SECTION 9
510(K) SUMMARY

JUN 30 1997

FOI RELEASABLE

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.

- COMMON/USUAL NAMES: Biliary Stent, Biliary Stent System, Biliary Endoprosthesis
- TRADE/PROPRIETARY NAME: The trade name has not yet been finalized.
- CLASSIFICATION NAME & DEVICE CLASSIFICATION: Class II

Name	Number	21 CFR Ref.
Biliary Catheter and Accessories	78 FGE	876.5010

- DEVICE PANEL/BRANCH: Gastroenterology-Urology (GU)
  Gastro-Renal (GRDB)
- OWNER/OPERATOR: Boston Scientific Corporation
  One Boston Scientific Place
  Natick, MA 01760
  Owner/Operator No. 9912058
- CONTACT PERSON: Daniel J. Dillon, Senior Regulatory Affairs Specialist

INDICATIONS FOR USE

The New Microvasive® Biliary Stent and Delivery System is intended for delivery of the stent to the biliary tract for drainage of the bile ducts, for splinting of a bile duct during healing, or for providing bile duct patency in a stricture or past a stone.

CONTRAINDICATIONS

None known.

POTENTIAL COMPLICATIONS

Potential complications that may result from a biliary stent placement procedure include, but may not be limited to, perforation of bile ducts; liver and/or duodenum; hemorrhage; hematoma; septicemia/infection; bile peritonitis; allergic reaction to contrast medium.

DESCRIPTIVE AND TECHNOLOGICAL CHARACTERISTICS OF PROPOSED AND PREDICATE DEVICES

Boston Scientific Corporation believes that the New Microvasive® Biliary Stent and Delivery System is substantially equivalent to the currently-marketed Solopass™ Percuflex Biliary Stent and Flexima™ Biliary Drainage Catheter. Table 9-1 compares the descriptive characteristics of these products.

PERFORMANCE CHARACTERISTICS

Laboratory testing regarding characteristics was performed on New Microvasive® Biliary Stent and Delivery System to verify its safety and performance. A biocompatibility assessment was performed on the patient- and fluid-contact materials of the New Microvasive® Biliary Stent and Delivery System with satisfactory results.

PACKAGING, STERILIZATION, AND PYROGENICITY

The New Microvasive® Biliary Stent and Delivery System will be packaged using Tyvek/Mylar. The New Microvasive® Biliary Stent and Delivery System will be sterilized using ethylene oxide gas using the AAMI protocol for ethylene oxide sterilization. Pyrogenicity testing will be performed on a periodic basis to monitor bacterial endotoxin levels.

CONCLUSION

Boston Scientific Corporation believes that New Microvasive® Biliary Stent and Delivery System is substantially equivalent to the currently-marketed Solopass™ Percuflex Biliary Stent and Flexima™ Biliary Drainage Catheter. Table 9-1 compares the descriptive characteristics of these products. As demonstrated in Table 9-1, the New Microvasive® Biliary Stent and Delivery System is equivalent in its indications for use, while being very similar in design and materials. In addition, Boston Scientific Corporation has presented laboratory testing and biocompatibility information. The information presented provides assurance that the New Microvasive® Biliary Stent and Delivery System will meet the minimum requirements that are considered acceptable for its intended use.

TABLE 9-1: COMPARISON OF NEW MICROVASIVE® BILIARY STENT AND DELIVERY SYSTEM, SOLOPASS™ PERCUFLEX BILIARY STENT, AND FLEXIMA™ BILIARY DRAINAGE CATHETER

	New Microvasive® Biliary Stent and Delivery System (This 510(k))	*Solopass™ Percuflex Biliary Stent (K834468)*	*Flexima™ Biliary Drainage Catheter (K944290)*
USE			
Indication	Biliary Drainage	«— Same	«— Same
Route of Administration	Endoscopic	«— Same	Percutaneous Transhepatic
STENT			
Type	Amsterdam	«— Same	Pigtail
Material	Flexima	Percuflex	Flexima
Dissolvable Tip	No	Yes	Yes
Available Diameters (Fr)	7 - 11.5	7 - 12	8 - 14
Available Lengths (cm)	5 - 15	5 - 15	35
DELIVERY SYSTEM			
Preloaded Stent?	Yes	Yes	Not Applicable
Working Length (cm)	200	195	Not Applicable
Compatible Guidewire (in)	0.035	0.035	0.018/0.038

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 30 1997

Mr. Daniel J. Dillon
Senior Regulatory Affairs Specialist
Boston Scientific Corporation
One Boston Scientific Place
Natick, Massachusetts 01760-1537

Re: K965147
New Microvasive® Biliary Stent and Delivery System
Dated: April 29, 1997
Received: May 1, 1997
Regulatory class: II
21 CFR §876.5010/Product code: 78 FGE

Dear Mr. Dillon:

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

SECTION 1
INDICATIONS FOR USE

510(k) Number: To Be Determined

Device Name: New Microvasive® Biliary Stent and Delivery System

Indication for Use:

The New Microvasive® Biliary Stent and Delivery System is intended for delivery of the stent to the biliary tract for drainage of the bile ducts, for splinting of a bile duct during healing, or for providing bile duct patency in a stricture or past a stone.

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K965147

Prescription Use ✓
(Per 21 CFR 801.109)

Over-the-Counter Use _____