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

April 3, 2017

Airxpanders, Inc.
Ms. Belinda Pinedo
Director, Regulatory Affairs
1047 Elwell Ct.
Palo Alto, California 94303

Re: K170075
Trade/Device Name: Aeroform Tissue Expander (v3.0), Aeroform Dosage Controller (v1.5)
Regulation Number: 21 CFR 878.3510
Regulation Name: Carbon Dioxide Gas Controlled Tissue Expander
Regulatory Class: Class II
Product Code: PQN
Dated: January 6, 2017
Received: January 9, 2017

Dear Ms. 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. 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)*

K170075

Device Name
AeroForm® Tissue Expander System

Indications for Use *(Describe)*

The AeroForm® Tissue Expander System 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 is intended for temporary subcutaneous or submuscular implantation and is not intended for use beyond 6 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.

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1. 510(K) SUMMARY

A 510(k) Summary begins on the next page and is being submitted in accordance with the requirements of the Safe Medical Devices Act of 1990. This 510(k) Summary meets the requirements identified in 21 CFR 807.92.

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4.1 510(k) Summary

DATE OF SUMMARY

March 31, 2017

510(K) APPLICANT

AirXpanders, Inc.
1047 Elwell Court
Palo Alto, California 94303
Phone: (650) 390-9000
FAX: (650) 390-9007

Contact Person: Belinda Pinedo
Phone: (650) 390-8131
Fax: (650) 390-9007
E-mail: bpinedo@airxpanders.com

SUBJECT DEVICE OVERVIEW

Trade Name: **AeroForm® Tissue Expander System**
Common Name: **Expander, Skin, Inflatable**
Classification: **II**
Product Code: **PQN**
Regulation Name: **Carbon Dioxide Gas Controlled Tissue Expander**

PREDICATE DEVICE

The predicate device for this premarket submission is:

Trade Name	Submitter	DeNovo Number
AeroForm® Tissue Expander System	AirXpanders, Inc.	DEN 150055

The predicate device has not been subjected to a design-related recall.

DEVICE DESCRIPTION

The AeroForm Tissue Expander System (AeroForm System) is a sterile temporary implant for breast reconstruction and is comprised of a sterile, implantable tissue expander (Expander), a remote control (Controller), and a Master Key. The AeroForm Tissue Expander is a comprised of an outer textured silicone shell, an inner gas barrier (bag), with an internal reservoir of compressed Carbon Dioxide (CO_2) gas, which 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 is used in 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 is intended for temporary subcutaneous or submuscular implantation and is not intended for use beyond six months.

TECHNOLOGICAL CHARACTERISTICS

The subject AeroForm Tissue Expander is a modification of the predicate AeroForm Tissue Expander. There are no technological differences between the subject device and the predicate device. Both the AeroForm System and the predicate AeroForm device cause expansion of the silicone shell of the expanders by incremental inflation with a gas medium, mechanically stretching the surrounding tissue. The breast tissue expanders are textured, and made of silicone.

The AeroForm System 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 System 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

Performance testing for the Expander included extensive 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:

- Endurance / Stress Tests (cycle, impact, elongation, and sustained pressure)
- Break Force
- Fused or Adhered Joint Testing
- Overexpansion

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

Sterilization and Package Integrity Testing

Sterilization validation, package integrity and shelf-life testing were performed, per applicable standards, demonstrating the package remains intact following climactic conditioning, gross leak, and seal strength testing.

Software Testing

Unit, System and Regression Testing was performed, as described in Software test plans and testing protocols. Software development is compliant with EN 62304, and applicable US FDA guidance documents.

Biocompatibility

The Expander was tested for biological safety according to the requirements of EN ISO 10993-1: “Use of International Standard ISO 10993, "Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing. Biological testing includes the following:

- Genotoxicity (ISO 10993-3)
- Cytotoxicity (ISO 10993-5)
- Sensitization (ISO 10993-10)
- Irritation (ISO 10993-10)
- Acute Systemic Toxicity (ISO 10993-11)
- Sub-chronic Toxicity (ISO 10993-11)
- Chronic Toxicity (ISO 10993-11)
- Implantation (ISO 10993-6)

All biocompatibility and chemical testing passed the requirements of EN ISO 10993, demonstrating biological safety. A Biological Risk Assessment (BRA) established the safety of the Expander, supported by information gathered from biological testing data on the material components, published literature and the long history of safe and effective use of the materials used to construct the device.

COMPARISON TO PREDICATE DEVICE

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

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

- Same operating principle
- Same textured 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 Expander and predicate device is the same: the silicone shell of the Expanders increases in size gradually with incremental filling of gas, resulting in stretching of the surrounding tissue. The main difference between the AeroForm Expander and the predicate device is the change in the barrier film material and the driver protection system.

There are no technological differences between the subject device and the predicate device. The subject AeroForm Expander has not introduced any new harms or risks and does not raise new types of safety and effectiveness questions compared to the predicate device. Performance testing shows effective mitigations that minimize patient overall risk to a level similar to the predicate device.

SPECIAL CONTROLS

AirXpanders complies with the general controls and good manufacturing practices and established quality system in compliance with 21 CFR 820. AirXpanders has determined that special controls are sufficient to provide assurance of the safety and effectiveness of the AeroForm Tissue Expander System. Special controls for the AeroForm Tissue Expander System include:

- Design validation & In-vivo performance testing including clinical data, as presented in the predicate device DeNovo submission
- Biocompatibility
- Sterilization validation
- Design verification / non-clinical performance testing
  a) Cycle testing to ensure no leaks or tears in tissue expander
  b) High impact testing and mechanical assessment of implanted CO_2 canister
  c) Leak testing showing that device does not leak CO_2 with tissue expander
  d) Gas permeability assessment during and after full expansion
  e) Mechanical assessment of tissue expander (tensile set, breaking force, shell joint test, and fused or adhered joint testing)
- Electrical Safety & EMC testing
- Software validation
- Shelf life testing
- Human factors evaluation
- Labeling
- Training

CONCLUSION

The subject AeroForm Tissue Expander System has identical intended use and indications for use and the same technological characteristics, principles of operation, and performance as the predicate device. Therefore, this device is considered substantially equivalent to the predicate AirXpanders AeroForm Tissue Expander device that was granted permission for marketing on December 21, 2016 per De Novo #DEN 150055. Performance and biological safety (biocompatibility) testing support the risk assessment and demonstrate that the

functionality, integrity, safety and effectiveness of the subject AeroForm Tissue Expander System are adequate for its intended use and support a determination of substantial equivalence to the predicate device.