

SECTION 9
510(K) SUMMARY

DEC - 5 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: Sphincterotome
- TRADE/PROPRIETARY NAME: None at this time
- CLASSIFICATION NAME & DEVICE CLASSIFICATION: Class II

Name	Number	21 CFR Ref.
Endoscopic Electrosurgical Unit and Accessories.	78 KNS	876.4300
- DEVICE PANEL/BRANCH: Gastroenterology-Urology (GU)
Gastro-Renal (GRDB)
- OWNER/OPERATOR: Boston Scientific Corporation
One Boston Scientific Place
Natick, MA 01760
- CONTACT PERSON: Daniel J. Dillon, Senior Regulatory Affairs Specialist

INDICATIONS FOR USE

The Microvasive® Needle Knife Sphincterotome is indicated for use in transendoscopic sphincterotomy of the Papilla of Vater and/or the Sphincter of Oddi.

CONTRAINDICATIONS

Contraindications for this device are those specific to endoscopic retrograde cholangiopancreatography (ERCP) and endoscopic sphincterotomy (ES).

COMPLICATIONS

Possible complications include, but may not be limited to: pancreatitis; perforation; hemorrhage, hematoma, cholangitis; stone impaction; septicemia/infection; and allergic reaction to contrast medium

SUBSTANTIAL EQUIVALENCE

Boston Scientific Corporation believes that the Microvasive® Needle Knife Sphincterotome is substantially equivalent to the currently-marketed Microvasive® Rapid Exchange Sphincterotome and Ultratome XL™ Triple Lumen Sphincterotome.

PERFORMANCE CHARACTERISTICS

Laboratory testing regarding characteristics was performed on the Microvasive® Needle Knife Sphincterotome to verify its safety and performance. A biocompatibility assessment was performed on the patient- and fluid-contact materials of the Microvasive® Needle Knife Sphincterotome with satisfactory results.

PACKAGING, STERILIZATION, AND PYROGENICITY

The Microvasive® Needle Knife Sphincterotome will be sterile in a tray sealed with a Tyvek lid. The Microvasive® Needle Knife Sphincterotome 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 Microvasive® Needle Knife Sphincterotome is substantially equivalent to the currently-marketed Microvasive® Rapid Exchange Sphincterotome and Ultratome XL™ Triple Lumen Sphincterotome. A comparison of the descriptive characteristics of these products demonstrate the Microvasive® Needle Knife Sphincterotome 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 Microvasive® Needle Knife Sphincterotome will meet the minimum requirements that are considered acceptable for its intended use.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC - 5 1997

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

Re: K973826
Microvasive® Needle Knife Sphincterotome
Dated: October 3, 1997
Received: October 7, 1997
Regulatory class: II
21 CFR §876.4300/Product code 78 KNS

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 Current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS 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) 594-4613. 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~~ K973826

Device Name: Microvasive® Needle Knife Sphincterotome

Indication for Use:

The Microvasive® Needle Knife Sphincterotome is indicated for use in transendoscopic sphincterotomy of the Papilla of Vater and/or the Sphincter of Oddi. The Microvasive Needle Knife can also be used to cannulate and inject contrast medium.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Robert R. Rathling
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K973826

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use