

MAY 16 2002

1002/232

**Attachment 4  
510(k) Summary**

<b>Category:</b>	<b>Comments</b>
<b>Sponsor:</b>	Boston Scientific Corporation 2710 Orchard Parkway San Jose, CA 95134
<b>Correspondent:</b>	Christina L. Rowe Associate II, Regulatory Affairs 2710 Orchard Parkway San Jose, CA 95134
<b>Contact Information:</b>	E-mail: <a href="mailto:rowec@bsci.com">rowec@bsci.com</a> Phone: 408.895.3526 Fax: 408.895.2202
<b>Device Common Name</b>	Catheter, Intracardiac, High Density Array
<b>Device Proprietary Name</b>	Constellation® Multiple Electrode Recording and Pacing Catheter
<b>Device Classification</b>	Class II, MTD
<b>Predicate Device</b>	Catheter, Intracardiac, High Density Array
<b>Predicate Device Manufacturer(s)</b>	Boston Scientific/EP Technologies Inc.
<b>Predicate Device Proprietary Name(s)</b>	Constellation® Multiple Electrode Recording and Pacing Catheter
<b>Predicate Device Classification Number</b>	MTD
<b>Predicate Device Classification(s)</b>	21 CFR § 870.1220

**Date Summary  
Was Prepared:**

April 17, 2002

**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 between 32 to 64 electrodes mounted along eight resilient support structures called "splines". Several configurations are available, including unipolar (electrodes evenly spaced), bipolar (electrodes evenly distributed into pairs), and lower density arrays. EPT furnishes the

Constellation® Catheter either with or without the Duraflo® coating. 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:**

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.

Additionally, all Constellation® Catheter Directions for Use (DFU) contain a boxed warning with text which is 2 points larger than the surrounding text.

The use of this device in conjunction with radiofrequency ablation, as part of the diagnosis and therapeutic treatment of atrial 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.

**Technological Characteristics:**

The modified Constellation® catheter features identical technological characteristics to currently approved Constellation® models under K983171, K992777, K000277, and K003782. The only new characteristic of the proposed Constellation® model 8031M is electrode spacing reduced from a range between 2 - 13mm to a range between 1 - 13mm.

**Comparison to  
Predicate  
Device:**

	<b>Constellation® Catheter 38, 48, 60 &amp; 75 mm</b>	<b>Modified Device</b>
510(k) Reference	K983171; K992777; K000277; K003782	Current Submission
Intended Use	Intracardiac electrophysiological mapping and or pacing	Same
Device Description	Multiple Electrode Mapping and Pacing Catheter	Same
Electrode Spacing	2 - 13 mm	1 - 13 mm
Single Use?	Yes	Same
EO Sterilized?	Yes	Same
Manufacturer	BSC/EPT	Same
Device Classification	Class II / MTD 21 CFR 870.1220	Same

**Summary of the  
Non-clinical  
Data:**

Performance testing with the new configuration demonstrated substantial equivalence with the predicate device. Specifically, non-clinical tests included electrical integrity testing.

**Abstract of the  
Clinical Data:**

Bench testing was sufficient to assess safety and effectiveness and, thus, to establish the substantial equivalence of the new configuration. Clinical data was therefore determined to be unnecessary.



MAY 16 2002

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Ms. Christina L. Rowe  
Associate II, Regulatory Affairs  
Boston Scientific Corporation  
2710 Orchard Parkway  
San Jose, CA 95134

Re: K021232

Trade Name: Constellation® Multiple Electrode Recording and Pacing Catheters System  
Regulation Number: 21 CFR 870.1220  
Regulation Name: Electrode Recording Catheter or Electrode Recording Probe  
Regulatory Class: Class II (two)  
Product Code: MTD  
Dated: April 17, 2002  
Received: April 18, 2002

Dear Ms. Rowe:

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). 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 in 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.

Page 2 - Ms. Christina L. Rowe

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.

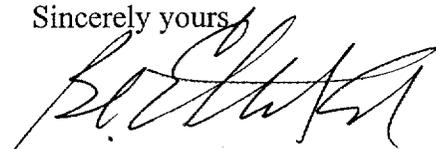
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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.

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 Section 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 Part 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 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,



Bernard E. Statland, M.D., Ph.D.  
Director  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

510(k) Number (if known): K021232

Device Name: Constellation® Multiple Electrode Recording and Pacing Catheters System

Indications For Use for device:

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 Catheters System may also be used for delivery of externally generated pacing stimuli.

Prescription Use X OR Over-The-Counter Use \_\_\_\_\_  
(Per 21 CFR 801.109)

  
Division of Cardiovascular & Renal Diseases  
510(k) Number K021232