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Section 5 Summary of Safety and Effectiveness

(Pursuant To Section 12 of the SAFE MEDICAL DEVICES ACT of 1990)

5.1 General Provisions

Submitter's Name and Address	Boston Scientific Corporation One Scimed Place Maple Grove, Minnesota 55311
Contact Person	Todd Kornmann (763) 494-2467
Classification Name	Biliary Catheter and Accessories Product Code – FGE Regulation Number 21 CFR Part 876.5010 Device Class II
Common or Usual Name	Biliary Stent
Proprietary Name	Boston Scientific Corporation Sentinol Nitinol Biliary Stent System

5.2 Name of Predicate Devices

Boston Scientific Wallstent Biliary Endoprosthesis with Unistep Plus RP Delivery System, Cordis S.M.A.R.T.™ Nitinol Stent Transhepatic Biliary System, and Guidant DYNALINK™ Biliary Self-Expanding Stent System.

5.3 Device Description

The Sentinol Nitinol Biliary Stent System consists of a self-expanding, open mesh, laser cut nitinol stent that is loaded into a delivery system consisting of two coaxially arranged shafts. The delivery system is designed to deliver the stent to the stricture site via transhepatic access. Once postitioned at the stricture site, the retractable exterior shaft is used to facilitate stent placement. Upon deployment, the stent expands and conforms to the inner lumen of the biliary duct. The stent is designed to maintain patency of biliary ducts which have been obstructed by malignant neoplasms.

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Stent

The Sentinol Nitinol Biliary Stent is a self expanding metallic stent intended to maintain patency of biliary strictures produced by malignant neoplasms. The stent will be available in a variety of sizes to address clinician needs.

The Sentinol Nitinol Biliary Stent is made from nitinol tubing. The seamless tubing is initially extruded to a cylindrical shape, and is then drawn down in a series of steps to the final tubing dimension. The stent is formed by laser cutting the pattern from the tube, after which it is cleaned and electropolished to obtain smooth rounded struts.

The Sentinol Nitinol Biliary Stent will be offered in various sized models with stent diameters ranging from 5 mm through 10 mm in one mm increments, and with stent lengths of 20 mm, 40 mm, 60 mm, and 80 mm.

Delivery System

The delivery system consists of two coaxially arranged shafts: an inner shaft and a retractable exterior shaft. The central lumen within the inner shaft continues to the tip and accepts a 0.035" guidewire through the distal tip that exits the proximal inner shaft hub.

The stent is loaded into the delivery system over the distal segment of the inner shaft. Two radiopaque marker bands on the inner shaft and one radiopaque marker band on the retractable exterior shaft are used to facilitate stent placement. The distal end of the exterior shaft covers the stent and is retracted to allow for stent deployment. The space between the coaxial inner shaft and the exterior shaft is accessed through the Y-manifold. The catheter models will be available in 75 cm and 135 cm working lengths.

5.4 Intended Use

The Sentinol Nitinol Biliary Stent System is indicated for palliation of malignant neoplasms in the biliary tree.

5.5 Summary of Technological Characteristics

The Boston Scientific Sentinol Nitinol Biliary Stent System will incorporate a substantially equivalent design, method of deployment, packaging, fundamental technology, manufacturing, sterilization and intended use as those featured in the currently marketed biliary stent systems. The subject and predicate stents are self-expanding and have a tubular open mesh design intended for palliation of malignant neoplasms in the biliary tree. The subject and predicate stents are delivered percutaneously via sheathed type delivery systems.

Section 5 Summary of Safety and Effectiveness

5.6 Non-clinical Test Summary

The safety and effectiveness of the Sentinol Nitinol Biliary Stent System have been demonstrated via data collected from non-clinical design verification tests and analyses. Comparative testing was also conducted which confirmed substantial equivalence of the subject device and predicate devices on a comparison of intended use, the design, and the device performance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 5 2003

Mr. Todd Kornmann
Sr. Regulatory Affairs Specialist
Boston Scientific Corporation
One Scimed Place
Maple Grove, Minnesota 55311-1566

Re: K032025
Trade/Device Name: Boston Scientific Sentinol™ Nitinol Biliary Stent System
Regulation Number: 21 CFR §876.5010
Regulation Name: Biliary catheter and accessories
Regulatory Class: II
Product Code: 78 FGE
Dated: June 27, 2003
Received: June 30, 2003

Dear Mr. Kornmann:

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). You may, therefore, market the device, subject to the general controls provisions of the Act and the limitations described below. 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.

The Office of Device Evaluation has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must appear in the Warnings section of the device's labeling:

> The safety and effectiveness of this device for use in the vascular system have not been established.

Furthermore, the indication for biliary use must be prominently displayed in all labeling, including pouch, box, and carton labels, instructions for use, and other promotional materials, in close proximity to the trade name, of a similar point size, and in bold print.

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.

The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification if the limitation statement described above is added to your labeling.

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

If you desire specific information about the application of other labeling requirements to your device (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4616. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Daniel G. Schultz, M.D.
Director
Office of Device Evaluation
Center for Devices and Radiological Health

510(k) Number: K032025

Device Name: Boston Scientific Sentinol™ Nitinol Biliary Stent System

FDA's Statement of the Indications For Use for device:

The Boston Boston Scientific Sentinol™ Nitinol Biliary Stent System is indicated for palliation of malignant neoplasms in the biliary tree.

Prescription Use ✓ OR Over-the-Counter Use _____
(Per 21 CFR 801.109)

David A. Ekman

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K032025