K 981669
1 of 2

JUN 4 1998

SECTION 9
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: May 11, 1998
- COMMON/USUAL NAMES: Hemorrhoidal Ligator, Esophageal Variceal Ligator
- TRADE/PROPRIETARY NAME: Speedband Superview Multiple Band Ligator
- CLASSIFICATION NAME & DEVICE CLASSIFICATION: Class II

Name	Number	21 CFR Ref.
Ligator, Homorrhoidal	78 FHN	876.4400

- DEVICE PANEL/BRANCH: Gastroenterology-Urology (GU)
  Gastro-Renal (GRDB)
- OWNER/OPERATOR: Boston Scientific Corporation
  One Boston Scientific Place
  Natick, MA 01760
- CONTACT PERSON: Lisa M. Quaglia, Regulatory Affairs Manager

DESCRIPTION OF DEVICE

The Microvasive *Modified Speedband* is a Multiple Band Ligator composed of two major components.

1. The Ligating Unit

The main component of the ligating unit is a cylinder which fits at the distal end of the endoscope. Elastic bands are stretched around the distal portion of the cylinder.

2. Handle Unit with Trip Wire and Scope Fastener

The main components of the Handle Unit is a plastic spool which turns only in the clockwise direction. A trip wire is attached to the plastic spool. When the plastic spool is rotated, the handle will make a distinct "click" sound, and one band will be fired automatically. The Handle Unit also incorporates a scope fastener to secure the handle onto the endoscope. An irrigation valve is located on the side of the Handle Unit.

INDICATIONS FOR USE

The Modified Speedband is indicated for use in endoscopic ligation of esophageal varices and anorectal hemorrhoids.

DESCRIPTIVE AND TECHNOLOGICAL CHARACTERISTICS OF PROPOSED AND PREDICATE DEVICES

Boston Scientific Corporation believes that the Modified Speedband is substantially equivalent to the currently-marketed Speedband. The major components of the Modified Speedband are the Ligating Unit and the Handle. A thorough comparison of the descriptive characteristics between the Modified Speedband and the currently-marketed Speedband show equivalence.

PERFORMANCE CHARACTERISTICS

Laboratory testing regarding characteristics was performed on the Modified Speedband to verify its safety and performance. A biocompatibility assessment was performed on the patient- and fluid-contact materials of the Modified Speedband with satisfactory results.

CONCLUSION

Boston Scientific Corporation believes that Modified Speedband is substantially equivalent to the currently-marketed Speedband. A comparison of the descriptive characteristics of these products demonstrate the Modified Speedband is equivalent in its indications for use, while being very similar in design and materials. In addition, Boston Scientific Corporation has performed laboratory testing and biocompatibility information. The information presented provides assurance that the Modified Speedband 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
9200 Corporate Boulevard
Rockville MD 20850

JUN 4 1998

Ms. Lisa M. Quaglia
Regulatory Affairs Manager
Boston Scientific Corporation
One Boston Scientific Place
Natick, MA 01760-1537

Re: K981669
Speedband Multiple Ligator
Dated: May 11, 1998
Received: May 12, 1998
Regulatory Class: II
21 CFR 876.4400/Procode: 78 FHN
78 MND

Dear Ms. Quaglia:

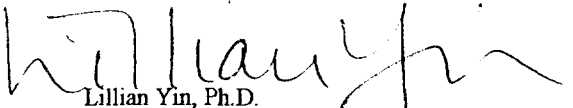
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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 requirements, 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/dsma/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

K981669

SECTION 1
INDICATIONS FOR USE

510(k) Number: To Be Determined

Device Name: Modified Speedband

Indication for Use:

The *Modified Speedband* is indicated for use in endoscopic ligation of esophageal varices and anorectal hemorrhoids.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Robert D Sattler

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K981669

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.1091)

(Optional Format 1-2-96)