SECTION 5
510(k) SUMMARY

510(k) SUMMARY

1. Submitter:

Boston Scientific Corporation
100 Boston Scientific Way
Marlborough, MA 01752
Telephone: 508-683-4347
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Contact: Elena Nieves
Senior Regulatory Affairs Specialist
Date Prepared: May 10, 2010

JUL 2 3 2010

2. Proposed Device:

Trade Name: Advanix™ Biliary Stent with NaviFlex™ RX Delivery System Classification Name: Biliary Catheters and Accessories
Regulation Number: 876.5010
Product Code: FGE
Classification: Class II

3. Predicate Device:

Trade Name: Microvasive® Biliary Stent and Delivery System
Manufacturer and Clearance Number: Boston Scientific Corporation, K965147
Classification Name: Biliary Catheters and Accessories
Regulation Number: 876.5010
Product Code: FGE
Classification: Class II

4. Proposed Device Description:

The proposed Advanix™ Biliary Stent with NaviFlex™ RX Delivery System consists of biliary plastic stents and delivery system catheters. They are sold separately or in a pre-loaded configuration, in which a stent comes attached to the catheter via a suture. The system is comprised of two (2) primary components: stent and delivery catheter with a locking mechanism. The Advanix Biliary Stent allows for drainage of the biliary duct and gall bladder by preventing closure and maintaining the patency of the biliary duct. These biliary stents are provided in center bend and duodenal bend shapes and have leading and trailing bars, a tapered leading end tip to facilitate access through the papilla, and a rounded tailing end to match the profile of the push catheter portion of the delivery system.

The Advanix Biliary Stent will be will be offered in 7Fr, 8.5Fr, and 10Fr diameters. The stent lengths for each diameter vary from 5cm-18cm stent lengths. The Advanix biliary stents are constructed of a Polyethylene material.

The NaviFlex RX Delivery System will be offered in 202.5cm working length. The delivery system consists of a guide catheter and outer push catheter. The guide catheter is constructed of Polyvinylidene fluoride material. The guide catheter also includes a radiopaque marker. The push catheter is composed of polyether block amide material and also has a Nylon repositioning suture.

5. Intended Use:
Advanix™ Biliary Stent with NaviFlex™ RX Delivery System is intended for delivery of the stent to the biliary tract for drainage of the bile ducts, for splinting of a bile duct during healing, or for providing bile duct patency in a stricture or past a stone.

6. Technological Characteristics:
The proposed Advanix™ Biliary Stent with NaviFlex™ RX Delivery System has the same technological characteristics as the predicate Microvasive® Biliary Stent and Delivery System (K965147).

The proposed device has the same intended use and is placed using the same methodology as the predicate device. Both the proposed and predicate device function in the same manner allowing for biliary drainage through the lumen.

The shape of the proposed Advanix Biliary Stent is the same as the predicate Microvasive Biliary Stent and Delivery System and also includes an additional center bend stent shape.

The materials of the proposed Advanix Biliary Stent have been modified to the polymer materials mentioned above in part 4 of this 510(k) Summary.

7. Performance Data:
In-vitro testing has been performed and all components, subassemblies, and/or full devices met the required specifications for the completed tests.

The proposed Advanix™ Biliary Stent was evaluated in accordance with EN ISO 10993-1:2009. The following tests were performed on the stent: Cytotoxicity, Sensitization, Intracutaneous Reactivity, Systemic Toxicity -Acute Systemic Toxicity, Subacute Toxicity – Intravenous and Intraperitoneal, Genotoxicity - Ames Assay and Mouse Lymphoma, Implantation, and USP Physicochemical.

The NaviFlex™ RX Delivery System was evaluated in accordance with EN ISO 10993-1:2009. The following tests were performed on the delivery system: Cytotoxicity, Sensitization, Intracutaneous Reactivity, and USP Physicochemical.

The following tests were conducted on the Advanix™ Biliary Stent with NaviFlex™ RX Delivery System: Drainage Lumen ID, Stent Length, Stent OD, Stent Shape, Repositionability, Deployment Force, Trackability Force, Guidewire Compatibility, Duodenoscope Compatibility, Barb Flap Cover Compatibility, Biopsy Cap Compatibility, Delivery System Working Length, Delivery System OD, Guide Catheter Pushability, RX Port Buckling Resistance, Locking Mechanism Retention Ability, Locking Mechanism to Dual Lumen Catheter Tensile Strength, Dual Lumen Catheter to Single Lumen Catheter Tensile Strength, Pullwire Assembly to Guide Catheter Tensile Strength, Pullwire Cap to Pullwire Tensile Strength, Guide Catheter RO Marker Band Strength, and Push Catheter RO Marker Band Strength.

8. Conclusion:
All biocompatibility tests conducted on the Advanix™ Biliary Stent with NaviFlex™ RX Delivery System passed. Therefore, the Advanix Biliary Stent with NaviFlex RX Delivery System is considered biocompatible for its intended use..

All device bench test results were acceptable. The data demonstrate that the Advanix™ Biliary Stent with NaviFlex™ RX Delivery System sufficiently meets the design specifications and is suitable for the intended use.

Boston Scientific Corporation has demonstrated that the proposed Advanix™ Biliary Stent with NaviFlex™ RX Delivery System is substantially equivalent to Boston Scientific Corporation's currently marketed Microvasive® Biliary Stent and Delivery System (K965147).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Ms. Elena Nieves
Sr. Regulatory Affairs Specialist
Boston Scientific Corporation
100 Boston Scientific Way
MARLBOROUGH MA 01752

JUL 23 2010

Re: K101314
Trade/Device Name: Advanix™ Biliary Stent with NaviFlex™ RX Delivery System
Regulation Number: 21 CFR§ 876.5010
Regulation Name: Biliary catheter and accessories
Regulatory Class: II
Product Code: FGE
Dated: May 10, 2010
Received: May 11, 2010

Dear Ms. Nieves:

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,

Janine M. Morris
Acting Director, Division of Reproductive, Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K101314

Device Name: Advanix™ Biliary Stent with NaviFlex™ RX Delivery System

Indications for Use: Advanix™ Biliary Stent with NaviFlex™ RX Delivery System is intended for delivery of the stent to the biliary tract for drainage of the bile ducts, for splinting of a bile duct during healing, or for providing bile duct patency in a stricture or past a stone.

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 Reproductive, Abdominal,
and Radiological Devices
510(k) Number K101314