DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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October 17, 2014

EndoChoice, Incorporated
C/O Ms. Bosmat Friedman
Regulatory Consultant
Push-Med LLC/MJ RAC
1208-12 Rockford Road
Toronto, ON M2R3A2
CANADA

Re: K140472
Trade/Device Name: BONASTENT® Tracheal/Bronchial
Regulation Number: 878.3720
Regulation Name: Prosthesis, Tracheal, Expandable
Regulatory Class: Class II
Product Code: JCT
Dated: September 15, 2014
Received: September 17, 2014

Dear Ms. Friedman:

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 Small Manufacturers, International and Consumer Assistance 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" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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 yours,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental 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: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*

K140472

Device Name
BONASTENT® Tracheal/Bronchial

Indications for Use *(Describe)*
The BONASTENT® Tracheal/Bronchial Stent System is indicated for the treatment of tracheobronchial strictures caused by malignant neoplasms.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Section 5

510(k) Summary

510(K) SUMMARY

[as required by section 807.92(c)]

BONASTENT® Tracheal/Bronchial

510(k) Number K140472

1. SUBMITTER

Applicant's Name:

EndoChoice, Inc.
18110 Wills Road, Suite 100
Alpharetta, GA 30009
Phone: 678-534-6021
Fax: 770-410-9008

Contact Person:

Bosmat Friedman
Regulatory Affairs Consultant
647-975-3974
bosmat@pushmed.com

Date Prepared (revised):

October 15, 2014

2. DEVICE

Trade Name:

BONASTENT® Tracheal/Bronchial

Common or Usual Name:

Tracheal Prosthesis

Classification:

Name: Prosthesis, Tracheal, Expandable
Product Code: JCT
Regulation No: 878.3720
Class: 2
Classification Panel: General & Plastic Surgery

3. PREDICATE DEVICES

Main Predicate:

- AERO Tracheobronchial Stent System by Alveolus, Inc; K062511.

Reference devices:

- Bonastent™ Esophageal by EndoChoice Inc.; K092144.
- Bonastent™ Biliary by EndoChoice Inc.; K093003.

4. DEVICE DESCRIPTION

The BONASTENT® Tracheal/Bronchial (BTB) is a self-expanding tubular prosthesis designed to maintain patency of tracheobronchial strictures caused by malignant tumors. The stent is made of Nitinol wire and is weaved using a hook & cross wire construction; a silicon membrane covers the stent and is designed to prevent stent migration. Stent sizes range in diameter from 10mm to 20mm and in length from 50mm to 80mm.
The BONASTENT® Tracheal/Bronchial is available on two types of delivery devices. The Y-Shape Handle Delivery Device is used for stents with an outer diameter of 10Fr and less. The I-Shape Handle Delivery Device which is used for stents with an outer diameter larger than 10F.

5. INDICATIONS FOR USE

The BONASTENT® Tracheal/Bronchial Stent System is indicated for the treatment of tracheobronchial strictures caused by malignant neoplasms.

6. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The stent weaving and construction is identical to the weaving and construction of both Bonastent predicates. The Y-shape Handle delivery device is identical to the delivery device of the BONASTENT Biliary cleared under K093003. The I-Shape Handle delivery device is identical to the delivery device of the Bonastent Esophageal cleared under K092144.
The stent part was tested for compression and expansion and compared to the AERO stent. The results of the tests support the company's claim of substantial equivalence.

7. PERFORMANCE DATA

Bench Testing
The following performance tests were conducted in accordance with FDA *Guidance for Industry - Guidance for the Content of Premarket Notifications for Esophageal and Tracheal Prostheses*:

#	Name of Test	Purpose
1	Deployment Testing	To validate the accuracy and repeatability of the delivery system
2	Expansion Force	To measure the force exerted by the metal self-expanding stent during expansion (compared to predicate)
3	Compression Force Testing	To measure the force required to compress the metal self-expanding types of stents after expansion (compared to predicate)
4	Dimensional Testing	To verify the reproducibility of the metal self-expanding types of stents length and diameter after deployment
5	Corrosion Testing	To establish the compatibility of the stent materials with the corrosive environment in the tracheobronchial tree
6	Tensile strength tests	Performed for any deployment system that includes components that are bonded or welded

The in-vitro tests that were performed confirm that all components, subassemblies, and/or full devices met the required specifications.
The comparative tests that were performed (expansion and compression) support our substantial equivalence claim to the AERO Tracheobronchial Stent System (K062511).

Biocompatibility
Due to the similarities in materials and manufacturing techniques between the Bonastent Tracheal/Bronchial stent and its reference predicate devices the company relied on the previous results that were obtained. The following tests were conducted on the reference devices:

Stent Part
- Cytotoxicity
- Maximization sensitization
- Acute systemic toxicity
- Rabbit Pyrogen Study
- Intracutaneous reactivity
- Bacterial reverse mutation assay
- Intramuscular implantation study (13 and 26 week).

Delivery Device
- Cytotoxicity
- Maximization sensitization
- Rabbit Pyrogen Study
- Intracutaneous reactivity

8. SUBSTANTIAL EQUIVALENCY TABLE

The following table illustartes the similarties and differences bewteen the subject device and the main predicate, the AERO stent:

Product name	BONASTENT® Tracheal/Bronchial Stent System	AERO Tracheobronchial Stent System
510(k) No.	K140472	K062511
Intended Use	The BONASTENT® Tracheal/Bronchial Stent System is indicated for the treatment of tracheobronchial strictures caused by malignant neoplasms.	The Alveolus AERO™ Tracheobronchial Stent System is indicated for use in the treatment of tracheobronchial strictures produced by malignant neoplasms.
Stent material	Nitinol	Nitinol
Covering material	Silicone	polyurethane membrane
Stent diameter (mm)	10, 12, 14, 16, 18 and 20	10, 12, 14, 16, 18 and 20
Stent length (mm)	20-80	20-80
Delivery diameter	8F – 12F	16F and 22F
Deployment time	Non-aged stents average 16.97 sec Aged stents 16.4 sec	Unknown

Expansion Force	10X20 0.367 lbs. 20X80 0.748 lbs.	10X20 0.390 lbs. 20X80 0.763 lbs.
Compression force	10X20 0.517 lbs. 20X80 1.026 lbs.	10X20 0.519 lbs. 20X80 1.026 lbs.
Corrosion (in simulated gastric fluid)	Resistant to corrosion for a duration equivalent to 3 years	Unknown

Conclusion:

The Bonastent Tracheal/Bronchial has the same intended use and indication as the AERO stent. The two main differences between the Bonastent Tracheal/Bronchial and the AERO are: 1) different covering material and 2) different delivery device diameter. The results of the comparative testing (expansion and compression testing) as well as the biocompatibility results support our claim that the Bonastent Tracheal/Bronchial stent is substantially equivalent to the AERO stent.

Furthermore, the Bonastent Tracheal/Bronchial is substantially equivalent in technological characteristics to the two reference devices, Bonastent™ Esophageal and Bonastent™ Biliary.

Consequently, it is clear that the Bonastent Tracheal/Bronchial is substantially equivalent to its predicate and reference devices.