JAN - 4 2000

K994252

510(k) Summary *[as required by 21 CFR 807.87(h)]*

Date Prepared: December 15, 1999

Sponsor:
Boston Scientific Corporation
2710 Orchard Parkway
San Jose, CA 95134
Telephone: (408) 895-3625
Contact: Andrea Boumis
Title: Regulatory Affairs Associate

Trade Name: n/a
Common Name: Intracardiac Introducing Sheath and Accessories
Classification Name: Catheter, Introducer
Classification: Class II-21 CFR 870.1340

Predicate Devices: Intracardiac Sheath

Device Description: The intracardiac introducing sheath and accessories consists of: (1) a disposable introducer sheath, (2) a vessel dilator and (3) guidewire.

The intracardiac introducing sheath consists of a braided shaft, a soft distal tip, and marker band. The sheath comes with either a Hemostasis valve or a luer fitting. The introducer sheaths are constructed in a range of curve reach configurations, diameters and lengths to respond to physician preferences. The introducer sheath configurations covered under the subject 510(k) Premarket Notification include 8.5F and 9.5F diameter, angles ranging form 0° - 180

Intended Use: The Boston Scientific/EP Technologies intracardiac introducing sheaths and accessories are designed to facilitate the intracardiac placement of interventional devices.

Technical Features: The intracardiac introducer sheath combines design features of marketed predicate devices. The design features of the subject device fall within ranges specified by the predicate devices. All the devices are open lumen through which other medical devices can be passed. Further, all predicate devices allow for sideports through which air can be aspirated, fluids can be infused, blood can be sampled, etc.

Performance Data: *In vitro* testing qualified the equivalence between the subject device and the predicate devices for the intracardiac deployment of devices and verified that no new safety or effectiveness issues. The type of testing is summarized below:

1. Biocompatibility testing on manufactured sheaths and dilators;
2. Sterilization validation of packaged units per ISO 11135 guidelines;

3. Reliability testing such as shipping, and accelerated aging of packaged units;
4. Tensile testing of the critical bond joints;
5. Rotational testing on the sheath to luer bond;
6. Leak, friction forces and insertions tests of the subject device in an *in vitro* setup;

Conclusions:

The results of the performance tests indicate that the intracardiac introducing sheath and accessories perform as well as the predicate devices. Any differences in testing outcome are not significant. Therefore, Boston Scientific Corporation/ EP Technologies concludes that the intracardiac introducing sheath and accessories is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Ms. Andrea Boumis
Regulatory Affairs Associate
Boston Scientific Corporation
2710 Orchard Parkway
San Jose, CA 95134

Re: K994252
Trade Name: Soft Tip Sheath Intracardiac Introducer with Accessories
Regulatory Class: II
Product Code: DYB
Dated: December 13, 1999
Received: December 17, 1999

Dear Ms. Boumis:

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. 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 (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

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.

This letter will allow you to begin marketing your device as described in your 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 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. 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/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure