February 26, 2019

Arrinex, Inc
Ms. Tracey Henry
Vice President, Regulatory Affairs, Quality Assurance, Clinical Affairs
127 Independence drive
Menlo Park, California 94025

Re: K190356
Trade/Device Name: ClariFix
Regulation Number: 21 CFR 878.4350
Regulation Name: Cryosurgical Unit and Accessories
Regulatory Class: Class II
Product Code: GEH
Dated: February 12, 2019
Received: February 15, 2019

Dear Ms. Henry:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

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,

Long H. Chen -S

Digitally signed by Long H. Chen -S
Date: 2019.02.26 13:22:06 -05'00'

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)*
K190356

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

I. Submitter

Submitter name: Information	Arrinex, Inc 127 Independence Drive Menlo Park, CA 94025
Contact person:	Tracey Henry VP Regulatory Affairs, Quality Assurance, Clinical Affairs 650-468-6176
Date Prepared:	February 8, 2019

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 (K162608)
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, including in adults with chronic rhinitis. 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 device is provided with a 10mL nitrous oxide Canister.

To perform cryosurgery, the ClariFix Device is removed from the sterile packaging and a nitrous oxide 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 (K162608). The intended use for the ClariFix Device, destruction of tissue with extreme cold, remains unchanged for the subject device.

There has been no change to the subject device's indications for use.

The subject and the 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 ClariFix Device are substantially equivalent to the predicate device.

VII. Performance Data

The following performance data were collected in support of the substantial equivalence determination:

- Simulated Use: temperature reproducibility, leakage
- Dimensional Testing
- Mechanical integrity for device and Cannula
- Mechanical Integrity, canister removal testing
- Shelf-Life testing

Biocompatibility testing was not required for this change as there were no changes in patient contacting materials.

A sterilization adoption study was performed to confirm the existing sterilization dosage was acceptable.

VIII. Conclusions

The ClariFix device has the same intended use and Indications for Use as the predicate device. In addition, it has the same technological characteristics and performance data to support substantial equivalence in terms of safety and effectiveness. Therefore the ClariFix device is substantially equivalent to the predicate device.