JUL 23 2010

SECTION 5
510(k) SUMMARY

510(k) SUMMARY

1. Submitter:

Boston Scientific Corporation
100 Boston Scientific Way
Marlborough, MA 01752
Telephone: 508-683-4347
Fax: 508-683-5939

Contact: Elena Nieves
Senior Regulatory Affairs Specialist
Date Prepared: June 22, 2010

2. Proposed Device:

Trade Name: Advanix™ Double Pigtail Biliary Stent
Classification Name: Biliary Catheters and Accessories
Regulation Number: 876.5010
Product Code: FGE
Classification: Class II

3. Predicate Device(s):

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

Trade Name: Microvasive® Drainage Stent
Manufacturer and Clearance Number: Boston Scientific Corporation, K834468
Classification Name: Biliary Catheters and Accessories
Regulation Number: 876.5010
Product Code: FGE
Classification: Class II

4. Proposed Device Description:

The proposed Advanix™ Double Pigtail Biliary Stent consists of a biliary plastic stent. The Advanix double pigtail stent will be sold in a single stent configuration. The double pigtail stent has proximal and distal pigtails, lateral drainage holes in the pigtails, and a tapered tip.

The Advanix Double Pigtail Stent will be offered in 7Fr and 10Fr. diameters. The stent lengths for each diameter vary from 3cm-15cm stent lengths. The Advanix Double Pigtail Stent is constructed of a Styrene Butadiene Styrene material.

5. Intended Use:
Advanix™ Double Pigtail Biliary Stent is intended 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™ Double Pigtail Biliary Stent has the same technological characteristics as the predicate Microvasive® Drainage Stent (K834468) and Microvasive® Biliary Stent and Delivery System (K965147).

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

The pigtail shape and material for the Advanix Double Pigtail Biliary Stent are the same as the predicate Microvasive Drainage Stent.

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™ Double Pigtail 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 following tests were conducted on the Advanix™ Double Pigtail Biliary Stent: Drainage Lumen ID, Stent Length, Stent OD, Stent Shape, Deployment Force, Trackability Force, Duodenoscope Compatibility, and Barb Flap Cover Compatibility.

8. Conclusion:
All biocompatibility tests conducted on the Advanix™ Double Pigtail Biliary Stent passed. Therefore, the Advanix Double Pigtail Biliary Stent is considered biocompatible for its intended use.

All device bench test results were acceptable. The data demonstrate that the Advanix Double Pigtail Biliary Stent sufficiently meets the design specifications and is suitable for the intended use.

Boston Scientific Corporation has demonstrated that the proposed Advanix™ Double Pigtail Biliary Stent is substantially equivalent to Boston Scientific Corporation's currently marketed Microvasive® Drainage Stent (K834468) and 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: K101786
Trade/Device Name: Advanix™ Double Pigtail Biliary
Regulation Number: 21 CFR§ 876.5010
Regulation Name: Biliary catheter and accessories
Regulatory Class: II
Product Code: FGE
Dated: June 22, 2010
Received: June 25, 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

510(k) Number (if known): K101786

Device Name: Advanix™ Double Pigtail Biliary

Indications for Use: Advanix™ Double Pigtail Biliary Stent 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 K101786