



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 11 1999

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

Re: K983171

Trade Name: Constellation Multiple Electrode Pacing and
Recording System (see attached list of model
numbers)

Regulatory Class: II

Product Code: MTD - High density array intracardiac mapping
catheter

Dated: September 9, 1998

Received: September 10, 1998

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.

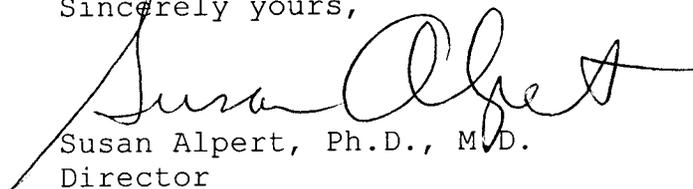
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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,

A handwritten signature in black ink, appearing to read "Susan Alpert". The signature is written in a cursive style with a long, sweeping underline that extends to the left.

Susan Alpert, Ph.D., M.D.
Director
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Device Description	Model Number
Constellation Catheters (Uncoated)	
48mm Constellation, unipolar, uncoated	8048 U
60mm Constellation, unipolar, uncoated	8060 U
75mm Constellation, unipolar, uncoated	8075 U
48mm Constellation, bipolar, uncoated	8048 BU
60mm Constellation, bipolar, uncoated	8060 BU
75mm Constellation, bipolar, uncoated	8075 BU
Constellation Catheters (Coated)	
48mm Constellation, unipolar, coated	8048 C
60mm Constellation, unipolar, coated	8060 C
75mm Constellation, unipolar, coated	8075 C
48mm Constellation, bipolar, coated	8048 BC
60mm Constellation, bipolar, coated	8060 BC
75mm Constellation, bipolar, coated	8075 BC
Sheaths	
Straight	961
Curved	960 7962
Pacing Switchbox	
Standard Switchbox	951
Cables	
Universal, primary	900
Universal, secondary	901A 901B
Single spline, primary	657
Single spline, secondary	626

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K983171

Device Name: Constellation © Multiple Electrode Recording and Pacing Catheter System, and Accessories

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 Mapping Catheter may also be used to deliver 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 K983171

Prescription Use X OR Over-The-Counter Use _____

Per 21 CFR 801.109)