Stylus family of products to a Sterility Assurance Level (SAL) of 10^{-6} using the overkill half-cycle method approach and establishing the sterilization process parameters for routine sterilization. The packaging and devices passed all aging and transit testing acceptance criteria, thereby allowing all styluses to be labeled with a two-year shelf life. A tray usability study was conducted; user ratings and comments received were positive, demonstrating the overall satisfaction of polled users with the tray packaging configuration. All packaging biocompatibility test acceptance criteria were met.

Summary of clinical tests

The primary efficacy endpoint was defined as a statistically significantly greater than 1-point improvement in the mean 12-hour reflective 4-item Total Nasal Symptom Scale (rTNSS) from baseline to 12 weeks. The secondary efficacy endpoint was defined as a treatment responder rate of 55% or greater, where a responder is defined as achieving a 1 point or greater improvement (decrease) from baseline to 12 weeks. Safety was assessed by characterizing the type and frequency of adverse events reported throughout the study. Additional evaluations included physical and endoscopic nasal assessment and Patient Satisfaction Survey.

Fifty (50) subjects from 5 study sites were treated in the study. The subjects received bilateral treatment of the nasal airway in the area of the posterior nasal nerve with the RHIN1 Stylus. Twelve (12) week rTNSS scores were obtained from

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49 subjects with one patient's score failed to be taken at their 12-week visit. The primary and secondary efficacy endpoints of the study were met and demonstrated significant and clinically meaningful improvement in the rhinitis symptoms as reported in the rTNSS at 12 weeks of follow up.

Significant clinical improvement in symptoms was demonstrate by marked improvement in the Total Nasal Symptom Scale (rTNSS) in nearly all subjects and across all centers. The mean rTNSS at baseline was 8.5 (SD 1.8), which improved to 3.4 (SD 2.3) at the 12-week primary endpoint with a mean decrease of 5.1 points (SD 2.6) from baseline (59.2% improvement) (paired t-test, $p<0.0001$, lower 95% confidence bound=50). Responses to all four items of the rTNSS demonstrated a statistically significant improvement in the mean question score. The responder rate, defined as at least a 1-point improvement in the rTNSS Score, was 94%.

Patient-reported satisfaction with the procedure and quality of life improvement were high. Physical and endoscopic nasal status assessments showed a favorable recovery process following the procedure. Two serious adverse events were reported from 2 subjects, neither was related to the device or the procedure. The reported adverse events were relatively mild, transient, and not unexpected for this type of procedure.

The study results support the conclusion that the treatment has a lasting effect on symptoms of chronic rhinitis and provides a less invasive alternative to traditional chronic rhinitis surgeries. The results from this study support the safety and efficacy of the proposed indication expansion to include destruction of tissue for patients with chronic rhinitis.

Conclusion

Testing demonstrates that the RHIN1 Stylus is substantially equivalent to the predicate in terms of both intended use and delivered RF treatment and is safe and effective for its intended use.