MAR 2 5 2003

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
Proprietary Name	Boston Scientific Corporation Express Biliary LD Unmounted Stent

6.2 Name of Predicate Device

Boston Scientific Express Biliary LD
Premounted Stent System

6.3 Device Descriptions

Stent Description

The Express Biliary LD Unmounted Stent will be the identical stent that is currently marketed as the Express Biliary LD Premounted Stent System (K021630 and K024048). The stent will be hand mounted by the user upon its recommended balloon delivery catheter.

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.

Section 6 Summary of Safety and Effectiveness

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. The stent is formed by laser cutting the pattern from the tube, then 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 Express Biliary LD Stent will be offered in Small Lumen (SL) and Large Lumen (LL) models. The SL model will be offered in lengths of 17 mm, 27 mm, 37 mm, and 57 mm and is designed to expand from 6 mm to 8 mm in diameter. The LL model will be offered in lengths of 25 mm, 37 mm, and 57 mm and is designed to expand from 9 mm to 10 mm in diameter. They are the identical stent sizes in which the Express Biliary LD Premounted Stent System is offered.

Recommended Delivery Catheter

The delivery catheter recommended for use with the proposed Express Biliary LD Stent will be the currently marketed Boston Scientific Ultra-thin SDS Balloon Dilatation catheter (K011889 and K011909). The Ultra-thin SDS catheter was determined substantially equivalent for PTA indications under K011889, and for the indication of stent deployment / optimization of a Biliary Stent under K011909.

The recommended delivery catheter, the Ultra-thin SDS Balloon Dilatation Catheter, is the identical catheter that is utlized for the Express Biliary LD Premounted Stent System, with the exception of a slighty different hub design.

The Ultra-thin SDS Balloon Dilatation 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 guidewire. The Ultra-thin SDS catheter is designed to be placed over guidewires which have outer diameters of 0.035" or smaller. The second lumen communicates with the balloon and is used to inflate and deflate the balloon during the procedure. The guidewire lumen and the balloon lumen terminate at the proximal end of the catheter by means of a bifurcated hub with luer lock fittings.

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A more detailed device description is provided in the original 510(k) applications (K011909 or K011889, Attachment A, Device Description) and is provided in Section 8 of this submission.

6.4 Intended Use

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

6.5 Summary of Technological Characteristics

The Boston Scientific Express Biliary LD Unmounted Stent will incorporate the identical design, method of deployment, fundamental technology, manufacturing, sterilization, and intended use as those featured in the currently marketed Express Biliary LD Premounted Stent System (K021630 and K024048).

6.6 Non-clinical Test Summary

The safety and effectiveness of the the Express Biliary LD Unmounted Stent have been demonstrated via data collected from non-clincal design verification tests and analyses.

Biocompatibility, product and packaging shelf life testing have also been conducted. Test results verified that the Express Biliary LD Unmounted Stent is adequate for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Todd Kornmann
Sr. Regulatory Affairs Specialist
Boston Scientific Scimed, Inc.
One Scimed Place
MAPLE GROVE MN 55311-1566

MAR 2 5 2003

Re: K030645
Trade/Device Name: Express™ Biliary LD Unmounted Stent
Regulation Number: 21 CFR §876.5010
Regulation Name: Biliary catheter and accessories
Regulatory Class: II
Product Code: 78 FGE
Dated: February 27, 2003
Received: February 28, 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

Enclosure

510(k) Number (if known): K030645

Device Name: Boston Scientific Express™ Biliary LD Unmounted Stent

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

The Boston Scientific Express™ Biliary LD Unmounted Stent is indicated for use in 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 K030645