K121048

REVISED
SECTION 6

AUG 3 2012

510(k) Summary

1. **Submitter:**

Boston Scientific Corporation
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Contact: Thomas Hirte
Senior Manager Regulatory Affairs
Date Prepared: May 18, 2012

2. **Proposed Device**

Trade Name: Ultraflex™ Tracheobronchial Uncovered Stent System
Classification Name: Tracheal Prosthesis
Regulation Number: 878.3720
Product code: JCT
Classification: Class II

3. **Predicate Device:**

Trade Name: Ultraflex™ Tracheobronchial Stent System
Manufacturer and Clearance No.: Boston Scientific Corporation, K963241; K012883
Classification Name: Tracheal Prosthesis
Regulation Number: 878.3720
Product code: JCT
Classification: Class II

Trade Name: Ultraflex™ Esophageal NG Stent System
Manufacturer and Clearance Number: Boston Scientific Corporation, K091816
Classification Name: Esophageal Prosthesis
Regulation Number: 878.3610
Product code: ESW
Classification: Class II

Trade Name: Aero DV™ Tracheobronchial Stent System
Manufacturer and Clearance Number:
Alveolus Inc. (Merit Medical Endotek), K083625, K082284
Classification Name: Tracheal Prosthesis
Regulation Number: 878.3720
Product code: JCT
Classification: Class II

4. Proposed Device Description

The Ultraflex™ Tracheobronchial Uncovered Stent System consists of a self-expanding nitinol stent preloaded onto a flexible delivery catheter. The stent is a permanent implant designed to provide intraluminal support to keep open the inner wall of the tracheobronchial tree. A suture is threaded through the stent loops at the proximal end of the stent, to aid in stent removal during the initial procedure in the event of incorrect placement. The stent is preloaded onto the delivery catheter via crocheting of the deployment suture around the stent onto the delivery catheter. The system is provided sterile.

The Ultraflex™ Tracheobronchial Stent is available with either a proximal or distal release system. The distal release system begins stent deployment from the lower (distal) end of the delivery catheter. The proximal release system begins stent deployment from the upper (proximal) end of the delivery catheter.

The delivery system accepts a 0.035 in (0.89 mm) or 0.038 in (0.97 mm) guidewire, and has two (2) radiopaque (RO) markers on the delivery system to facilitate fluoroscopic placement.

To deliver the stent, the stent delivery system is passed over the guidewire into the tracheobronchial lumen. The delivery catheter is advanced, so that the stent is in the appropriate implant position. This positioning step is conducted under fluoroscopy and/or by bronchoscopic visualization of the stent. The stent is deployed by holding the handle hub in the palm of one hand, and grasping the finger ring, that is attached to the deployment suture, with the other hand. By retracting the finger ring the suture crochet knots are unraveled in a circular manner along the length of the stent, gradually deploying the stent. This deployment technique is identical to the predicate Ultraflex stent. The deployed stent expands and creates a scaffold support to assist in maintaining lumen patency of the airway at the implant position.

The materials of the stent material, the delivery catheter and the deployment suture are identical to those of the predicate Ultraflex™ Tracheobronchial Stent System (K012883, K963241).

The retention suture material is identical to that of the predicate Ultraflex™ Esophageal NG Stent System (K091816). The wire knot adhesive and the retention suture knot adhesives have been changed to Ultraviolet (UV) cured adhesives with enhanced strength and shorter manufacturing curing times.

Boston Scientific believes that these changes are minor improvements and do not significantly impact the overall performance of the device for its intended use.

The uncovered product offerings are as follows:

Ultraflex™ Tracheobronchial Stent System

Stent Diameter (mm)	Stent length (mm)			
	20	30	40	60
8	✓	N/A	✓	N/A
10	✓	✓	✓	N/A
12	✓	✓	✓	N/A
14	✓	✓	✓	✓
16	N/A	N/A	✓	✓
18	N/A	N/A	✓	✓
20	N/A	N/A	✓	✓

N/A – Not Offered

5. **Intended Use:**

The Ultraflex™ Tracheobronchial Stent System is intended for use in the treatment of tracheobronchial strictures produced by malignant neoplasms.

6. **Technological Characteristics:**

The material changes discussed in this premarket notification are identical to the materials changes cleared for the Ultraflex™ Esophageal NG Stent System (K091816). The proposed Ultraflex™ Tracheobronchial Stent System is nearly identical in design, materials, and manufacturing processes to the Ultraflex™ Esophageal NG Stent System (K091816) and the Ultraflex™ Tracheobronchial Stent System (K012883). The proposed Ultraflex Tracheobronchial Stent System is similar in design, and mode of action and intended use of the Merit Medical Endotek Aero DV™ Tracheobronchial Stent System (K082284, K083625).

7. **Performance Data:**

In-vitro and *In-vivo* testing has been performed and all components, subassemblies, and/or full devices met the required specifications for the completed tests. This 510(k) Notification contains physical test results for the Ultraflex™ Tracheobronchial Stent System as specified in the FDA "Guidance for the Content of Premarket Notifications for Esophageal and Tracheal Prosthesis" document (April 28, 1998) as requested by the FDA. Testing included but was not limited to: Dimensional, fatigue, compression, expansion, deployment accuracy, integrity, sterility and biocompatibility.

Fatigue, compression, expansion, deployment accuracy and integrity testing were successfully conducted in simulated use bench models. Testing was conducted on both the proposed sterile Ultraflex™ Tracheobronchial Stent and the non-sterile Aero™ Tracheobronchial Stent System.

Sterility was performed using Ethylene Oxide according ANSI/AAMI 11135-1: 2007 with an Sterility Assurance Level of 10^{-6}. Sterilization residuals comply with ANSI/AAMI 10993-7: 2008.

Biocompatibility was confirmed via AAMI/ANSI/ISO 10993-1: 2009. Testing included cytotoxicity, sensitization, intracutaneous reactivity, systemic toxicity, acute systemic toxicity, subacute toxicity – intravenous and intraperitoneal, genotoxicity – Ames assay and mouse lymphoma, and an intramuscular toxicity implant test.

No detectable endotoxin was confirmed via Pyrogen testing conducted according to AAMI ST72 and USP 85 and USP 161.

8. **Conclusion:**

Boston Scientific Corporation has demonstrated that no significant differences exist between the proposed Ultraflex™ Tracheobronchial Stent System and the predicate Ultraflex™ Tracheobronchial Stent System (K012883), the predicate Ultraflex™ Esophageal NG Stent System (K091816), and the predicate Merit Medical Endotek Aero™ Tracheobronchial Stent System (K082284, K083625). Therefore, the Ultraflex™ Tracheobronchial Stent System is as safe, as effective and performs as well as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Boston Scientific Corporation
Ms. Janis F. Taranto
Endoscopy Division
100 Boston Scientific Way
Marlborough, Massachusetts 01752

AUG 3 2012

Re: K121048
Trade/Device Name: UltraFlex™ Tracheobronchial Stent System
Regulation Number: 21 CFR 878.3720
Regulation Name: Tracheal Prosthesis
Regulatory Class: II
Product Code: JCT
Dated: June 15, 2012
Received: June 18, 2012

Dear Ms. Taranto:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 4

INDICATIONS FOR USE STATEMENT

510(k) Number (if known):	TBD
Device Name:	Ultraflex™ Tracheobronchial Stent System
Indications for Use:	The Ultraflex™ Tracheobronchial Stent System is intended for use in the treatment of tracheobronchial strictures produced by malignant neoplasms.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K121048