



Food and Drug Administration
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July 27, 2016

Micro Interventional Devices, Inc.
Ms. Linda Morgan
VP of Operations
5 Caufield Pl.
Suite 102
Newtown, PA 18940

Re: DEN150029
Permaseal
Evaluation of Automatic Class III Designation – *De Novo* Request
Regulation Number: 21 CFR 870.4510
Regulation Name: Apical Closure Device
Regulatory Classification: Class II
Product Code: PNQ
Dated: June 23, 2015
Received: June 25, 2015

Dear Ms. Morgan:

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 Permaseal, a prescription device under 21 CFR Part 801.109 that is indicated *for soft tissue approximation of cardiac apical tissue during transcatheter valve replacement procedures*. FDA concludes that this device should be classified into class II. This order, therefore, classifies the Permaseal device, and substantially equivalent devices of this generic type, into class II under the generic name, Apical Closure Device.

FDA identifies this generic type of device as:

Apical Closure Device. An apical closure device is a prescription device consisting of a delivery system and implant component that is used for soft tissue approximation of cardiac apical tissue during transcatheter valve replacement procedures.

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 June 25, 2015, FDA received your *de novo* requesting classification of the Permaseal device into class II. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the Permaseal device 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, FDA has determined that the Permaseal, indicated *for soft tissue approximation of apical tissue during transcatheter valve replacement procedures*, 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
Infection	Sterilization Validation Shelf Life Testing Labeling
Adverse Tissue Reaction	Biocompatibility Evaluation <i>In vivo</i> Performance Testing
Bleeding <ul style="list-style-type: none"> ▪ At ventricular puncture or anchor deployment sites 	Non-clinical Performance Testing <i>In vivo</i> Performance Testing Labeling
Tissue Damage <ul style="list-style-type: none"> ▪ Apical tearing ▪ Myocardial tearing (local or diffuse) 	Non-clinical Performance Testing <i>In vivo</i> Performance Testing Labeling Training
New Hypokinesia or Akinesis of Apex	<i>In vivo</i> Performance Testing Labeling
Thromboemboli and Full Thickness Injury	<i>In vivo</i> Performance Testing Labeling Training
Pericardial Tamponade	<i>In vivo</i> Performance Testing Labeling

In combination with the general controls of the FD&C Act, the Apical Closure Device is subject to the following special controls:

1. The patient contacting materials must be demonstrated to be biocompatible.
2. Performance data must demonstrate the sterility of the patient-contacting components of the device.

3. Performance data must support the shelf life of the device by demonstrating continued sterility, package integrity, and device functionality over the labeled shelf life.
4. Non-clinical performance testing data must demonstrate that the device performs as intended under anticipated conditions of use. The following performance characteristics must be tested:
 - a. Consistent and reliable implant deployment;
 - b. Assessment of implant pull-out force; and
 - c. Sheath size compatibility with implant.
5. *In vivo* evaluation of the device must demonstrate device performance, including device operation resulting in closure of the myocardial wound.
6. Labeling must include the following:
 - a. Detailed information explaining how the device operates;
 - b. Sheath size that device can accommodate;
 - c. Identification of the minimum myocardial wall thickness to ensure optimal device function; and
 - d. A shelf life.

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 apical closure device 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 Jennifer Piselli at (240) 402-6646.

Sincerely,

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