K013349
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510(k) Summary of Safety and Effectiveness

Table 1 - Sponsor Information

Category:	Comments
Sponsor:	Boston Scientific Corporation 2710 Orchard Parkway San Jose, CA 95134
Correspondent:	Andrea L. Ruth, RAC Senior Associate, Regulatory Affairs 2710 Orchard Parkway San Jose, CA 95134
Contact Numbers:	Phone: 408.895.3625 Pager: 888.509.6375 Fax: 408.895.2202

Table 2 - Device Information

Device Common Name	Programmable Diagnostic Computer
Device Proprietary Name	Astronomer *Plus*™ with SLD
Device Classification Name	Programmable Diagnostic Computer
Device Classification	Class II DQK 21 CFR §870.1425
Predicate Devices	BSC/EPT Astronomer *Plus*™; Cardiac Pathways Arrhythmia Mapping and Tracking System; Biosense CARTO™ System; Endocardial Solutions EnSite 3000® System; Medtronic LocaLisa® Cardiac Navigation System
Predicate Device Reference(s)	K003362; K992912; K992968; K001437; K002869
Predicate Device Classification Name(s)	Programmable Diagnostic Computer
Predicate Device Classification(s)	Class II DQK 21 CFR §870.1425

Date Summary Was Prepared: October 5, 2001.

Description of the Device: This device is a data management system intended for use within a cardiac electrophysiology lab for the creation, maintenance, and review of patient files generated during a typical electrophysiology study to assist in the diagnosis of complex cardiac arrhythmias. The device consists of a workstation running proprietary software, and catheter interface.

Intended Use:

The Astronomer Plus™ System is a computerized system to assist in the diagnosis of complex cardiac arrhythmias. The Astronomer Plus™ System can be used to:

* Display the relative location of catheters during cardiac mapping procedures (used exclusively with the Constellation® Catheter);
* Route externally generated pacing stimuli and transmit cardiac electrogram (EGM) signals to electrophysiology recorders; and
* To document electrophysiological procedures which make use of the Constellation® Catheter.

Technological Characteristics: The Astronomer Plus System is an accessory for the Constellation Catheter. Its function and intended use are similar to several commercially available systems, such as Cardiac Pathways' Arrhythmia Mapping and Tracking System, Biosense's CARTO® System, and Endocardial Solutions' EnSite 3000. Like these other systems, the Astronomer *Plus*™ system is comprised of a catheter input box (the Switching & Locating Device) and a Computer, running a proprietary GUI (Astronomer *Plus*™). The system provides data to the physician obtained from the Constellation Catheter and a Roving (or auxiliary) Catheter (typically a quad catheter). The System has two window displays that simultaneously show: Constellation catheter orientation, roving catheter proximity indication, and user-defined markers. Additionally, the SLD routes signals received from the Constellation and Roving Catheters 1-to-1 to stand-alone EP recorders for acquisition, storage, and display purposes.

Summary of Testing Performed: Tests were performed both in vitro and in vivo to confirm safety and effectiveness. Further, conformance to several recognized standards is maintained.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 9 2002

Ms. Andrea L. Ruth
Senior Associate, Regulatory Affairs
Boston Scientific/EP Technologies, Inc.
2710 Orchard Parkway
San Jose, CA 95134

Re: K013349
Trade Name: Astronomer Plus™ System
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: II (two)
Product Code: DQK
Dated: January 16, 2002
Received: January 18, 2002

Dear Ms. Ruth:

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 such 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 Section 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 and additionally 21 CFR 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" (21CFR 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,

Donna-Bea Tillman, Ph.D.
Acting Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Intended Use Statement

510(k) Number (if known): K013349

Device Name: Astronomer *Plus*™ System

Indication for Use:

The Astronomer Plus™ System is a computerized system to assist in the diagnosis of complex cardiac arrhythmias. The Astronomer Plus™ System can be used to:

* Display the relative location of catheters during cardiac mapping procedures (used exclusively with the Constellation® Catheter);
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* Document electrophysiological procedures which make use of the Constellation® Catheter.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use_____

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Division of Cardiovascular & Respiratory Devices
510(k) Number K013349