DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 9, 2017

Arrinex, Inc.
Vahid Saadat
CEO
1755 East Bayshore Rd, Ste 26
Redwood City, California 94063

Re: K160669
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: May 19, 2016
Received: May 23, 2016

Dear Vahid Saadat:

This letter corrects our substantially equivalent letter of June 24, 2016.

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,

Jennifer R. Stevenson -S

FDA

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)*
K160669

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.

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."

Section 5: 510(k) Summary

I. Submitter Information

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

Contact person: Vahid Saadat
CEO
408.802.2052

Date Prepared: 24 June 2016

II. Product Classification

Device Name:	ClariFix Device
Common Name:	Cryosurgical Unit and accessories
CFR Classification:	21 CRF 878.4350
Device Class:	2
Product Code:	GEH

III. Predicate Device

Predicate:	H&O Equipment, CryoProbe (K024009)
Reference:	C2 Therapeutics, CryoBalloon Ablation System (K131523)

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 the desired nitrous oxide Canister (a.k.a. cryogen Canister) size from two different options.

To perform a treatment, 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 which allows cryogen to flow down the Cannula into the Cryoprobe.

Prior to initiating a treatment, 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, treatment can start.

The Cryoprobe is held in contact with the treatment area during the treatment. 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. Treatment is stopped by the user closing the Valve. Once the Cryoprobe has thawed it can be safely removed from the treatment area. Additional treatment 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.

VI. Comparison of Indication for Use and Technological Characteristics with the Predicate Device

Cryoablation is the fundamental technological principle for the ClariFix subject device and the predicate, the CryoProbe (K024009). It is also the fundamental technological principle for the reference device, the CryoBalloon Ablation System (K131523).

The ClariFix Device has the same Indications for Use as the predicate device (CryoProbe (K024009).

Comparison of Indications for Use

ClariFix Device (Subject device)	The ClariFix Device is intended to be used as a cryosurgical tool for the destruction of unwanted tissue during surgical procedures.
CryoProbe (K024009)	To destroy tissue during surgical procedures by applying extreme cold.

The subject and predicate device are based on the following same technological elements:

- Hand-held, portable device containing a single use nitrous oxide cryogen cartridge
- Application of cryogen to ablate (freeze) unwanted tissue
- User controls treatment time
- No power source, electronics or software required to use the device.
- Use of direct visualization to the treatment area

The subject and reference device have a similar technological element in that they both use a cryo balloon as the mechanism for applying cold treatment and containment and exhaust of the cryogen, however, the Subject cryo balloon (a.k.a. “Cryoprobe”) is not pressurized during treatment, whereas the reference device’s balloon is pressurized.

VII. Performance Data

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

- Simulated Use: temperature repeatability, leakage
- Dimensional Testing
- Mechanical Integrity: Cryoprobe seal strength (burst), bond strength
- Biocompatibility: testing performed to ISO 10993
- Sterility and Packaging Testing

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.