K990864

JUN 11 1999

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: March 15, 1999
- 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: Abby Lipman, Senior Regulatory Affairs Specialist

DESCRIPTION OF DEVICE

The Microvasive *Modified Superview* 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.

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2. Handle Unit with Trip Wire and Scope Fastener

The main component 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 Superview is indicated for use in treatment of esophageal varicies utilizing combination ligation/injection therapy. The Modified Superview is indicated for band ligation treatment of anorectal hemorrhoids.

DESCRIPTIVE AND TECHNOLOGICAL CHARACTERISTICS OF PROPOSED AND PREDICATE DEVICES

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

PERFORMANCE CHARACTERISTICS

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

CONCLUSION

Boston Scientific Corporation believes that Modified Superview is substantially equivalent to the currently-marketed Superview. A comparison of the descriptive characteristics of these products demonstrate the Modified Superview 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 Superview 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 11 1999

Ms. Abby Lipman
Senior Regulatory Affairs Specialist
Boston Scientific Corporation
One Boston Scientific Place
Natick, Massachusetts 01760

Re: K990864
Speedband Modified Superview
Multiple Band Ligator
Regulatory Class: II
21 CFR §876.4400
Product Codes: 78 KHN/78 MND
Dated: March 15, 1999
Received: March 16, 1999

Dear Ms. Lipman:

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 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). You may, therefore, market the device, subject to the general controls provisions of the Act. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. *Please note*: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and 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, 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 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 the 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/dsma/dsmamain.html".

Sincerely yours,

CAPT Daniel G. Schultz, M.D.
Acting 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: Modified Superview

Indication for Use:

The Modified Superview is indicated for use in treatment of esophageal varicies utilizing combination ligation /injection therapy. The Modified Superview is indicated for band ligation treatment of anorectal hemorrhoids.

(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)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K990864

(Optional Format 1-2-96)