DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 3 2006

Boston Scientific Corporation
% Ms. Angela Byland
Manager, Regulatory Affairs
Cardiovascular
Two Scimed Place
Maple Grove, Minnesota 55311-1566

Re: K963241
Trade/Device Name: Ultraflex® Tracheobronchial Stent System
Regulation Number: 21 CFR 878.3720
Regulation Name: Tracheal prosthesis
Regulatory Class: II
Product Code: JCT
Dated: August 16, 1996
Received: August 19, 1996

Dear Ms. Byland:

This letter corrects our substantially equivalent letter of November 14, 1996.

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 (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.

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.

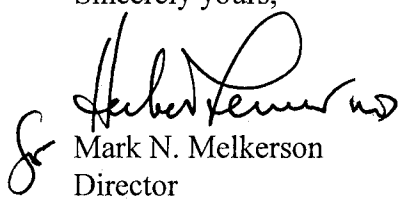
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); 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.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Indications for Use

510(k) Number (if known): K963241

Device Name: Ultraflex™ Tracheobronchial Stent System

Indications for Use:

The Ultraflex Tracheobronchial Stent System is indicated for 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 801 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 General, Restorative, and Neurological Devices

510(k) Number K963241

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Boston Scientific

510(K) SUMMARY
K963241

1. Submitter:

Boston Scientific Corporation
100 Boston Scientific Way
Marlborough, MA 01545
Telephone: 508-683-4942
Fax: 508-683-5939

Contact: Kathleen Morahan
Director Regulatory Affairs
Original Date Prepared: August 16, 1996
Revision Date: July 14, 2006

2. Device:

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

3. Predicate Device:

Boston Scientific Corporation's Wallstent Tracheobronchial Stent System

4. Device Description:

The proposed Ultraflex Tracheobronchial Stent System is comprised of two components, a metallic expandable stent and a flexible delivery catheter. The stent is mounted on a delivery catheter. The delivery catheter is placed over a guidewire and through the working channel of an endoscope to deliver the stent. The stent is available in a variety of diameters and lengths.

5. Intended Use:

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

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6. Technological Characteristics:

The purpose of this 510(k) submission is to introduce the Ultraflex Tracheobronchial Stent System. The design characteristics are similar to the predicate Wallstent Tracheobronchial Stent System.

7. Performance Data:

Bench testing was conducted to evaluate the design features of the Ultraflex Tracheobronchial Stent System and to demonstrate substantial equivalence of the proposed device to the predicate device.

8. Conclusion:

Boston Scientific Corporation has demonstrated that the proposed Ultraflex Tracheobronchial Stent System is substantially equivalent to Boston Scientific Corporation's currently marketed Wallstent Tracheobronchial Endoprosthesis.