July 11, 2019

AirXpanders, Inc.
Belinda Pinedo
Director, Regulatory Affairs
3047 Orchard Parkway
San Jose, California 95134

Re: K191138
Trade/Device Name: AeroForm Tissue Expander, Smooth
Regulation Number: 21 CFR 878.3510
Regulation Name: Carbon Dioxide Gas-Controlled Tissue Expander
Regulatory Class: Class II
Product Code: PQN
Dated: June 10, 2019
Received: June 11, 2019

Dear Belinda Pinedo:

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,

Nina Mezu-Nwaba, PharmD., MPH., MSc,
CAPT., United States Public Health Service
Assistant Director (Acting), Plastic Surgery Implant Devices Team
Division of Infection Control and Plastic Surgery Devices
Office of Surgical and Infection Control 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)*

K191138

Device Name
AeroForm Tissue® Expander System, Smooth

Indications for Use *(Describe)*

The AeroForm® Tissue Expander System, Smooth is used for soft tissue expansion in breast reconstruction following mastectomy, for the treatment of underdeveloped breasts and for the treatment of soft tissue deformities in the breast.

The AeroForm® Tissue Expander, Smooth is intended for temporary subcutaneous or submuscular implantation and is not intended for use beyond six months

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."

3.1 510(k) Summary

DATE OF SUMMARY

April 29, 2019

510(K) APPLICANT

AirXpanders, Inc.
3047 Orchard Parkway
San Jose, California 95134
Phone: (650) 282-8131

Contact Person: Belinda Pinedo
Phone: (650) 282-8131
E-mail: bpinedo@airxpanders.com

SUBJECT DEVICE OVERVIEW

Trade Name:	AeroForm® Tissue Expander System, Smooth
Common Name:	Expander, Skin, Inflatable
Classification:	II
Product Code:	PQN
Regulation Number:	21 CFR 878.3510
Regulation Name:	Carbon Dioxide Gas Controlled Tissue Expander

PREDICATE DEVICE

The predicate device for this premarket submission is:

Trade Name	Submitter	510(k) Number	510(k) Clearance Date
AeroForm® Tissue Expander System	AirXpanders, Inc.	K170075	04/03/2017

REFERENCE DEVICES

There are other tissue expanders with a smooth shell construction that have been cleared as a Special 510(k); these are referenced below.

Trade Name	Manufacturer Name	510(k) Number	510(k) Clearance Date
Natrelle 133S Tissue Expander	Allergan	K182054	08/29/2018
Artoura Breast Tissue Expander with Smooth Surface	Mentor	K161176	05/23/2016

DEVICE DESCRIPTION

The AeroForm Tissue Expander System, Smooth is a sterile, temporary implant for breast reconstruction. This device is comprised of an implantable tissue expander (Expander), a remote control (Controller), and a Master Key. The AeroForm Tissue Expander, Smooth is constructed of an outer silicone shell and an inner gas barrier (bag) with an internal reservoir of compressed Carbon Dioxide (CO_2) gas. The CO_2 gas is released within the Expander by using the remote control (Controller), resulting in gradual expansion of the Expander. In a typical, two-stage breast reconstruction, a tissue expander device is placed under the pectoralis major muscle and remaining skin following a mastectomy procedure. The Expander is gradually expanded over time through the release of carbon dioxide, causing the overlying skin and muscle to stretch. When adequate tissue coverage is achieved, the expansion device is removed and replaced with a breast implant.

INTENDED USE / INDICATIONS FOR USE

The AeroForm® Tissue Expander System, Smooth is used for soft tissue expansion in breast reconstruction following mastectomy, for treatment of underdeveloped breasts, and for the treatment of soft tissue deformities in the breast.

The AeroForm Tissue Expander, Smooth is intended for temporary subcutaneous or submuscular implantation and is not intended for use beyond six months.

TECHNOLOGICAL CHARACTERISTICS

The subject AeroForm Tissue Expander, Smooth has a modified outer shell that has a smooth surface finish, as opposed to the predicate AeroForm Tissue Expander which has a textured outer shell. This change does not alter the fundamental scientific technology of the device. The subject Expander is made of the same material as the predicate device, but eliminates the final outer shell texture processing, which results in a smooth outer shell surface.

Both the AeroForm Tissue Expander, Smooth and the predicate AeroForm device expand with the same internal operating mechanism which includes an internal Driver reservoir that contains a gas medium that when actuated, releases incremental inflations that gradually stretch the surrounding tissue.

The AeroForm Tissue Expander System, Smooth uses software and electronics to provide controlled, gradual expansion by pressing the button on the Controller, allowing carbon dioxide (CO_2) to be released from a reservoir inside the Expander. A small amount of CO_2 (10cc) is released and the Controller is programmed to allow the patient to dose up to 30cc per day. The Controller provides power to the Expander, which has a receiving antenna and electronics to enable communication with the Controller. The AeroForm Tissue Expander System, Smooth has been evaluated against safety and performance testing described in the tissue expander standard, as well as design verification and validation testing criteria in accordance with

internal company controls and design control procedures to support the safety and intended use of the product.

PERFORMANCE DATA

Mechanical Performance Testing

Testing was performed, as required, to verify and validate that the design outputs of the modified device meet the design input requirements. Performance testing for the smooth Expander included evaluation of the device through performance and functional testing as described in ASTM F1441, *Standard Specification for Soft Tissue Expanders*. The following mechanical tests were performed:

- Simulated Use Testing
- Endurance / Stress Tests
- Dimensional Measurement
- Shell Tensile Set, Shell Break Force, Non-Critical Fused or Adhered Joints

All mechanical performance testing results met their pre-determined acceptance criteria and the requirements of the ASTM F1441 standard for tissue expanders, demonstrating that the modified device is substantially equivalent to the predicate device.

COMPARISON TO PREDICATE DEVICE

The AeroForm Tissue Expander System, Smooth has the same intended use and indications for use as the predicate device: intended for skin/tissue expansion. The System is a single-use device and is intended for subcutaneous or submuscular implantation and is not intended for use beyond six months.

The subject and predicate devices are based on the following comparable technological elements:

- Same operating principle
- Same outer shell elastomeric material
- Same dimensional and volume ranges
- Suture tabs to attach device to surrounding tissue
- Compliance with recognized standards and test requirements.

The principle of operation for both the AeroForm Tissue Expander, Smooth and predicate device is the same: the silicone shell of the Expanders gradually increases

in size with incremental filling of gas, resulting in stretching of the surrounding tissue. The main difference between the AeroForm Tissue Expander, Smooth and the predicate device is the change in the surface texture of the outer shell. The predicate device is made of a textured outer shell, and the subject device is made of a smooth outer shell where no texture is applied.

There are no technological differences between the subject device and the predicate device. The subject AeroForm Tissue Expander has not introduced any new harms or risks and does not raise new types of safety or effectiveness questions compared to the predicate device.

CONCLUSION

The subject AeroForm Tissue Expander System has an identical intended use and indications for use, principles of operation, performance, and technological characteristics with the exception of the shell surface texture, as the predicate device. No new risks were introduced as a result of the device modifications discussed in this submisssion. Performance testing supports the risk assessment and demonstrate that the functionality, integrity, safety and effectiveness of the subject AeroForm Tissue Expander System, Smooth as compared to the predicate device are adequate for its intended use.

Therefore, this device is considered substantially equivalent to the AirXpander's predicate AeroForm Tissue Expander device that was FDA cleared on April 3, 2017 in 510(k) #K170075.