FEB - 8 2005

K050120

510 (k) SUMMARY

SPONSOR:
Boston Scientific Corporation
One Boston Scientific Place
Natick, MA 01760

CONTACT PERSON:
Michelle M. Berry
Regulatory Affairs Specialist

Or

Lorraine M. Hanley
Director Regulatory Affairs

DEVICE:
Trade Name: To Be Determined
Common Name: Biopsy Instrument
Classification: Class II, per 21 CFR Part 876.1075

PREDICATE DEVICE: Easy Core Biopsy System (K040893)

DESCRIPTION: The proposed device is designed to simultaneously fire a stylet followed by a cannula to capture a biopsy sample of soft organs, tumor or masses for histological analysis. The design includes a handle with a thumb tab activated drive mechanism, a side fire button, a rear fire button, and a cannula with a needle tip. The cannula may have marker bands spaced at 1 cm (10 mm) intervals starting from the stylet tip and extending various lengths depending upon the needle. When the device is fully loaded, the yellow indicator is visible when looking at the top of the handle.

INTENDED USE: The proposed device is indicated for use endoscopically or percutaneously to retrieve tissue sampling of soft organs, tumors or masses for histological analysis. Soft tissue sampling includes but not limited to organs such as breast, liver, kidney and prostate.

TECHNOLOGICAL CHARACTERISTICS: The intended use, design, operating principles and materials are similar to devices previously cleared via the 510(k) process.

PERFORMANCE DATA: Performance standards have not been established by FDA under Section514 of the Food, Drug and Cosmetic Act.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 8 2005

Boston Scientific Corporation
c/o Ms Michelle M. Berry
One Boston Scientific Place
NATICK, MA 01760 1537

RE: K050120
Trade/Device Name: Easy Core Biopsy System
Regulation Number: 21 CFR § 876.1075
Regulation Name: Gastroenterology-Urology Biopsy Instrument
Regulatory Class: II
Product Code: 78 FCG
Dated: January 14, 2005
Received: January 18, 2005

Dear Ms Berry:

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

INDICATIONS FOR USE STATEMENT

510(k) Number	To be determined
Device Name	To be determined (Biopsy Instrument)
Indications For Use	The proposed device is indicated for use endoscopically or percutaneously to retrieve tissue sampling of soft organs, tumors or masses for histological analysis. Soft tissue sampling includes but not limited to organs such as breast, liver, kidney and prostate.

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 801.109)

Nancy C. Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K050120