FEB - 3 2009



## 5.0 510(k) Summary

### Modified Device Information

**Table 1: Modified Device Information**

| Category: | Comments: |
|---|---|
| Sponsor: | Boston Scientific Corporation<br>150 Baytech Drive<br>San Jose, CA 95134 |
| Correspondent: | Ronald C. Allen, Ph.D.<br>Director, Regulatory Affairs<br>150 Baytech Drive<br>San Jose, CA 95134 |
| Contact Information: | Email: allenr@bsci.com<br>Phone: (408) 935-6310<br>Fax: (408) 957-6202 |
| Device Common Name: | Electrode recording and pacing catheter; steerable catheter |
| Device Proprietary Name: | Blazer Dx-20 Diagnostic Catheter |
| Device Classification Number: | 21 CFR §870.1220 |
| Device Classification | Class II |

### Predicate Device Information

**Table 2: Predicate Device Information**

| Category: | Comments: |
|---|---|
| Predicate Device: | SteeroCath Dx Diagnostic Catheter (K940168/ K913375) |
| Predicate Device Manufacturer: | Boston Scientific Corporation |
| Predicate Device Common Name: | Electrode recording and pacing catheter; steerable catheter |
| Predicate Device Classification Number: | 21 CFR §870.1220 |
| Predicate Device Classification: | Class II |

**Date Summary Was Prepared**
June 4, 2008

**Description of the Device**

The Boston Scientific Corporation Blazer Dx-20 is a sterile, single use steerable diagnostic electrophysiology catheter used to record intracardiac electrical potentials. The Blazer Dx-20 Catheter is also used to deliver pacing stimuli from an external source. The Blazer Dx-20 Catheter is a bi-directionally steerable diagnostic catheter built on a modified SteeroCath Dx shaft platform with a molded handle. It has one tip electrode and up to 19 ring electrodes for a total of 20. The ring spacing configurations vary with each model.

The catheter shaft of the Blazer Dx-20 is equivalent to the SteeroCath Dx Catheter, which is designed to allow for a standard curve of the catheter distal section. The catheter shaft has a soft distal section in order to minimize trauma and risk of perforation.

The Blazer Dx-20 Catheters use a thumb-actuated bidirectional steering mechanism, contained within an ergonomically shaped cylindrical handle that is also utilized by the currently marketed SteeroCath Dx Diagnostic catheters. A thumb-level motion of the piston actuates the steering of the distal tip. The catheter is placed into the heart and is guided to location by steering the distal tip area of the catheter. Tip and ring electrodes come into contact with the endocardium where electrical contact is made and pacing and recording of electrograms becomes possible. No new technology or circuitry is associated with the transmission of electrical signals to or from the endocardium – the Blazer Dx-20 Catheter relies on platinum-iridium alloy, ring electrodes whose circuitry is identical to standard electrode and pacing catheters. Additionally, the electrical connections made (catheter to EP recorder) are similar to those for commercially available electrode recording and pacing catheters.

**Intended Use**

The Blazer Dx-20 Catheter is intended for temporary use in electrophysiology studies for intracardiac stimulation (pacing) and/or recording of electrical potentials.

**Comparison to Predicate Device**

**Table 3: Comparison to Predicate Device**

| | **Predicate Device** | **Subject Device** |
|---|---|---|
| Manufacturer | Boston Scientific Corporation | Same |
| Device Description | Electrode Recording Catheter; Steerable Catheter | Same |
| 510(k) Reference | K940168<br>K913375 | Current Submission |
| Regulatory Class | II | Same |
| Device Classification | 21 CFR §870.1220 | Same |
| Intended Use | Record electrical potentials and pacing from intracardiac locations | Same |
| Single Use? | Yes | Same |
| EO Sterilized? | Yes | Same |

**Summary of the Non-clinical Data**

Specifically, non-clinical tests adopted by and conducted for the Blazer Dx-20 Catheter included biocompatibility, sterility, packaging, physical integrity, and electrical integrity testing that all passed and have shown substantial equivalence to the predicate device, the SteeroCath Diagnostic Catheter.

**Abstract of the Clinical Data**

As the non-clinical tests demonstrated the safety and effectiveness of the device, no clinical studies were conducted for the Blazer Dx-20 Catheter.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 3 2009

Boston Scientific Corporation
c/o Ms. April Malmborg
Principal Regulatory Affairs Specialist
150 Baytech Drive
San Jose, CA 95134

Re: K081576
Trade/Device Name: Blazer Dx-20 Diagnostic Catheter
Regulation Number: 21 CFR 870.1220
Regulation Name: Electrode Recording Catheter or Electrode Recording Probe
Regulatory Class: Class II (two)
Product Code: DRF
Dated: December 19, 2008
Received: December 22, 2008

Dear Ms. Malmborg:

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), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

# Indications for Use

510(k) Number (if known): K081576

Device Name: Blazer Dx-20 Diagnostic Catheter

Indications For Use: The Blazer Dx-20 is a diagnostic catheter indicated for temporary use in electrophysiology studies for intracardiac stimulation (pacing) and/or recording of electrical potentials.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(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 Devices
510(k) Number K081576