DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Aerin Medical Incorporated
Scott Wolf, M.D.
President and Chief Medical Officer
690 West Fremont Avenue, Unit 3
Sunnyvale, California 94087

November 19, 2015

Re: K150637
Trade/Device Name: Aerin Medical Wand Model FG011
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: October 23, 2015
Received: October 26, 2015

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" (21CFR 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,

Joshua C. Nipper -S

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical 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)*
K150637

Device Name
Aerin Medical Wand Model FG011

Indications for Use *(Describe)*
The Aerin Medical Wand 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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510(k) Summary

K150637

Aerin Medical, Inc.

Aerin Medical Wand (Model FG011)

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

General 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
Date Prepared:	November 18, 2015

Device Name

Proprietary Name:	Aerin Medical Wand (Model FG011)
Common Name:	Radiofrequency wand
Classification Name:	Electrosurgical cutting and coagulation device and accessories
Device Class:	Class II
Product Code:	GEI
CFR Section:	21 CFR 878.4400

Predicate Device

Device Name:	ArthroCare ENTec ReFlex Wand
510(k) Number:	K000778

Device Description

The Aerin Medical Wand is a handheld bipolar radiofrequency (RF) probe designed for use in otorhinolaryngology (ENT) surgery. The Wand 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 Wand 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).

All patient-contacting materials of the Aerin Medical Wand are polymers or stainless steel that have been shown to be biocompatible for short-term contact (less than 24 hours) with breached or compromised surfaces. The Wand is individually packaged and supplied radiation-sterilized for single use.

The Aerin Medical Wand 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 Wand 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.

Intended Use / Indications For Use

The Aerin Medical Wand 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 Technological Characteristics

The Aerin Medical Wand and the predicate device are both handheld electrode probes designed to connect to an RF generator, and both use bipolar RF energy to coagulate tissue in otorhinolaryngology procedures. Both devices are radiation-sterilized and supplied to the user as sterile, single use devices. Patient-contacting materials in both devices have been shown to be biocompatible and suitable for short-term (less than 24 hours) surface contact. Electrical safety has been shown with both devices through testing to applicable IEC standards. The Aerin Medical Wand tip is placed on the nasal mucosa; low-power, temperature-controlled RF energy is delivered through the mucosal layer to the submucosal tissues. The tip of the predicate device penetrates the mucosal tissue so that the electrodes are in submucosal tissue during energy delivery. Although the energy-delivery electrodes and placement are different, bench testing has shown the resulting lesion volumes to be similar. The Aerin Medical Wand incorporates a temperature sensor to maintain target tissue temperature between 50 - 70°C, with the RF generator power limited to an output level selected by the clinician user. The predicate device is also designed to operate at a relatively low temperature (40 - 70°C), although it does not

employ a temperature feedback control mechanism. Thus, both systems are designed to create lesions with a similar heating temperature range, but the Aerin Medical system uses temperature feedback as a safety measure to ensure that the desired range is not exceeded.

Performance Data – Bench Testing

Biocompatibility of the Aerin Medical Wand was demonstrated through testing performed in accordance with AAMI / ANSI / ISO standards 10993-1 (2009/(R) 2013), 10993-5 (2009/(R) 2014, 10993-10 (2010), 10993-11 (2006/(R) 2010) , and 10993-12 (2012). 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 (equivalent to 1 year), gross leak detection and seal strength testing in accordance with the applicable ASTM standards (ASTM D4169-09, ASTM F1980-07, ASTM F2096-11, and ASTM F88/F88M-09), and met all acceptance criteria.

Device performance testing demonstrated that the product met all design requirements, including usability factors, thermocouple response time and tissue heating times. Thermal imaging of the treatment area, using different tissue types and thicknesses, showed that the heating within the treatment area is uniform, without significant variation or hot spots. Thermocouple array testing demonstrated the thermal consistency of the Wand's treatment area at the Wand/tissue interface. Additional *ex vivo* testing was performed to verify substantial equivalence to the predicate device in terms of thermal effects, and showed that the Aerin Medical Wand creates thermal lesion volumes that are comparable to volumes created with the predicate device.

