

MAY 20 1997

ATTACHMENT 10
510(K) SUMMARY

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

➤ TRADE/PROPRIETARY NAME: Ultraflex™ Diamond

➤ 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 Ultraflex™ Diamond Biliary Stent System is indicated for palliative treatment of patients with malignant biliary strictures.

CONTRAINDICATIONS

The Ultraflex™ Diamond Biliary Stent System is contraindicated for biliary duct strictures of benign etiology; biliary obstruction preventing either endoscopic or percutaneous cholangiography; concurrent perforated bile duct, those patients for whom endoscopic or percutaneous procedures are contraindicated; any use other than those specifically outlined under Indications for Use.

POTENTIAL COMPLICATIONS

The following complications have been reported in the literature for plastic and metal biliary stent placement. Procedural: infection, bleeding, perforation of the duodenum or bile duct, pain, aspiration, oxygen desaturation related to sedation, stent misplacement, pancreatitis. Post-Stent Placement: stent migration, stent occlusion due to sludge formation, stent occlusion due to tumor ingrowth, stent occlusion due to tumor overgrowth of stent ends, stent occlusion due to excessive hyperplastic tissue ingrowth, recurrent obstructive jaundice related to stent occlusion or migration, infection, bleeding, bile duct ulceration and/or perforation

DESCRIPTIVE AND TECHNOLOGICAL CHARACTERISTICS OF PROPOSED AND PREDICATE DEVICES

Boston Scientific Corporation believes that the Ultraflex™ Diamond Biliary Stent System is substantially equivalent to the currently-marketed Schneider Wallstent® Endoscopic Biliary Endoprosthesis. Table 10-1 compares the descriptive characteristics of these products.

PERFORMANCE CHARACTERISTICS

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

PACKAGING, STERILIZATION, AND PYROGENICITY

The Ultraflex™ Diamond Biliary Stent System will be packaged in a Tyvek/Polyester-polyethylene pouch. The Ultraflex™ Diamond Biliary Stent 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 Ultraflex™ Diamond Biliary Stent System is substantially equivalent to the currently-marketed Ultraflex™ Diamond Biliary Stent System. Table 10-1 compares the descriptive characteristics of these products. As demonstrated in Table 10-1, the Ultraflex™ Diamond Biliary Stent 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 Ultraflex™ Diamond Biliary Stent System will meet the minimum requirements that are considered acceptable for its intended use.

**TABLE 10-1:
SIMILARITIES AND DIFFERENCES BETWEEN ULTRAFLEX™ DIAMOND BILIARY STENT SYSTEM AND
SCHNEIDER WALLSTENT® ENDOSCOPIC BILIARY ENDOPROSTHESIS**

	<i>Ultraflex Diamond Biliary Stent System (This 510(k))</i>	<i>Schneider Wallstent® Endoscopic Biliary Endoprosthesis (K925406)</i>
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USE

<i>Indication</i>	Malignant Biliary Strictures	«— Same
<i>Route of Administration</i>	Endoscopic	«— Same

STENT

<i>Overall OD</i>	10 mm	8 - 12 mm
<i>Overall Length</i>	40 -80 mm	«— Same
<i>Material</i>	Nitinol	Stainless Steel
<i>Construction Method</i>	Monofilament, Twisted	Monofilament, Braided
<i>Expansion Mode</i>	Self-Expanding	«— Same
<i>RO Marker Location</i>	Stent and Delivery System	Delivery System

DELIVERY SYSTEM

<i>Design</i>	Sliding Sheath	«— Same
<i>Usable Length</i>	194 cm	195 cm
<i>Shaft OD</i>	2.7 mm - 3.02 mm	2.5 mm
<i>Compatible Guidewire</i>	0.035"	0.035" - 0.038"



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 20 1997

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

Re: K962899
Ultraflex™ Diamond Biliary Stent System
Dated: February 25, 1997
Received: February 26, 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: Ultraflex™ Diamond Biliary Stent System

Indication for Use:

The Ultraflex™ Diamond Biliary Stent System is indicated for palliative treatment of patients with malignant biliary strictures.

Robert D. Mattingly
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K 962899

Prescription Use ✓
(Per 21 CFR 801.109)

Over-the-Counter Use _____