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

February 14, 2017

Arrinex, Inc.
Vahid Saadat
CEO
1755 East Bayshore RD., Suite 26
Redwood City, California 94063

Re: K162608
Trade/Device Name: ClariFix Device
Regulation Number: 21 CFR 878.4350
Regulation Name: Cryosurgical Unit and Accessories
Regulatory Class: Class II
Product Code: GEH
Dated: January 11, 2017
Received: January 12, 2017

Dear Vahid Saadat:

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,

Jennifer R. Stevenson -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)*
K162608

Device Name
ClariFix Device

Indications for Use *(Describe)*
The ClariFix Device is intended to be used as a cryosurgical tool for the destruction of unwanted tissue during surgical procedures, including in adults 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.

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510(k) Summary (K162608)

I. Submitter Information

Submitter name: Arrinex, Inc
1755 Bayshore Rd, Suite 26
Redwood City, CA 94063

Contact person: Vahid Saadat
CEO
408.802.2052

Date Prepared: 13 February 2017

II. Product Classification

Device Name:	ClariFix Device
Common Name:	Cryosurgical Unit and accessories
CFR Classification:	21 CRF 878.4350
Device Class:	II
Product Code:	GEH

III. Predicate Device

Predicate: Arrinex, Inc., ClariFix Device (K160669)
This predicate has not been subject to any recalls.

IV. Device Description

The ClariFix Device is a handheld, single patient-use, disposable cryosurgical device used for the destruction of tissue during surgical procedures. The device consists of a Handle attached to a Cannula with a Cryoprobe at the distal end. The ClariFix Device is provided sterile to the user. The user can select from two nitrous oxide Canister (cryogen Canister) sizes.

To perform cryosurgery, the ClariFix Device is removed from the sterile packaging and the desired cryogen Canister is inserted into the Handle. A Canister Cap is then tightened onto the Handle, which pierces the Canister. The cryogen is held in the Handle until the user opens a mechanical valve that allows cryogen to flow down the Cannula into the Cryoprobe.

The Cryoprobe is placed into contact with the target tissue via direct visualization. The Cannula can be rotated to ensure proper positioning. Once the Cryoprobe is in the desired position, cryosurgery can start.

The Cryoprobe is held in contact with the target location during cryosurgery. As cryogen flows into the Cryoprobe, the liquid partially evaporates and the inside of the Cryoprobe cools to < -80°C and a freezing zone forms in the adjacent tissue, destroying the unwanted tissue. Nitrous oxide is fully contained within the Cryoprobe and does not contact the tissue. Cryosurgery is stopped by the user closing the Valve. Once the Cryoprobe has thawed, it can be safely removed. Additional cycles can be initiated per the physician's discretion.

V. Indications for Use

The ClariFix Device is intended to be used as a cryosurgical tool for the destruction of unwanted tissue during surgical procedures, including in adults with chronic rhinitis.

VI. Comparison of Intended Use, Indications for Use and Technological Characteristics with the Predicate Device

Cryoablation is the fundamental technological principle for the ClariFix subject device and the predicate, the ClariFix Device (K160669). The intended use for the ClariFix Device, destruction of tissue with extreme cold, remains unchanged for the subject device.

The only modification to the subject device is to update the indications for use to include in adults with chronic rhinitis. Results from a clinical study combined with published literature demonstrated that the reference to adults with chronic rhinitis does not impact safety and effectiveness.

Comparison of Indications for Use

ClariFix Device (Subject)	The ClariFix Device is intended to be used as a cryosurgical tool for the destruction of unwanted tissue during surgical procedures, including in adults with chronic rhinitis
ClariFix Device (Predicate, K160669)	The ClariFix Device is intended to be used as a cryosurgical tool for the destruction of unwanted tissue during surgical procedures

The subject and the legally marketed predicate device share identical technological elements:

- Hand-held, portable device containing a single use nitrous oxide cryogen cartridge
- Application of cryogen to ablate (freeze) unwanted tissue
- Use of a cryo balloon as the mechanism for applying cold treatment and containment and exhaust of the cryogen
- User controls treatment time
- No power source, electronics or software required to use the device.
- Use of direct visualization to the target location

As such, the intended use, design, materials and function of the Arrinex ClariFix Device are substantially equivalent to the predicate device.

