



Food and Drug Administration
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December 21, 2016

AirXpanders
Robin Bush
Consulting Director, Regulatory Affairs and Quality Assurance
1047 Elwell Court
Palo Alto, CA 94303

Re: DEN150055
AeroForm® Tissue Expander System
Evaluation of Automatic Class III Designation – *De Novo* Request
Regulation Number: 21 CFR 878.3510
Regulation Name: Carbon dioxide gas controlled tissue expander
Regulatory Classification: Class II
Product Code: PQN
Dated: December 7, 2015
Received: December 8, 2015

Dear Ms. Bush:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your *de novo* request for classification of the AeroForm® Tissue Expander System, a prescription device under 21 CFR Part 801.109 that is indicated for the following:

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 Expander is intended for temporary subcutaneous or submuscular implantation and is not intended for use beyond six months.

FDA concludes that this device should be classified into class II. This order, therefore, classifies the AeroForm® Tissue Expander System, and substantially equivalent devices of this generic type, into class II under the generic name, carbon dioxide gas controlled tissue expander.

FDA identifies this generic type of device as:

Carbon dioxide gas controlled tissue expander. A carbon dioxide gas controlled tissue expander is a prescription device intended for temporary subcutaneous or submuscular implantation to stretch the skin for surgical applications, specifically to develop surgical flaps and additional tissue coverage. The device is made of an inflatable elastomer shell and is filled with carbon dioxide gas. The device utilizes a remote controller to administer doses of carbon dioxide gas from an implanted canister inside the device.

Section 513(f)(2) of the Food, Drug and Cosmetic Act (the FD&C Act) was amended by section 607 of the Food and Drug Administration Safety and Innovation Act (FDASIA) on July 9, 2012. This new law provides two options for *de novo* classification. First, any person who receives a "not substantially equivalent" (NSE) determination in response to a 510(k) for a device that has not been previously classified under the Act may, within 30 days of receiving notice of the NSE determination, request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act. Alternatively, any person who determines that there is no legally marketed device upon which to base a determination of substantial equivalence may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act without first submitting a 510(k). FDA shall, within 120 days of receiving such a request, classify the device. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the **Federal Register** classifying the device type.

On December 8, 2015, FDA received your *de novo* requesting classification of the AeroForm® Tissue Expander System into class II. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the AeroForm® Tissue Expander System into class I or II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use.

After review of the information submitted in the *de novo* request and subsequent supplement and interactive information, FDA has determined that the AeroForm® Tissue Expander System indicated for the following:

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 Expander is intended for temporary subcutaneous or submuscular implantation and is not intended for use beyond six months.

can be classified in class II with the establishment of special controls for class II. FDA believes that class II (special) controls provide reasonable assurance of the safety and effectiveness of the device type. The identified risks and mitigation measures associated with the device type are summarized in Table 1.

Table 1 – Identified Risks to Health and Mitigation Measures

Identified Risk	Mitigation Measure
Pain <ul style="list-style-type: none"> • From Overexpansion with Carbon Dioxide 	<ul style="list-style-type: none"> • Labeling • Software verification, validation and hazard analysis
Tissue Damage <ul style="list-style-type: none"> • From Overexpansion with Carbon Dioxide 	<ul style="list-style-type: none"> • <i>In-vivo</i> performance testing • Labeling • Software verification, validation and hazard analysis

Identified Risk	Mitigation Measure
Prolonged Treatment Time <ul style="list-style-type: none"> • Due to Under Expansion Because of Carbon Dioxide Permeation • Due to Overexpansion with Carbon Dioxide 	<ul style="list-style-type: none"> • <i>In-vivo</i> performance testing • Non-clinical performance testing • Labeling • Software verification, validation and hazard analysis
Re-operation <ul style="list-style-type: none"> • Due to No Expansion Because of Device Failure • Due to Overexpansion with Carbon Dioxide 	<ul style="list-style-type: none"> • <i>In-vivo</i> performance testing • Non-clinical performance testing
Underexpansion, Overexpansion, or No Expansion <ul style="list-style-type: none"> • Due to Interference With Other Devices • Due to Use Error 	<ul style="list-style-type: none"> • Electromagnetic compatibility, electrical safety, and wireless compatibility testing • Labeling • Software verification, validation and hazard analysis • Human factors testing • Patient training
Adverse Tissue Reaction	<ul style="list-style-type: none"> • Biocompatibility evaluation
Infection	<ul style="list-style-type: none"> • Sterilization validation • Shelf life testing

In combination with the general controls of the FD&C Act, the Carbon dioxide gas controlled tissue expander is subject to the following special controls:

1. *In-vivo* performance testing must be conducted to obtain the adverse event profile associated with use, and demonstrate that the device performs as intended under anticipated conditions of use
2. The patient-contacting components of the device must be demonstrated to be biocompatible
3. Performance data must demonstrate the sterility of patient-contacting components of the device
4. Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use. The following performance characteristics must be tested:
 - a. Cycle testing of expander showing that there are no leaks or tears after repeated cycling
 - b. Mechanical assessment of implanted CO₂ canister including high impact testing
 - c. Leak testing of expander showing that device does not leak CO₂
 - d. Assessment of gas permeability during expansion and after full expansion
 - e. Mechanical assessment of expander (tensile set, breaking force, shell joint test, and fused or adhered joint testing)

5. Performance data must be provided to demonstrate the electromagnetic compatibility, electrical safety, and wireless compatibility of the device
6. Software verification, validation and hazard analysis must be performed
7. Performance data must support shelf life by demonstrating continued sterility of the device or the sterile components, package integrity, and device functionality over the identified shelf life
8. Human factors testing and analysis must validate that the device design and labeling are sufficient for the end user
9. Physician labeling must include:
 - a. The operating parameters, name, and model number of the indicated external dosage controller
 - b. Information on how the device operates and the typical course of treatment
 - c. Information on the population for which the device has been demonstrated to be effective
 - d. A detailed summary of the device technical parameters
 - e. Provisions for choosing an appropriate size implant that would be exchanged for the tissue expander
10. Patient labeling must include:
 - a. Warnings, precautions, and contraindications, and adverse events/ complications
 - b. Information on how the device operates and the typical course of treatment
 - c. The probable risks and benefits associated with the use of the device
 - d. Post-operative care instructions
 - e. Alternative treatments
11. Patient training must include instructions for device use, when it may be necessary to contact a physician, and cautionary measures to take when the device is implanted.

In addition, this is a prescription device and must comply with 21 CFR 801.109. Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device type. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device type and, therefore, the device is not exempt from the premarket notification requirements of the FD&C Act. Thus, persons who intend to market this device type must submit a premarket notification containing information on the Carbon dioxide gas controlled tissue expander they intend to market prior to marketing the device and receive clearance to market from FDA.

Please be advised that FDA's decision to grant this *de novo* request does not mean that FDA has made a determination that your device complies with other requirements of the FD&C Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the FD & C 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 FD & C Act); 21 CFR 1000-1050.

A notice announcing this classification order will be published in the **Federal Register**. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market your device as described in the *de novo* request, subject to the general control provisions of the FD&C Act and the special controls identified in this order.

If you have any questions concerning this classification order, please contact Tajanay Ki at 301-796-6970.

Sincerely,

Jonette Foy, Ph.D.
Deputy Director
for Engineering and Science Review
Office of Device Evaluation
Center for Devices and
Radiological Health