DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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March 13, 2014

Mr. A. Thomas Doyle
Senior Manager, Regulatory Affairs
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3600 South West 47th Avenue
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Re: K082438
Bio-Seal Lung Biopsy Tract Plug System
Evaluation of Automatic Class III Designation – *De Novo* Request
Regulation Number: 21 CFR 878.4755
Regulation Name: Absorbable lung biopsy plug
Regulatory Classification: Class II
Product Code: OMT
Dated: April 16, 2009
Received: April 17, 2009

Dear Mr. Doyle:

This letter corrects our classification letter of December 19, 2012.

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 Bio-Seal Lung Biopsy Tract Plug System as a prescription device under 21 CFR Part 801.109 that is indicated to provide accuracy in marking a biopsy location for visualization during surgical resection and to plug pleural punctures associated with percutaneous, transthoracic needle lung biopsies to significantly reduce the risk of pneumothoraces (air leaks). FDA concludes that this device should be classified into class II. This order, therefore, classifies the Bio-Seal Lung Biopsy Tract Plug System, and substantially equivalent devices of this generic type, into class II under the generic name, Absorbable lung biopsy plug.

FDA identifies this generic type of device as:

> **Absorbable lung biopsy plug.** A pre-formed (polymerized) absorbable lung biopsy plug is intended to provide accuracy in marking a biopsy location for visualization during surgical resection and closure of pleural punctures associated with percutaneous, transthoracic needle lung biopsies. Upon, deployment into the biopsy tract, the plug expands to fill the biopsy void and remains in place until resorbed.

Section 513(f)(2) of 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.

In accordance with section 513(f)(1) of the FD&C Act, FDA issued an order on March 19, 2009 automatically classifying the Bio-Seal Lung Biopsy Tract Plug System in class III, because it was not within a type of device which was introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976, nor which was subsequently reclassified into class I or class II. On April 17, 2009, FDA filed your *de novo* requesting classification of the Bio-Seal Lung Biopsy Tract Plug System into class II. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the Bio-Seal Lung Biopsy Tract Plug 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, FDA has determined that the Bio-Seal Lung Biopsy Tract Plug System indicated to provide accuracy in marking a biopsy location for visualization during surgical resection and to plug pleural punctures associated with percutaneous, transthoracic needle lung biopsies to significantly reduce the risk of pneumothoraces (air leaks) 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**
Inability to deploy plug	Design and Material Characterization Bench Testing In Vivo Evaluation Labeling
Delayed plug expansion	Design and Material Characterization Bench Testing In Vivo Evaluation Labeling
Leakage around plug	Design and Material Characterization Bench Testing In Vivo Evaluation Labeling
Plug migration	Design and Material Characterization

Identified Risk	Mitigation Measure
(whole plug and/or fragments)	Bench Testing In Vivo Evaluation Labeling
Procedural complications	In Vivo Evaluation Labeling
Adverse tissue reaction	Biocompatibility Sterility Shelf Life Testing
Infection	Biocompatibility Sterility Shelf Life Testing
Use error	Labeling

In combination with the general controls of the FD&C Act, the Absorbable lung biopsy plug is subject to the following special controls:

1. The design characteristics of the device must ensure that the geometry and material composition are consistent with the intended use.

2. Performance testing must demonstrate deployment as indicated in the accompanying labeling, including the indicated introducer needles, and demonstrate expansion and resorption characteristics in a clinically relevant environment.

3. In vivo evaluation must demonstrate performance characteristics of the device including the ability of the plug to not prematurely resorb or migrate and the rate of pneumothorax.

4. Sterility testing must demonstrate the sterility of the device and the effects of the sterilization process on the physical characteristics of the plug.

5. Shelf-life testing must demonstrate the shelf-life of the device including the physical characteristics of the plug.

6. The device must be demonstrated to be biocompatible.

7. Labeling must include a detailed summary of the device-related and procedure-related complications pertinent to the use of the device and appropriate warnings. Labeling must include identification of compatible introducer needles.

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 Absorbable lung biopsy plug 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 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.

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*, 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 Neel Patel at 301-796-6274.

Sincerely yours,

Jonette R. Foy -S

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