OCT 24 2001

K012822

Section 6 Summary of Safety and Effectiveness

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

6.1 General Provisions

Submitter's Name and Address	Boston Scientific Scimed One Scimed Place Maple Grove, Minnesota 55311
Contact Person	Todd Kornmann (763) 494-2467
Classification Name	Biliary Catheter and Accessories Product Code – 78 FGE Regulation Number 21 CFR Part 876. 5010
Common or Usual Name	Biliary Stent
Proprietary Name	Boston Scientific Medi-Tech Transhepatic Biliary Wallstent Endoprosthesis with Monorail Delivery System

6.2 Name of Predicate Device

Boston Scientific Medi-Tech Transhepatic Biliary Wallstent Endoprosthesis with Unistep Plus Delivery System

6.3 Device Description

The Boston Scientific Medi-Tech Transhepatic Biliary Wallstent Endoprosthesis with Monorail Delivery System consists of the following components:

- Biliary Stent
- Monorail Delivery System

Biliary Stent

The Biliary Wallstent covered in this submission is a self-expanding endoprosthesis constructed of biomedical DFT (drawn filled tubing) monofilament wires, braided in a tubular mesh configuration. It is designed to self-expand to a specified diameter following deployment into the stricture. The Biliary Wallstent is provided pre-mounted on a monorail type delivery system.

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The stent will be available in unconstrained diameters of 6.0, 8.0 and 10.0 mm. The three stent diameters will be available in the following lengths.

Stent Diameter	Stent Unconstrained Length
6.0 mm	22 mm
8.0 mm	21 mm, 29 mm and 36 mm
10.0 mm	24 mm, 31 mm and 37 mm

Delivery Catheter

The monorail delivery instrument consists of two coaxially arranged shafts: an inner shaft made of stainless steel proximally and thermoplast distally, and an outer sheath made of thermoplast. The central lumen within the inner shaft continues to the tip and accepts a 0.014" guide wire through the distal tip that exits the inner lumen through two guide wire holes (inner and outer exit holes).

The stent is pre-loaded on the stent carrier located on the distal segment of the inner shaft. Two radiopaque markers on the inner shaft and one radiopaque marker on the retractable outer shaft are used to facilitate stent placement. The proximal end of the stent is firmly held on the inner shaft with a stent holder, which enables a partially deployed stent to be recaptured and repositioned, if desired. A black release marker on the proximal stainless steel shaft identifies the maximum deployment allowable for recapture of the stent.

The distal end of the outer sheath covers the stent and is retracted to allow for stent deployment. The space between the coaxial inner shaft and the outer sheath is accessed through the T-connector. All catheter models have the same overall length.

A more detailed description of the device is provided in Section 8.

6.4 Intended Use

The Biliary Wallstent Endoprosthesis with Monorail Delivery System is indicated for use in the treatment of biliary strictures produced by malignant neoplasms.

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6.5 Summary of Technological Characteristics

The Biliary Wallstent Endoprosthesis with Monorail Delivery System is manufactured in a substantially equivalent manner to the currently marketed Biliary Wallstent Endoprosthesis with Unistep Plus Delivery System (K993232). The major manufacturing differences are related to the differences in the delivery system design which will be utilized to place the stent.

6.6 Non-clinical Test Summary

Testing was conducted in accordance with the FDA Guidance for Metal Expandable Biliary Stents. The following functional testing was conducted.

- Stent Integrity Testing
  - Mounted Stent Profile (Stent Constrained Length)
  - Stent Foreshortening (Stent Unconstrained Length)
  - Stent Inner Diameter
  - Stent Expansion Uniformity (Implanted Length)
  - Radial (Hoop) Strength
  - Kink (Trackability) Testing
- Stent / Monorail Delivery Catheter System Integrity Testing
  - Deployment Testing
  - Tensile Testing
  - Crossing Profile
  - Compatibility with Accessories

Biocompatibility and 3.5 year product shelf life testing have also been conducted. All *in-vitro* test results verified that the Biliary Wallstent Endoprosthesis with Monorail Delivery System is adequate for its intended use. The Biliary Wallstent Endoprosthesis with Monorail Delivery System is considered substantially equivalent to the currently marketed Biliary Wallstent Endoprosthesis with Unistep Plus Delivery System, based on a comparison of intended use, device design, and the results of *in-vitro* testing and evaluation.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 2 4 2001

Mr. Todd Kornmann
Senior Regulatory Affairs Specialist
Boston Scientific Scimed, Inc.
One Scimed Place
MAPLE GROVE MN 55311

Re: K012822
Trade/Device Name: Biliary Wallstent® Endoprosthesis with Monorail Delivery System
Regulation Number: 21 CFR §876.5010
Regulation Name: Biliary Catheter and Accessories
Regulatory Class: II
Product Code: 78 FGE
Dated: September 24, 2001
Received: September 26, 2001

Dear Mr. Kornmann:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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 510(k) premarket notification if the limitation statement above is added to your labeling, as described.

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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4616. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained 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,

Bernard E. Statland, M.D., Ph.D.
Director
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K012822

Device Name: Biliary Wallstent® Endoprosthesis with Monorail Delivery System

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

The Biliary Wallstent® Endoprosthesis with Monorail Delivery System is indicated for use in the treatment of biliary strictures produced by malignant neoplasms.

Prescription Use ✓ OR Over-The-Counter Use ___
(Per 21 CFR 801.109)

Nancy C. Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K012822