AUG - 8 2003

510(K) SUMMARY

Category:	Comments
Sponsor:	Boston Scientific Corporation/EP Technologies, Inc. 2710 Orchard Parkway San Jose, CA 95134
Correspondent:	Ronald C. Allen, Ph.,D. Manager, Regulatory Affairs 2710 Orchard Parkway San Jose, CA 95134
Contact Numbers:	Phone: 408.895.3670 Fax: 408.895.2202 Email: allenr@bsci.com
Device Common Name	Pericardiocentesis Kit
Device Proprietary Name	PeriVac Kit
Device Classification	Class II
Predicate Device	Manfield PeriVac Kit
Predicate Device Manufacturer(s)	Mansfield, Boston Scientific Corporation
Predicate Device Proprietary Name(s)	Pericardiocentesis Kit
Predicate Device Classification(s)	Class II

Date Summary Was Prepared:

May 3, 2003.

Description of the Device:

The PeriVac Kit is a complete procedure tray for the purpose or pericardial aspiration and/or drainage. It contains the necessary components for site preparation, anesthesia, puncture, drainage, collection, and dressing.

Intended Use:

The PeriVac Kit is intended for use in pericardial aspiration and drainage in the presence of pericardial effusion or tamponade.

Comparison to Predicate Devices:

	Predicate Device	Modified Device
510(k) Reference	Pre-Amendment- Class II	TBD
Intended Use	Pericardial aspiration	Same
Device Description	Procedural Kit	Same
Single Use?	Yes	Same

	Predicate Device	Modified Device
EO Sterilized?	Yes	Same
Manufacturer	BSC/ EP Technologies	Same
Device Classification	Class II	Same

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 8 2003

Boston Scientific Corp.
c/o Dr. Ronald Allen
EP Technologies, Inc.
2710 Orchard Parkway
San Jose, CA 95134

Re: K032050
PeriVac Kit, models 4304, 4305, 4314, and 4315
Regulation Number: 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II
Product Code: DQX
Dated: June 30, 2003
Received: July 2, 2003

Dear Dr. Allen:

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 (the Act). You may, therefore, market the device, subject to the general controls provisions of Act. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit/tray. 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.

In addition, we have determined that your device kit contains 5 ml of 1% HCL Lidocaine which are subject to regulation as a drug.

Our substantially equivalent determination does not apply to the drug components of your device. We recommend you first contact the Center for Drug Evaluation and Research before marketing your device with the drug components. For information on applicable Agency requirements for marketing this drugs, we suggest you contact:

Director, Division of Drug Labeling Compliance (HFD-310)
Center for Drug Evaluation and Research
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857
(301) 594-0101

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, please contact the Office of Compliance at (301) 594-4648. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act 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/dsma/dsmamain.html

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INTENDED USE STATEMENT

510(k) Number:

Device Name: PeriVac Kit

Indication for Use:

The intended use of the subject kit remains the same as the pre-Amendment kit, and reads as follows:

The PeriVac Kit is intended for use in pericardial aspiration and drainage in the presence of pericardial effusion or tamponade.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IS NEEDED

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K032050

Prescription Use Only