Boston Scientific
MICROVASIVE

APR 12 2002

Microvasive Endoscopy
Boston Scientific Corporation
One Boston Scientific Place
Natick, MA 01760-1537
508-650-8000
www.bsci.com

Section 9
510(k) Summary

510(K) SUMMARY

1. SUBMITTER:

Boston Scientific Corporation
One Boston Scientific Place
Natick, MA 01760

Contact: Kathleen Morahan, Regulatory Affairs Manager
Date Prepared: March 12, 2002

2. DEVICE:

Trade Name: Speedband™ Superview Super7
Injection Speedband™ Superview Super7

Common Name: Hemorrhoidal Ligator and Esophageal Variceal Ligator

Class: II

Classification Name: Ligator, Hemorrhoidal (78 FHN)
Ligator, Esophageal (78 MND)

3. PREDICATE DEVICE:

Modified Injection Speedband™ Superview

Modified Speedband™ Superview

4. DEVICE DESCRIPTION:

The Speedband Superview Super7 and Injection Speedband Superview Super7 consist of two main components: a ligating unit and a handle assembly. The ligating unit consists of a cylindrical housing with a flexible silicone endoscope adapter, and seven elastic ligating bands. Suture is threaded around each band and passes through suture slots around the perimeter of the housing. The suture enters the endoscope through the working channel of an endoscope and is secured the tripwire on the handle assembly durning set-up.

The handle assembly consists of a handle knob and plastic spool mounted on a bracket with a stem. A tripwire is attached to the spool and passes through the septum and into the stem. The stem fits into the working channel of the endoscope. The septum seals the channel so suction can be maintained. On the Injection models, the septum has a port for insertion of an injection therapy needle.

5. INTENDED USE:

The Speedband™ Superview Super7 is indicated for use in endoscopic ligation of esophageal varices and anorectal hemorrhoids.

The Injection Speedband™ Superview Super7 is indicated for endoscopic treatment of esophageal varices utilizing combination ligation/injection therapy. The Injection Speedband™ Superview Super7 is also indicated for band ligation treatment of anorectal hemorrhoids.

6. TECHNOLOGICAL CHARACTERISTICS:

The intended use and the materials are identical predicate devices. The proposed ligating unit contains seven bands whereas the predicate device has up to eight bands. Other minor housing and band modifications were made. The proposed and predicate device handle assemblies are the same except for an increase in the handle knob diameter and shape for ergonomics.

7. PERFORMANCE DATA:

Bench testing was conducted to aid with the establishment of substantial equivalence of the proposed devices to the predicate device.

8. CONCLUSION:

BSC has demonstrated that the Speedband Superview Super7 and the Injection Speedband Superview Super7 are substantially equivalent to the predicate devices.

510(k) Number: K020824

Device Name: Speedband™ Superview Super7

Indication for Use:

The Speedband™ Superview Super7 is indicated for use in endoscopic ligation of esophageal varices and anorectal hemorrhoids.

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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)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 12 2002

Ms. Kathleen Morahan
Manager, Regulatory Affairs
Microvasive Endoscopy
Boston Scientific Corporation
One Boston Scientific Place
NATICK MA 01760-1537

Re: K020824
Trade/Device Name: Injection Speedband™ Superview Super7™, Model 4238 and Speedband™ Superview Super7™, Model 4205
Regulation Number: 21 CFR 876.4400
Regulation Name: Hemorrhoidal ligator
Regulatory Class: II
Product Codes: 78 FHN and 78 MND
Dated: March 13, 2002
Received: March 14, 2002

Dear Ms. Morahan:

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

510(k) Number: K020824

Device Name: Injection Speedband™ Superview Super7

Indication for Use:

The Injection Speedband™ Superview Super7 is indicated for use in endoscopic treatment of esophageal varices utilizing combination ligation/injection therapy. The Injection Speedband™ Superview Super7 is also indicated for band ligation treatment of anorectal hemorrhoids.

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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)

David G. Segerson

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K020824