K992373

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VI. 510(k) SUMMARY FOR THE ORBITER ST DIAGNOSTIC ELECTRODE CATHETER AND ORBITER ST EXTENSION CABLE

This 510(k) Summary of Safety and Effectiveness is being submitted in accordance with the requirements of the Safe Medical Devices Act of 1990.

A. Submitter's Information

Name:	C.R. Bard, Inc.
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Phone:	(978) 323-2216 (Direct Line)
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Contact Person:	Deborah L. Herrington Regulatory Affairs Manager
Date of Preparation:	July 14, 1999

B. Device Name:

Trade Name:	Orbiter ST Diagnostic Electrode Catheter
Common/Usual Name:	Electrode Recording Catheter
Classification Name:	Electrode Recording Catheter

C. Predicate Device Name(s):

Viking Diagnostic Electrode Catheter
Bard EP•XT Electrode Catheter
Bard Woven Electrode Catheter
Cordis Webster Electrophysiology Catheter

D. Device Description/Indications for Use:

Description
The Orbiter ST Diagnostic Electrode Catheter is a closed lumen, steerable device. Typical of electrode recording catheters currently sold, the Orbiter ST catheter will be offered in 7F diameter with 2-20 electrodes with a variety of inter-electrode spacings and curve styles.

Indications:
Bard Electrophysiology's steerable diagnostic electrode catheters are intended for temporary intracardiac sensing, recording, stimulation and temporary pacing during the evaluation of cardiac arrhythmias.

An accessory to the Orbiter ST Diagnostic Electrode Catheter, the Orbiter ST Extension Cable will be sold separately. The Orbiter ST catheter will be labeled that it is to be used with this cable (see Section V for proposed box and pouch labels). This cable will have the following indications (reference Information For Use in Section V):

Indications:

The Orbiter ST extension cable is indicated for use during electrophysiology studies in conjunction with the appropriate electrode catheter. This cable may be reused subject to the cleaning and sterilization restrictions herein.

E. Technological Characteristics/Performance Data Summary

The "510(k) Substantial Equivalence Decision-Making Process (Detailed)" decision tree (CDRH 510(k) Manual 92-4158) was utilized in conjunction with the technological characteristics and performance testing results to make a determination of substantial equivalence as follows:

1. **Does New Device Have Same Indication Statements?**

Yes. The indications for the Orbiter ST catheter are the same as those for the Viking catheter; they are diagnostic electrode catheters intended for temporary intracardiac sensing, recording, stimulation and temporary pacing during the evaluation of cardiac arrhythmias.

2. **Does New Device Have Same Technological Characteristics, e.g., Design, Materials, etc.?**

No. Although the Orbiter ST catheter has similar technological characteristics to the Viking catheter as shown in Table IV-1 (Section IV), they are not identical. The Orbiter ST catheter utilizes some materials that are not used for the construction of the Viking catheter. Some of these materials are used in the construction of various other catheters, currently sold, with similar indications for use. The successful results of biocompatibility and performance testing demonstrate that the use of the different materials do not have an adverse impact upon the device (see summary in Section III and results in Appendix 1 for the biocompatibility testing; see summary in Section IV and results in Appendix 2 for the performance testing).

3. **Could the New Characteristics Affect Safety or Effectiveness?**

Yes. Although the use of different materials could affect safety and effectiveness, successful biocompatibility testing demonstrates that the blood contacting materials used in the construction of the Orbiter ST catheter are nontoxic and biocompatible (see summary in Section III and results in Appendix1). Also, *in vitro* bench testing conducted on the Orbiter ST catheter demonstrates that the device meets the requirements of the specified performance testing (see summary in Section IV and results in Appendix 2 for the performance testing).

4. **Do the New Characteristics Raise New Types of Safety or Effectiveness Questions?**

No. The use of different materials do not raise new types of safety or effectiveness questions. This has been demonstrated through successful biocompatibility and testing and *in vitro* bench testing. (see summary in Section III and results in Appendix 1 for the biocompatibility testing; see summary in Section IV and results in Appendix 2 for the performance testing).

5. Do Accepted Scientific Methods Exist for Assessing Effects of the New Characteristics?

Yes. The Orbiter ST catheter (or a device containing the same blood contacting materials) was tested for safety and performance based on the required characteristics of electrode recording catheters as discussed in Section IIID, Principles of Operation. Tests were chosen and developed based on the 1995 Draft Guidance and through previous experience with the Viking catheter 510(k). A summary of this testing is provided in Part C below. Results for this testing may be found in Appendix 2. A copy of the checklist to the 1995 Draft Guidance, with references to the appropriate locations where each element of the guidance is discussed, is included in Appendix 2.

In addition, as previously mentioned, the Orbiter ST catheter (or a device containing the same blood contacting materials) was subjected to biocompatibility testing (see summary in Section III and results in Appendix 1).

6. Are Performance Data Available to Assess Equivalence?

Yes. Performance data are available to demonstrate equivalence to the Viking catheter or other commercially available devices with similar indications for use (see summary in this Section IV and results in Appendix 2).

7. Do Performance Data Demonstrate Equivalence?

Yes. The performance of the Orbiter ST catheter was found to meet all testing acceptance criteria and was therefore acceptable. In addition, as mentioned previously, the Orbiter ST catheter (or a device containing the same blood contacting materials) passed all tests of biocompatibility.

A summary of the safety and performance testing may be found in Section IV. Detailed protocols and results may be found in Appendix 2.

See summary in Section III and results in Appendix 1 for the biocompatibility testing; see summary in Section IV and results in Appendix 2 for the performance testing.

SUBSTANTIALLY EQUIVALENT DETERMINATION:

Based on the decision tree found in Section IV, Figure IV-1 and results of safety and performance testing, the Orbiter ST catheter is substantially equivalent to currently marketed devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 5 1999

Deborah L. Herrington
Regulatory Affairs Manager
Bard Electrophysiology Division
C.R. Bard. Inc.
55 Technology Drive
Lowell, MA 01851

Re: K992373
Orbiter™ ST Steerable Electrode Catheter
Regulatory Class: II (two)
Product Code: DRF
Dated: October 14, 1999
Received: October 29, 1999

Dear Ms. Herrington:

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 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) 594-4648. 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 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,

for

Celia M. Witten, Ph.D., M.D.
Acting Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

D. INDICATIONS FOR USE

Device Name: Orbiter ST Diagnostic Electrode Catheter

Indications for Use:

Bard Electrophysiology's steerable diagnostic electrode catheters are intended for temporary intracardiac sensing, recording, stimulation and temporary pacing during the evaluation of cardiac arrhythmias.

Contraindications:

The transseptal approach is contraindicated in patients with left atrial thrombus or myxoma, or interatrial baffle patch. The retrograde transaortic approach is contraindicated in patients with aortic valve replacement.

An accessory to the Orbiter ST Diagnostic Electrode Catheter, the Orbiter ST Extension Cable will be sold separately. The Orbiter ST catheter will be labeled that it is to be used with this cable (see Section V for proposed box and pouch labels). This cable will have the following indications (reference Information For Use in Section V):

Indications:

The Orbiter ST extension cable is indicated for use during electrophysiology studies in conjunction with the appropriate electrode catheter. This cable may be reused subject to the cleaning and sterilization restrictions herein.

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K992373

Prescription Use ✓ OR Over-the-Counter Use _____
(Per 21 CFR 801.109)