April 13, 2020

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

Re: K200300
Trade/Device Name: VivAer Stylus
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: March 13, 2020
Received: March 16, 2020

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)*

K200300

Device Name
VivAer® Stylus

Indications for Use *(Describe)*

The VivAer® 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 Sunnyvale, CA 94089
Contact Person:	Fred Dinger Chief Of Operations Phone: 210-316-7739
Establishment Registration Number	3011625895
Date Prepared:	04/07/2020
Name of the Device	
Proprietary Name:	VivAer® Stylus, Model FG722
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:	Vivaer® ARC Stylus (K172529)
Device Description	
The VivAer® Stylus is a disposable, handheld device capable of delivering bipolar radiofrequency energy to tissue. The stylus consists of an array of bipolar electrodes positioned on a non-conductive tip which is attached to a handle via a non-conductive shaft. A temperature sensor is located on the tip to monitor tissue temperature during treatment. The product's intended users are physicians including otolaryngologists, maxillofacial surgeons and other physicians specialized in nasal procedures.	

The VivAer® Stylus improves nasal breathing by modifying the soft tissues of the nasal airway through the use of low doses of radiofrequency energy. The low-power radiofrequency generates heat within the submucosal tissue, creating a coagulation lesion. As the lesion heals, the tissue retracts and stiffens. This decreases the nasal airflow resistance thereby improving inflow of air through the nose.

Indications for Use

The VivAer® 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® 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 handle design has been changed to improve tactile feel and appearance. The back (non-treatment) side of the distal tip has been re-designed to have a taper. The packaging system change from a pouch to a thermoformed tray was previously implemented and validated with shelf-life studies completed out to 2 years. The available optional custom treatment parameters (power, temperature, time) were modified to eliminate rarely used selections (specifically, 6 and 8 second treatment times and 0, 3 and 6 second cooling times).

Characteristic	**VivAer® Stylus (Model FG722)** **Subject Device**	**Vivaer® ARC Stylus (Model FG257)** **Predicate Device – K172529**
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	EO
Packaging System	Tray	Pouch

Characteristic	VivAer® Stylus (Model FG722) Subject Device	Vivaer® ARC Stylus (Model FG257) Predicate Device – K172529
Shelf-life	2 years	1 year
Use limit feature	Yes	Yes
Stylus validation feature	Yes	Yes

Summary of non-clinical tests

A packaging system change from pouch to lidded tray was previously documented through internal change control. The change 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 VivAer Stylus to a Sterility Assurance Level (SAL) of 10^{-6}. The current packaging and devices passed all accelerated aging and transit testing acceptance criteria, thereby allowing all styluses to be labeled with a two-year shelf life. The usability of the VivAer Stylus was evaluated based on a similar Aerin Medical device; no use-related errors that may result in serious harms were identified. Biocompatibility testing was not repeated as no new patient-contacting materials were used in VivAer Stylus compared to the predicate device.

The minor changes in the device and its tray were considered in the risk analysis and verification testing was completed to ensure that the changes had no impact on the functional performance of a sterilized device or on the durability of its packaging system. Device performance testing of the device included thermocouple accuracy and response time testing, treatment parameter verification to confirm correct programming of parameters, reuse prevention verification, and force load testing to verify adequate shaft strength. Additionally, tissue heating and conductive gel compatibility were evaluated by confirming energy delivery to tissue samples at a variety of treatment parameters. All performance testing requirements were met.

Summary of clinical tests

No additional clinical testing was deemed necessary for this device.

Conclusion

Verification testing demonstrates that the modifications to the Vivaer® ARC Stylus and/or its packaging design do not raise new questions of safety or effectiveness. Therefore, the subject device is substantially equivalent to the predicate device.