Boston
Scientific
Corporation

One Boston Scientific Place
Natick, MA 01760-1537
508·650·8000

MAY 21 1997 K963254

# 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Pursuant to §513(i)(3)(A) of the Food, Drug, and Cosmetic Act, Boston Scientific Corporation is required to submit with this Premarket Notification"...adequate summary of any information respecting safety and effectiveness or state that such information will be made available upon request of any person." Boston Scientific Corporation chooses to submit a summary of information respecting safety and effectiveness. According to §513(i)(3)(B), " Any summary under subparagraph (A) respecting a device shall contain detailed information regarding data concerning adverse health effects..."

The summary regarding the adverse health effects of the proposed **Symphony™ Nitinol Stent Transhepatic Biliary System** is as follows:

| | |
|---|---|
| **Trade Name:** | **Symphony™ Nitinol Stent Transhepatic Biliary System** |
| **Manufacturer:** | Boston Scientific Corporation<br>480 Pleasant Street<br>Watertown, MA 02172 |
| **Device Generic Name:** | Biliary Stent |
| **Classification:** | According to Section 513 of the Federal Food, Drug and Cosmetic Act, the device classification is Class II, Performance Standards (CFR 876.5010). |
| **Predicate Device:** | **Wallstent® Transhepatic Biliary Endoprosthesis with Unistep™ Delivery System** |

**Device Description:**

The proposed **Symphony™ Nitinol Stent Transhepatic Biliary System** is a two-part system consisting of a self-expanding stent and a flexible delivery catheter. The delivery catheter is designed to facilitate transhepatic access to the biliary tree and the stent is designed to maintain luminal patency of biliary strictures produced by malignant neoplasms.

The proposed **Symphony™ Nitinol Stent** will be provided pre-loaded by Boston Scientific Corporation onto the delivery catheter. The stent is mounted on the catheter shaft and an outer sheath is positioned over the stent/catheter subassembly. The delivery catheter is compatible with 7F introducer systems and the multi-lumen design provides a priming lumen and accomodates a .035" guidewire.

**Indications For Use:**

For use in the treatment of biliary strictures produced by malignant neoplasms.

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**Safety and Performance:**

Functional and integrity bench testing, Animal testing and Biocompatibility testing(according to the FDA guidance document, ODE Blue Book Memorandum #G95-1, May 1, 1995, *Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing"*) were performed, and the data supported the substantial equivalence of the **Symphony™ Nitinol Stent Transhepatic Biliary System** to the **Wallstent® Transhepatic Biliary Endoprosthesis with Unistep™ Delivery System**.

**Conclusion:**

Based on the indications for use, technological characteristics, and safety and performance testing, the **Symphony™ Nitinol Stent Transhepatic Biliary System** has been shown to be safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 21 1997

Ms. Laura Mondano
Project Manager, Regulatory Affairs
Boston Scientific Corporation
One Boston Scientific Place
Natick, Massachusetts 01760-1537

Re: K963254
Symphony™ Nitinol Stent Transhepatic Biliary System
Dated: February 19, 1997
Received: February 20, 1997
Regulatory Class: II
21 CFR 876.5010/Procode: 78 FGE

Dear Ms. Mondano:

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 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. 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.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (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 Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K963254



# INDICATION FOR USE

**510(k) Number (if known):** new application

**Device Name:** Symphony™ Nitinol Stent Transhepatic Biliary System

**Indications for Use:**

For Use in the treatment of biliary strictures produced by malignant neoplasms.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

**Concurrence of CDRH, Office of Device Evaluation (ODE)**

Peter R Rathmell
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K963254

**Prescription Use** √ **OR** **Over-The-Counter Use** _____

**(Per 21 CFR 801.109)**

(Option Format 1-2-96)