VII. Performance Data

Because there have been no technological changes to the subject device, no additional bench testing, preclinical testing, sterilization or biocompatibility testing was performed.

A prospective, multicenter clinical study was performed in the United States to support the modification of the indications for use statement to include in adults with chronic rhinitis. Twenty seven (27) subjects were enrolled and cryosurgery was successfully performed with the ClariFix device bilaterally (n=54 treatments) while the subjects were awake using local anesthesia. Cryosurgery was well-tolerated and subjects reported an average pain rating of 1.19 on the Wong-Baker FACES pain scale (0 = minimum score, 5 = maximum score).

The primary safety endpoint was the frequency of device and procedure-related serious adverse events (SAEs). No device or procedure-related SAEs were reported throughout the 90-day follow-up duration. The primary effectiveness endpoints were subject-reported outcomes of nasal symptoms using reflective Total Nasal Symptom Score (rTNSS) and Visual Analog Scale (VAS). Three subjects did not return for the 90-day follow-up visit. Of the remaining 24 subjects, the average rTNSS improved 56% from 6.2 at baseline to 2.7 at 90 days (0 = minimum score, 12 = maximum score). The average VAS score improved 53% from 7.6 at baseline to 3.7 at 90 days (0= minimum score, 10 = maximum score).

The secondary safety endpoint was the frequency of device and procedure-related adverse events (AEs). One subject reported moderate nasal bleeding at Day 27 that was controlled with standard nasal packing and cautery. The investigator deemed it to be remotely related to the device as the target treatment location was completely healed during endoscopic examination at Day 7. Other adverse events commonly associated with healing after cryosurgery in the nasal passageways (pain/discomfort, headache, facial pain, bleeding, dry nose and ear blockage) were observed and by day 90, they had either self-resolved or the remaining events rated as mild with a probable cause relating to pre-existing conditions. The secondary performance endpoint was investigator evaluation of the ease of use of the ClariFix device. Investigators rated cryosurgery using the ClariFix device as "easy" to "moderately easy" in 89% (24/27) of the subjects and "moderately difficult" in 11% (3/27) of the subjects.

Subjects were asked to rate their experience using a subject satisfaction questionnaire. A total of 17 of the 27 subjects responded and fifty nine percent (59%) of the subjects reported cryosurgery to be somewhat (53%) or very (6%) uncomfortable, 41% of the patients felt that it was somewhat (29%) or very (12%) comfortable. Additionally, endoscopic evaluation was performed by the investigators at the follow-up visits, and the average nasal congestion score improved 67% from 1.5 at baseline to 0.5 at 90 days (0 = minimum score, 3 = maximum score). On average, the investigators rated bleeding, swelling and crusting of the treatment site as 0 at 90 days (0 = minimum score, 3 = maximum score) and the average Lund-Kennedy assessment of the entire nasal passageway was 0.21 at 90 days (0 = minimum score, 10 = maximum score) indicating the treatment site was well healed.

A review of published literature over the last four decades was performed to determine clinical outcomes after cryosurgery in the nasal passageway. Eleven clinical studies examined use of various cryoprobes to deliver extreme cold to the nasal mucosal surface in order to treat nasal obstruction or symptoms of rhinitis. Cryosurgical ablation of tissue in the nasal passageways was shown to result in a reduction in rhinitis symptoms with rare reports of major adverse or permanent complications. Minor complications were transient in nature and resolved. There is paucity of studies concerning the vidian neurectomy by means of cryosurgery. Nevertheless, clinical study results demonstrated that both the safety profile and effectiveness results achieved by the ClariFix device in adults with chronic rhinitis are by and large comparable to those published in scientific literature.

The clinical study results demonstrated that when the subject device is used in the nasal passageway according to its Instructions for Use, it is a safe and effective tool for use in destroying unwanted tissue in adults with chronic rhinitis.

VIII. Conclusions

The ClariFix device is substantially equivalent to the predicate device. Clinical study results demonstrated that both the safety profile and effectiveness results achieved by the ClariFix device in adults with chronic rhinitis are comparable to that reported in published literature on cryosurgery in the nasal passageway.