December 5, 2017

Aerin Medical, Inc.
Shannon Scott
Director, Regulatory Affairs
232 E. Caribbean Drive
Sunnyvale, CA 94089

Re: K172529
Trade/Device Name: Vivaer ARC Stylus
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: November 2, 2017
Received: November 6, 2017

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. 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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

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)*

K172529

Device Name

Vivaer ARC Stylus

Indications for Use *(Describe)*

The Vivaer ARC 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, including cartilage in the internal nasal valve area.

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<br>Sunnyvale, CA 94089 |
| Contact Person: | Shannon Scott<br>Director, Regulatory Affairs<br>Phone: 512-221-9956 |
| Establishment Registration Number | 3011625895 |
| Date Prepared: | November 2, 2017 |
| **Name of the Device** | |
| Proprietary Name: | Vivaer ARC Stylus, Model FG257 |
| 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 Vivaer ARC 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 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 Vivaer ARC Stylus is used to treat patients experiencing chronic nasal airway obstruction. During a treatment procedure, the clinician inserts the tip of the Vivaer ARC Stylus into a patient's nostril to deliver low power RF energy to the target tissue of the nasal airway. The low-power radiofrequency energy generates heat within the tissue, allowing the tissue to be repositioned by applying lateral pressure, and creates a coagulation lesion. As the lesion heals, the tissue retracts and stiffens. The treatment shrinks and reshapes the tissue to lessen the degree of obstruction.

**Indications for Use**

The Vivaer ARC 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, including cartilage in the internal nasal valve area.

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

The Vivaer ARC 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** | **Vivaer ARC Stylus (Model FG257) 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) |
| RF generator compatibility | Same | Aerin Console, Model FG226 |
| Use limit feature | Yes | Yes |
| Stylus validation feature | Yes | Yes |

**Summary of non-clinical tests**

Device performance testing included system responsiveness and effectiveness for use in a clinical setting. 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 soft tissues of the nasal airway. The subject device met all the performance testing requirements. Additional performance testing was performed to verify substantial equivalence to the predicate devices in terms of thermal effects. The testing showed that the Vivaer ARC Stylus creates thermal

lesion volumes that are comparable to volumes created with the predicate device.

Device safety is supported through biocompatibility testing, sterilization and packaging validation activities, electrical safety testing and electromagnetic compatibility testing. Biocompatibility of the Vivaer ARC Stylus was demonstrated through testing performed in accordance with AAMI/ANSI/ISO 10993-1 (2009/(R) 2013). The sterilization validation was performed in accordance with ANSI/AAMI/ISO 11135:2014 and ISO 10993-7:2008. Electrical safety was demonstrated through testing to IEC 60601-1:2005/A1:2012 and IEC 60601-2-2:2009 and electromagnetic compatibility testing was performed according to IEC 60601-1-2:2007/AC:2010. The Vivaer ARC Stylus packaging system was 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 D4332-14, ASTM F1980-07(2011), ASTM F2096-11, and ASTM F88/F88M-15), and met all acceptance criteria.

In vivo testing was conducted in canines to evaluate the healing and long-term effects of temperature-controlled bipolar RF energy delivered to nasal tissue. The treatment sites were evaluated endoscopically post-procedure and at several timepoints out to 24 weeks (6 months). The treated tissue was evaluated histologically by a veterinary pathologist after 1, 4 and 24 weeks of healing. The study results at the end of the 6-month follow-up period support the long-term safety of the Vivaer ARC Stylus to treat the submucosal tissue including cartilage. Treatment with the Stylus resulted in a durable change of the submucosal gland population and did not result in significant fibrosis, tissue contraction, or cartilage degeneration after 6 months of healing. At 6 months, the healing process was complete or near-complete.

**Summary of clinical tests**

A prospective, multi-center, non-randomized, non-significant risk clinical study was conducted in the United States to confirm safety and effectiveness in a population presenting with a history of poor nasal breathing or chronic nasal obstruction. The primary efficacy endpoint was defined as a statistically significantly greater than 15-point improvement in the mean Nasal Obstruction Symptom Evaluation (NOSE) score from baseline to 26 weeks post-procedure. The secondary efficacy endpoint was defined as a treatment responder rate of 55% or greater, where a responder is defined as achieving a 15 point or greater improvement (decrease) in the NOSE score from baseline to 26 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 8 study sites were treated in the study. The subjects received bilateral treatment of the internal nasal valve with the Vivaer Stylus. The primary and secondary efficacy endpoints of the study were met and demonstrated significant and clinically meaningful improvement in the nasal

obstructions symptoms reported by the subjects.

Significant clinical improvement in symptoms was demonstrated by marked improvement in the NOSE score of nearly all subjects and across the multiple study centers. The mean NOSE score at the 26-week endpoint decreased 55 points (SD 21) from baseline (paired t-test, $p<0.0001$, lower 95% confidence bound=50). The responder rate, defined as at least a 15-point improvement in the NOSE Score, was 94% (95% CI [84, 98]). Three subjects were non-responders at the 26-week evaluation. Each of these non-responders had external circumstances that likely contributed to their status at the final evaluation. One subject was lost-to-follow-up for the evaluation at 26 weeks; at previous evaluations up through 18 weeks the subject had significant improvement and was a responder.

Patient-reported opinion and satisfaction with the tolerability, recovery process, and effect of the procedure was high. Physical and endoscopic nasal status assessments showed improvement from baseline condition and a favorable recovery process following the procedure.

Two serious adverse events in 2 subjects were reported. Neither of the events was related to the device or procedure. Both subjects continued to participate in the study and were treatment responders. There were no device-related adverse events and no unanticipated adverse events. The adverse events associated with the procedure were relatively mild, transient, and not unexpected for this type of procedure, demonstrating that the risks associated with the Vivaer ARC Stylus and procedure are minimal.

The results from this study support the safety and efficacy of the proposed indication expansion to include treatment the internal nasal valve area.

**Conclusion**

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