Performance Data – Pre-Clinical Testing

In vivo testing was conducted to evaluate the effects of temperature-controlled bipolar RF energy delivered to nasal tissue. Several combinations of energy delivery durations and target temperatures were used in order to assess relative safety of different parameter settings. The treatment sites were evaluated endoscopically post-procedure and at several time points out to 8 weeks. The treated tissue was evaluated histologically by a veterinary pathologist after 8 weeks of healing. Histological changes were determined to be absent, minimal or mild for tissue treated with 4 watts of power, delivered up to 18 seconds, with a target temperature 60°C or less.

Clinical Performance Data

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 safety endpoint was freedom from unanticipated serious adverse events (SAEs) directly attributable to the Aerin Medical Wand. Technical feasibility evaluated the ability of the Wand to deliver RF energy to the target tissue. Additional evaluations included change in Nasal Obstruction Symptom Evaluation (NOSE) score between baseline and 90-days post-procedure, and physician evaluation of the tissue healing progression.

Thirty-three (33) subjects with complaints of chronic nasal obstruction were enrolled in the study; all received treatment of the nasal airway with the Aerin Medical device. A total of 47 nostrils were treated in the 33 subjects' index procedures. Ten (10) subjects had repeat treatment (12 nostrils), for a total of 59 nostril treatments in the study.

One of the subjects was lost-to-follow-up after the 30-day follow-up, at which time the subject reported no adverse events and had experienced a clinically significant 25-point improvement in his NOSE score. The safety endpoint was met since there were no SAEs reported in the study. With the exception of one subject who experienced a common cold one month following treatment, all other adverse events were observations anticipated as a result of thermal treatment of tissue and the resulting healing process. External photographs of each treated nostril revealed no changes in outward appearance, confirming that the energy was delivered only to the internal tissue as needed. Endoscopic intranasal assessments indicated limited tissue disruption following treatment with the Aerin Medical Wand, and demonstrated a progression in healing and nasal obstruction improvement during the 90-day follow-up period. At 90 days, a clinically significant improvement was reported in 88% of subjects, as assessed with the NOSE scale.

Clinical performance data were not required to obtain clearance of the predicate device. As such, the clinical performance data obtained with the subject device were compared to the published literature on the predicate device. In general, reported complications with the predicate device have been minor, such as temporary bleeding, post-procedure edema or nasal obstruction, crusting, or mucosal tears.

In terms of effectiveness, improvement has been reported with the use of the predicate device in 82 to 88% of subjects. The clinical evaluation of the Aerin Medical Wand also demonstrated very minimal complications of the types observed with the predicate device, and a clinically significant improvement in 88% of subjects, as assessed with the NOSE scale. Visual and endoscopic intranasal assessments demonstrated a progression in healing similar to that reported in the literature for the predicate device.

Substantial Equivalence

All testing demonstrates that the Aerin Medical Wand system performs as intended, and complies with performance standards applicable to radiofrequency systems (including biocompatibility, electrical safety and electromagnetic compatibility). As described in previous sections, the Aerin Medical Wand is substantially equivalent to the predicate device in that both devices utilize handheld bipolar electrode probes, connected to RF generators, to coagulate tissue in otorhinolaryngology procedures. Bench testing has shown that the lesion volumes created by the two systems are similar, despite the differences between the subject device and predicate device (e.g. energy-delivery electrode shape, placement of the probe relative to the target tissue, control mechanisms incorporated in the RF generators). Clinical performance testing with the Aerin Medical Wand indicated a level of clinical improvement comparable to that cited in the medical literature for the predicate device. Thus, through evaluation of device comparisons, bench testing and clinical performance testing, the Aerin Medical Wand has been demonstrated to be substantially equivalent to the predicate device and is as safe and effective for its intended use.