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SECTION 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.

Date:	August 21, 2001
Common/Usual Names:	needle, endoscope
Trade/Proprietary Name:	Interject™ Injection Therapy Needle
Classification Name & Device Classification:	Class II

Name	Number	21 CFR Ref.
Needle, Endoscope	78 FBK	876.1500
Endoscope & Accessories	78 KOG	876.1500

Device Panel/Branch:	Gastroenterology-Urology (GU) GASTRO-RENAL (GRBD)
Owner/Operator:	Boston Scientific Corporation One Boston Scientific Place Natick, MA 01760
Contact Person:	James D. McMahon Regulatory Affairs Specialist

DESCRIPTION OF DEVICE

The Interject Injection Therapy Needle is an injection needle designed to be used with an endoscope to perform endoscopic injections.

INDICATIONS FOR USE

The Interject Injection Therapy Needle Catheter is used endoscopically to introduce a sclerosing agent or vasoconstrictor into selected sites to control actual or potential bleeding lesions in the digestive system; and the injection of saline to aid in Endoscopic Mucosal Resection (EMR), polypectomy procedures and to control non-variceal hemorrhage.

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DESCRIPTIVE AND TECHNOLOGICAL CHARACTERISTICS OF PROPOSED AND PREDICATE DEVICES

Boston Scientific Corporation believes that the Interject™ Injection Therapy Needle with additional indications is substantially equivalent to the currently marketed Boston Scientific Corporation's Interject™ Injection Therapy Needle, Variject™ Needle Catheter (K961846) and US Endoscopy Goup, Coaxial Needle (K971842). The major components of the devices are the catheter, needle, and hub. A thorough comparison of the descriptive characteristics between the proposed Interject device and the predicate device show equivalence.

PERFORMANCE CHARACTERISTICS

A biocompatibility assessment was performed on the patient- and fluid-contact materials of the predicate Interject Injection Therapy Needle with satisfactory results. The proposed Interject device and predicate Interject device are identical therefore no additional biocompatibility was performed to include the new indication.

CONCLUSION

BSC has demonstrated that the Interject™ Injection Therapy Needle with additional indications is substantially equivalent to BSC's currently marketed Interject Injection Therapy Needle, Variject Needle Catheter and US Endoscopy Group, Coaxial Needle.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 24 2001

Mr. James D. McMahon
Regulatory Affairs Specialist
Microvasive Endoscopy
Boston Scientific Corporation
One Boston Scientific Place
NATICK MA 01760-1537

Re: K012864
Trade/Device Name: Interject™ Injection Therapy Needle
Regulation Number: 21 CFR 876.1075
Regulation Name: Gastroenterology-urology biopsy instrument
Regulatory Class: II
Product Code: 78 FCG
Dated: August 24, 2001
Received: August 27, 2001

Dear Mr. McMahon:

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) that do not require approval of a premarket approval application (PMA). 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 (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.

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), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

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 Part 807.97). Other general information on your responsibilities under the Act may be obtained 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,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

SECTION 3
INDICATION FOR USE

510(k) Number: ~~To Be Determined~~ K012864

Device Name: Interject™ Injection Therapy Needle

Indication for Use:

The Interject™ Injection Therapy Needle Catheter is used endoscopically to introduce a sclerosing agent or vasoconstrictor into selected sites to control actual or potential bleeding lesions in the digestive system; and the injection of saline to aid in Endoscopic Mucosal Resection (EMR), polypectomy procedures and to control non-variceal hemorrhage.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.1091) (Optional Format 1-2-96)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K012864