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K024048

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 Corporation 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 and Balloon Dilatation Catheter
Proprietary Name	Boston Scientific Corporation Express Biliary LD Premounted Stent System

6.2 Name of Predicate Device

Boston Scientific Express Biliary LD Premounted Stent System

6.3 Device Description

Stent Description

The 27 mm Express Biliary LD Premounted Stent System will be identical to the currently marketed Express Biliary LD Premounted Stent Systems (K021630).

The Express Biliary LD Stent is a balloon expandable 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 Express Biliary LD Stent is made from 316L surgical grade stainless steel 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.

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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 geometry is a continuous pattern consisting of large and small sinusoidal bands connected by axial struts. The deployed stent provides radial strength while conforming to the natural curvature of the anatomy. The stent provides a ghost like image using conventional radiographic imaging equipment.

The currently marketed Express Biliary LD Premounted Stent System is offered with stent diameters of 6 – 10 mm, in one mm increments. The 6 – 8 mm diameter stents has lengths of 17 mm, 37 mm, and 57 mm. The 27 mm length is proposed for these stent diameters and is the subject of this submission. These are considered to be the Small Lumen (SL) models. The 9 mm and 10 mm diameter stents have lengths of 25 mm, 37 mm, and 57 mm. These are considered to be the Large Lumen (LL) models.

Balloon Delivery Catheter

The balloon delivery catheter for the 27 mm Express Biliary LD Premounted Stent System will be identical to the one utilized on the currently marketed Express Biliary LD Premounted Stent Systems (K021630).

The Balloon Delivery Catheter is an over-the-wire catheter offered in a two lumen catheter shaft design. One lumen is used to pass the catheter over a guide wire. The proposed device is designed to be placed over guide wires which have outer diameters of 0.035" or smaller. This lumen can also be used for infusion of contrast medium.

The second lumen communicates with the balloon and is used to inflate and deflate the balloon during the stenting procedure. The guide wire lumen and the balloon lumen terminate at the proximal end of the catheter by means of a bifurcated hub with luer lock fittings.

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

6.4 Intended Use

The Express Biliary LD Premounted Stent System is indicated for the treatment of biliary strictures produced by malignant neoplasms.

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6.5 Summary of Technological Characteristics

The Boston Scientific 27 mm Express Biliary LD Premounted Stent System will incorporate the identical design, method of deployment, fundamental technology, manufacturing, packaging, labeling, sterilization, and intended use as those in the currently marketed the Express Biliary LD Premounted Stent System (K021630).

6.6 Non-clinical Test Summary

Functional testing presented for the stent component consisted of tensile and elongation, bile corrosion resistance, dimensional verification (strut widths, stent lengths), foreshortening, recoil, expansion uniformity, compression resistance, over expansion, and deployment accuracy.

Functional testing presented for the balloon delivery catheter consisted of multiple balloon inflation within a stent, balloon burst within a stent, balloon inflation and deflation time, balloon proximal bond tensile, stent / balloon crossing profile, sheath insertion / withdrawal force, stent securement force, tracking, and hub to shaft tensile.

Biocompatibility and 2 year product shelf life have also been conducted. Test results verified that the Express Biliary LD Premounted Stent System is adequate for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 6 - 2003

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

Re: K024048
Trade/Device Name: Express™ Biliary LD Premounted Stent System (27 mm)
Regulation Number: 21 CFR §876.5010
Regulation Name: Biliary catheter and accessories
Regulatory Class: II
Product Code: 78 FGE
Dated: December 6, 2002
Received: December 9, 2002

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.

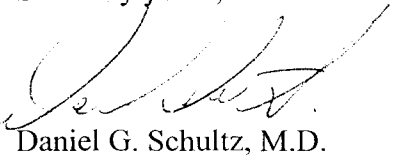
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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 Section 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 Part 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 Part 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,



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

Enclosure

510(k) Number (if known): K024048

Device Name: Express™ Biliary LD Premounted Stent System (27 mm)

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

The Express™ Biliary LD Premounted Stent System is indicated for the palliation of malignant neoplasms in the biliary tree.

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 K024048