K 942301

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Section V

FOI RELEASABLE

510(k) Summary

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510(k) Summary

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.

A. GENERAL INFORMATION

Owner Operator Submitting this Premarket Notification:	Boston Scientific Corporation 480 Pleasant Street Watertown, MA 02172 (617) 923-1720
Contact Person:	Sheri D. O'Brien Senior Regulatory Affairs Specialist
Device Generic Name:	Electrohemostasis and Injection Therapy Catheter
Device Trade Name:	Microvasive® Injection Gold Probe™
Classification Name:	Boston Scientific Corporation believes that the Injection Gold Probe is best described by the following device classification names:

Unit, Electrosurgical, Endoscopic (with Accessories):	78KNS
Endoscope and/or Accessories:	78KOG

Device Classification:

Although the Injection Gold Probe has not been specifically classified under 21 CFR § 876, the status of the classification names presented below supports a Class II device classification.

Endoscope Electrosurgical Unit and Accessories:	Class II, 21 CFR § 876.4300
Endoscope and Accessories:	Class II, 21 CFR § 876.1500

B. INDICATIONS FOR USE

The Microvasive *Injection Gold Probe* is indicated for use in endoscopic injection therapy and electrohemostasis of actual or potential bleeding sites in the gastrointestinal tract, including, but not limited to: the esophagus, stomach, duodenum, and colon. These sites include the following: peptic ulcers; Mallory-Weiss tears; arteriovenous malformations (AVMs); Dieulafoy lesions; bleeding polyp stocks; and angiomata.

C. CONTRAINDICATIONS

Contraindications for this device are those specific to injection therapy and bipolar electrohemostasis treatments. These contraindications include, but are not limited to: non-focal bleeding sites; esophageal/gastric varices; diffuse lesions; allergies to injection agents; and use of the *Injection Gold Probe* with monopolar electrosurgical generators

D. POTENTIAL COMPLICATIONS

Potential complications include, but may not be limited to: perforation; bleeding, post-injection ulceration with delayed bleeding; aspiration pneumonia; pleural effusion; other respiratory difficulties; hepatic failure; septicemia/infection; chest pain; esophageal ulcers; esophageal strictures; and dysphagia.

E. DESCRIPTIVE AND TECHNOLOGICAL CHARACTERISTICS OF PROPOSED AND PREDICATE DEVICES

Boston Scientific Corporation believes that the proposed Microvasive Injection Gold Probe is substantially equivalent to the currently marketed Microvasive Gold Probe™ and Microvasive Variject™ Clear Injection Therapy Needle catheter. Table 1 compares the descriptive characteristics of these products.

Table 1:
Similarities and Differences between the
Proposed Microvasive Injection Gold Probe and the
Predicate Microvasive Gold Probe and Variject Clear Injection Therapy Needle Catheter

Device Characteristic	Microvasive® Gold Probe™ (Predicate Device) (K885005)	Microvasive® Variject™ Clear Injection Therapy Needle Catheter (Predicate Device) (K854238)	Microvasive® Injection Gold Probe™ (Proposed Device) (This 510(k))
Indications for Use	Endoscopic electrohemostasis of visible bleeding and non-bleeding sites in the gastrointestinal tract.	Used endoscopically to introduce a sclerosing agent or vasoconstrictor into selected sites to control actual or potential bleeding lesions in the digestive system.	Endoscopic injection therapy and electrohemostasis of actual or potential bleeding sites in the gastrointestinal tract.
Catheter Shaft:			
Material	Confidential	Confidential	Confidential
Usable Length	290 cm - 350 cm	200 cm	210 - 350 cm
Shaft OD	7 - 10 F	5.4 F (1.8 mm)	7 - 10 F
Coating	Confidential	NA	Confidential
Bipolar Electrohemostasis:			
Bipolar Ceramic Tip	Confidential	NA	Confidential
Electrical Wires	Confidential	NA	Confidential
Generator Connector	Bipolar Erbe Connector	NA	Bipolar Erbe Connector
Electrical Bifurcation	Confidential	NA	Confidential
Injection Therapy:			
Needle Material	NA	Confidential	Confidential
Needle Gauge	NA	23 & 25 Gauge	25 Gauge
Needle Extension Length	NA	5 mm	4 - 6 mm
Needle Luer Hub Material	NA	Confidential	Confidential
Irrigation Capability:			
Irrigation Capability	Yes	No	Yes
Irrigation Luer Hub Material	Confidential	NA	Confidential

F. PERFORMANCE CHARACTERISTICS

In vitro laboratory testing regarding both clinical performance characteristics and product integrity was performed on finished, sterilized Injection Gold Probe catheters to verify the device's safety and effectiveness. In addition, Full Tripartite Biocompatibility testing was performed on the Injection Gold Probe with satisfactory results.

G. PACKAGING, STERILIZATION, AND PYROGENICITY

The package is the same as that presently used for the currently marketed Microvasive Gold Probe. The Injection Gold Probe 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.

H. CONCLUSION

Boston Scientific Corporation believes that the proposed Microvasive Injection Gold Probe is substantially equivalent to the Microvasive Gold Probe and Variject catheters. As demonstrated in Table 1, the Injection Gold Probe combines their indications for use, while combining their designs. In addition, BSC has presented Laboratory and Biocompatibility Testing data to verify the safety and effectiveness of the proposed Injection Gold Probe.

Based on the information presented, Boston Scientific Corporation believes that the proposed Microvasive Injection Gold Probe is safe and effective and it will meet the minimum requirements that are considered acceptable for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
1390 Piccard Drive
Rockville MD 20850

NOV 2 1994

Ms. Sheri D. O'Brien
Senior Regulatory Affairs Specialist
Boston Scientific Corporation
480 Pleasant Street
Watertown, MA 02172-2414

Re: K942301/B
Microvasive Injection Gold Probe
Dated: October 19, 1994
Received: October 20, 1994
Regulatory Class: II
21 CFR 876.4300 Procode: 78 KNS

Dear Ms. O'Brien:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and have determined the device is substantially equivalent 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, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (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 immediately will allow you to begin marketing your device as described in your 510(k) premarket notification. An FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market, but it does not mean that FDA approves your device. Therefore, you may not promote or in anyway represent your device or its labeling as being approved by FDA. 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), promotion, or advertising please contact the Office of Compliance, Promotion and Advertising Policy Staff (HFZ-300) at (301) 594-4639. Other general information on your responsibilities under the Act, may be obtained from the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597.

Sincerely yours,

Lillian Yin

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