DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

September 22, 2016

Scott Wolf, M.D.
President and Chief Medical Officer
Aerin Medical, Inc.
690 W. Fremont Avenue, Unit 3
Sunnyvale, CA 94087

Re: K161994
Trade/Device Name: Aerin Medical Stylus
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: August 19, 2016
Received: August 23, 2016

Dear Dr. Wolf:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Eric A. Mann -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K161994

Device Name
Aerin Medical Stylus

Indications for Use *(Describe)*
The Aerin Medical Stylus is indicated for use in otorhinolaryngology (ENT) surgery for the coagulation of soft tissue in the nasal airway, to treat nasal airway obstruction by shrinking submucosal tissue.

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

General Information

Submitter Information	
Company:	Aerin Medical, Inc.
Submitter's Address:	690 W. Fremont Avenue, Unit 3 Sunnyvale, CA 94087
Contact Person:	Scott Wolf, M.D. President and Chief Medical Officer Phone: 650-434-3247 Fax: 408-716-2438
Establishment Registration Number	3011625895
Date Prepared:	September 21, 2016
Name of the Device	
Proprietary Name:	Aerin Medical Stylus
Common Name:	Radiofrequency wand
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:	Aerin Medical Wand (K150637)
Device Description	
The Aerin Medical 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 radiofrequency energy delivery. The stylus is connected, via a flexible cable, to a commercially-available RF generator (the ORA-50 S, cleared under K993854) meeting the following requirements: RF operating frequency of 460 kHz (± 5 kHz); bipolar low power (3 watts to 5 watts) RF energy delivery; and sensitive temperature control with low overshoot (50°C to 70°C).	

The Aerin Medical Stylus is used in the treatment of patients experiencing chronic nasal airway obstruction. During a treatment procedure, the clinician inserts the tip of the Aerin Medical Stylus into a patient's nostril to deliver low power RF energy to the target tissue of the nasal airway. Radiofrequency treatment of tissue creates a coagulative lesion which fibroses and retracts as it heals, thereby shrinking the tissue to lessen the degree of obstruction.

Indications for Use

The Aerin Medical Stylus is indicated for use in otorhinolaryngology (ENT) surgery for the coagulation of soft tissue in the nasal airway, to treat nasal airway obstruction by shrinking submucosal tissue.

Summary of the technological characteristics of the device compared to the predicate device

The Aerin Medical Stylus was found to be equivalent to the predicate device in design and intended use to deliver bipolar RF energy to coagulate tissue in otorhinolaryngology procedures.

Characteristic	Aerin Medical Stylus (Models FG011 & FG174) **Subject Device**	Aerin Medical Wand (Model FG011) **Predicate Device K150637**
Indications for Use	Same	Indicated for use in otorhinolaryngology (ENT) surgery for the coagulation of soft tissue in the nasal airway, to treat nasal airway obstruction by shrinking submucosal tissue.
Design configuration	Same	Integrated cable, handle and electrode
Energy type	Same	Bipolar radiofrequency
Tissue temperature	Same	50 – 70 °C (temperature controlled)

Summary of non-clinical tests

Device safety is supported through biocompatibility testing, sterilization and packaging validation activities, electrical safety testing and electromagnetic compatibility testing. Biocompatibility of the Aerin Medical Stylus was demonstrated through testing performed in accordance with AAMI / ANSI / ISO standards 10993-1 (2009/(R) 2013). Radiation sterilization was validated per AAMI / ANSI / ISO 11137-1 (2006/(R) 2010) and 11137-2 (2013). Electrical safety was demonstrated through testing to IEC 60601-1 (2005/(R) 2012) and

60601-2-2 (2009) and electromagnetic compatibility testing was performed according to IEC 60601-1-2 (2007). The packaging systems were subjected to transit testing, visual inspection, accelerated aging, gross leak detection and seal strength testing in accordance with the applicable ASTM standards (ASTM D4169-14, ASTM F1980-07, ASTM F2096-11, and ASTM F88/F88M-15), and met all acceptance criteria. Device performance testing included usability factors as well as factors related to system responsiveness and effectiveness for use in a clinical setting. Usability factors, such as ergonomics, visualization, orientation and force application, were evaluated as part of a cadaver study. Additionally, 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 via water bath immersion and tissue heating time testing. Tissue heating time testing was performed using tissues representative of the submucosal tissues of the nasal airway. The subject device met all performance testing requirements, thereby supporting its equivalency to the predicate device in terms of delivery of RF energy.
Summary of clinical tests
Not applicable. No clinical tests were necessary.
Conclusion
Testing demonstrates that the Aerin Medical Stylus is substantially equivalent to the predicate in terms of both indications for use and delivered RF treatment and is as safe and effective for its intended use.