K992777

NOV 1 2 1999

Attachment 4
510(k) Summary

Category:	Comments
Sponsor:	Boston Scientific Corporation 2710 Orchard Parkway San Jose, CA 95134
Correspondent:	Steve Jwanouskos Senior Director, Regulatory Affairs and Quality Compliance 2710 Orchard Parkway San Jose, CA 95134
Contact Numbers:	Phone: 408.895.3529 Fax: 408.895.2202
Device Common Name	Electrode Recording and Pacing Catheter
Device Proprietary Name	Constellation® Multiple Electrode Recording and Pacing Catheter
Device Classification	Class II, 74 DRF
Predicate Device	Electrode Recording and Pacing Catheter
Predicate Device Manufacturer(s)	Boston Scientific/EP Technologies Inc.
Predicate Device Proprietary Name(s)	Constellation® Multiple Electrode Recording and Pacing Catheter
Predicate Device Classification Number	74 DRF
Predicate Device Classification(s)	21 CFR § 870.1220

Date Summary Was Prepared:

August 17, 1999

Description of the Device:

The Boston Scientific/EP Technologies (EPT) Constellation® Multiple Electrode Recording and Pacing Catheter is a sterile, single use device used to detect and record electrical potentials from the endocardial surfaces of the heart, and to deliver externally generated pacing stimuli. The distal, expandable "basket" assembly is, in essence, eight miniature octapolar "catheters". The basket assembly contains an array of 64 electrodes mounted along eight resilient support structures called "splines". Two configurations are available, unipolar (electrodes evenly spaced) and bipolar (electrodes evenly distributed into 32 pairs). EPT furnishes the Constellation® Catheter either with or without the

Duraflo® coating (Baxter CVG). EPT also furnishes accessories that include EPT Constellation Accessory Cables (sterile, re-useable), an EPT Constellation Pacing Switchbox (non-sterile, re-useable), and EPT Constellation extension cables (non-sterile, re-useable).

Intended Use:

The EP Technologies (EPT) Constellation® Multiple Electrode Catheter is used to detect and record electrical potentials from the endocardial surfaces of the heart, and to deliver externally generated pacing stimuli.

Technological Characteristics:

The basket assembly contains an array of 64 electrodes mounted along eight resilient support structures called "splines". The Constellation® Catheter is delivered to the right atrium using a Guiding Catheter. After proper position has been achieved, the Guiding Catheter is withdrawn allowing the basket assembly to expand and achieve intimate contact with the endocardium. The physician either connects the electrical connector of the catheter to an accessory pacing switchbox, or selects the output of cardiac electrograms according to the electrode, or electrode pair, of interest. Alternatively, the catheter may be connected to a commercially available EGM recorder or an external pulse wave generator. No new technology or circuitry is with the transmission of electrical signals to or from the endocardium -- the Constellation® Catheter relies on platinum-iridium alloy, ring electrodes (1.25mm in length) whose circuitry is identical to standard electrode and pacing catheters. Additionally, the electrical connections made are similar to those for commercially available electrode recording and pacing catheters.

Comparison to Predicate Device:

Predicate Device	Constellation® Catheter 48, 60 & 75 mm	38 mm Constellation® Catheter
510(k) Reference	K983171	Current Submission
Intended Use	Intracardiac electrophysiological mapping and or pacing	Same
Device Description	Multiple Electrode Mapping and Pacing Catheter	Same
Single Use?	Yes	Same
EO Sterilized?	Yes	Same
Manufacturer	BSC/EPT	Same
Device Classification	Class II / 74DRF 21 CFR 870.1220	Same

Summary of the Non-clinical Data:

Where appropriate, testing conformed to the requirements of 21 CFR Part 58 (Good Laboratory Practices (GLP). Specifically, non-clinical tests conducted for the EPT Mapping and Ablation System, included biocompatibility, sterility, in vivo performance, reliability, physical integrity, and electrical integrity testing.

Abstract of the Clinical Data:

As part of IDE G940162, used to support approved 510(k) K983171, the Constellation catheter was used in the right atrium in 116 patients. Twenty-five atrial patients received standard catheters. The complication rates for the atrial patients were 16% (17/116) for the Constellation Group and 14% (3/25) for the standard group.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 12 1999

Steve Jwanouskos
Senior Director, Regulatory Affairs
and Quality Compliance
Boston Scientific/EP Technologice, Inc.
2710 Orchard Parkway
San Jose, CA 95134

Re: K992777
Constellation Multiple Electrode Pacing and Recording System - 38mm (see attached list of model numbers)
Regulatory Class: II
Rroduct Code: MTD
Dated: August 17, 1999
Received: August 18, 1999

Dear Mr: Jwanouskos:

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 and the limitations described below. 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.

The Office of Device Evaluation has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must appear in the Warnings section of the device's labeling:

WARNING: The use of this device in conjunction with radiofrequency ablation, as part of the diagnosis and treatment of cardiac arrhythmias, may pose an increased risk of adverse events, such as cardiac perforation, myocardial infarction, air embolism, and hematoma requiring surgical repair and/or blood transfusion.

The Warning must be presented within a black box, and the font size of the text should be at least 2 points larger than any surrounding text. The Warning must be present on the first page of your Operator's Manual, and on the packaging for each individual device.

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.

The 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. This letter will allow you to begin marketing your device as described in your 510(k) premarket notification if the limitation statement above is added to your labeling, as described.

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

If you desire specific information about the application of other labeling requirements to your device (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. 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,

for David W. Feigal, Jr., M.D., M.P.H.
Acting Director
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosures

510(k) Number (if known): K992777

Device Name: Boston Scientific 38mm Constellation

Indications For Use:

"For use in right atrial electrophysiology procedures to assist in the diagnosis of complex arrhythmias that may be difficult to identify using conventional mapping systems alone (i.e., linear mapping catheters). The Constellation Multiple Electrode Recording and Pacing Catheter System may also be used for delivery of externally generated pacing stimuli."

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular, Respiratory, and Neurological Devices
510(k) Number K992777

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)