October 16, 2024

Peytant Solutions, Inc.
Lisa Pritchard
VP, Regulatory, Quality, Clinical & Engineering
Duval & Associates, P.A.
825 Nicollet Mall
Suite 1820
Minneapolis, MN 55402

Re: DEN230087
Trade/Device Name: AMStent® Tracheobronchial Covered Stent System
Regulation Number: 21 CFR 868.3721
Regulation Name: Tracheal prosthesis with cover material derived from human sources
Regulatory Class: Class II
Product Code: SDB
Dated: December 19, 2023
Received: December 20, 2023

Dear Lisa Pritchard:

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 AMStent® Tracheobronchial Covered Stent System, a prescription device under 21 CFR Part 801.109 with the following indications for use:

> The AMStent® Tracheobronchial Covered Stent System (AMStent® System) is indicated for use in the treatment of tracheobronchial strictures produced by malignant neoplasms in adult patients.

FDA concludes that this device should be classified into Class II. This order, therefore, classifies the AMStent® Tracheobronchial Covered Stent System, and substantially equivalent devices of this generic type, into Class II under the generic name tracheal prosthesis with cover material derived from human sources.

FDA identifies this generic type of device as:

> Tracheal prosthesis with cover material derived from human sources. The tracheal prosthesis with cover material derived from human sources is an expandable tubular device made of a metal material covered with a human-sourced decellularized material. It is intended to be implanted to restore the structure and/or function of the trachea or tracheobronchial tree. This device may also include a device delivery system. This device type does not include products that are intended to promote regeneration, impede inflammatory cascades, and release growth factors.

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 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 request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act. On December 13, 2016, the 21st Century Cures Act removed a requirement that a De Novo request be submitted within 30 days of receiving an NSE determination. 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 announcing the classification.

On December 20, 2023, FDA received your De Novo requesting classification of the AMStent® Tracheobronchial Covered Stent System. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the AMStent® Tracheobronchial Covered Stent 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, for the previously stated indications for use, the AMStent® Tracheobronchial Covered Stent System 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 the following table:

Risks to Health	**Mitigation Measures**
Device mispositioning, migration, erosion, and fracture	Animal performance testing Non-clinical performance testing Labeling
Adverse tissue reaction	Biocompatibility evaluation
Device repositioning or removal during implantation	Animal performance testing Non-clinical performance testing Labeling
Infection	Material characterization and infection control measures Sterility testing Shelf-life testing Labeling

In combination with the general controls of the FD&C Act, the tracheal prosthesis with cover material derived from human sources is subject to the following special controls:

(1) Human tissue characterization and infection control measures must be provided for all human cells, tissues, and cellular and tissue-based products (HCT/P's), including documentation demonstrating:

(i) Determination of donor eligibility, based on donor screening and testing for relevant communicable disease agents and diseases;

(ii) Testing of all donor tissue for evidence of infection by relevant communicable disease agents, including (but not limited to): Human immunodeficiency virus type 1 and type 2, Hepatitis B and C viruses, and *Treponema pallidum*;

(iii) Material sourcing from facilities that are registered for handling and processing of HCT/P materials and that incorporate the following procedures:

(A) The facility must monitor environmental conditions for contamination or cross-contamination of HCT/Ps or equipment, or accidental exposure of HCT/Ps to communicable disease agents;

(B) Processing must ensure materials have undergone defined decellularization processing and demonstrate sufficient viral inactivation potency across RNA, DNA, enveloped, non-enveloped virus types, and viruses native to the tissue, and removal of residual human nucleic acids via lot-based testing;

(C) A distinct identification code must be affixed to the HCT/P container that relates the HCT/P to the donor and to all accompanying records pertaining to the HCT/P, except for Personally Identifiable Information, and must enable tracking from the donor to the consignee or final disposition; and

(D) All HCT/P material must be kept in quarantine until completion of the donor-eligibility determination;

(iv) Material characterization activities demonstrating that the processing of the human-derived material both within and across lots is appropriately controlled to result in material that is consistently able to meet final product specifications.

(2) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use. The following performance characteristics must be tested:

(i) Deployment testing to evaluate the accuracy and repeatability of any delivery system;
(ii) Compression and expansion forces;
(iii) Dimensional testing;
(iv) Fatigue and corrosion testing; and
(v) Compatibility of the device in a magnetic resonance (MR) environment.

(3) Animal performance testing must demonstrate that the device performs as intended under anticipated conditions of use, including an animal study with chronic time points to evaluate device migration, occlusion, and granuloma formation.

(4) The device must be demonstrated to be biocompatible.

(5) Labeling must include:

(i) Magnetic resonance compatibility information;
(ii) Labeling must include a detailed summary of the device-related and procedure-related complications pertinent to the use of human-derived material and appropriate warnings;
(iii) A summary of bench and in vivo testing that describes the duration of testing;
(iv) Descriptions of claims and functionality must be limited to device functionality information demonstrated from performance testing; and
(v) A shelf life.

(6) Performance data must demonstrate the sterility of patient-contacting components of the device.

(7) Performance data must support the shelf-life of the device by demonstrating continued sterility, package integrity, tissue integrity, and device functionality over the identified shelf life.

In addition, this is a prescription device and must comply with 21 CFR 801.109.

Although this letter refers to your product as a device, please be aware that some granted products may instead be combination products. If you have questions on whether your product is a combination product, contact CDRHProductJurisdiction@fda.hhs.gov.

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 tracheal prosthesis with cover material derived from human sources they intend to market prior to marketing the device.

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) 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 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.

For comprehensive regulatory information about medical devices and radiation-emitting products, 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).

If you have any questions concerning the contents of the letter, please contact Jason Ferrante at jason.ferrante@fda.hhs.gov.

Sincerely,

Denise L. Hampton -S

for Malvina B. Eydelman, M.D.
Director
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT, and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health