C.R. Bard, Inc.
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K971265

BARD

OCT 23 1997

510(k) SUMMARY FOR THE VIKING DIAGNOSTIC ELECTRODE CATHETER

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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Contact Person:	Douglas E. Ferguson, Senior Regulatory Affairs Coordinator
Date of Preparation:	March 31, 1997

B. Device Name:

Trade Name:	Viking Diagnostic Electrode Catheter
Common/Usual Name:	Electrode Recording Catheter
Classification Name:	Electrode Recording Catheter

C. Predicate Device Name(s):

Cordis Webster Electrophysiology Catheter
Bard Woven Electrode Catheter

D. Device Description/Indications for Use:

Description

The Viking Diagnostic Electrode Catheter is a closed lumen, non-steerable device. Typical of electrode recording catheters currently sold, the Viking catheter will be offered in 6F diameter with 2-10 electrodes with a variety of inter-electrode spacings and curve styles.

Indications:

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

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. Although the indications for the Viking catheter are more detailed than those of the Cordis Webster catheter, the uses of these devices are the same; they are to be used during the evaluation of cardiac arrhythmias for electrophysiological mapping of cardiac structures. The longer description in the indications for the Viking catheter identifies standard uses of diagnostic electrode catheters which are also contained in the indications for the currently sold preamendment Bard Woven electrode catheters and are referred to in the indications and instructions for use in the Bard® Steerable catheters (K921872; later referred to as the EP•XT™ catheters) and the Bard® Dynamic Tip and Tip Deflecting catheters (K891908, K904080, and K912213).

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

   No. Although the Viking catheter has similar technological characteristics and component materials, they are not identical.

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

   No. The only technological difference is in electrode width. However, since the distal and proximal electrode widths of the Viking catheter are within the range of those of the predicate devices, this is not an issue. Differences in materials are minor, such as the use of different colorants. Although these minor material differences are unlikely to affect safety, biocompatibility was verified through testing.

4. **Are the Descriptive Characteristics Precise Enough to Ensure Equivalence?**

   No. Although the materials and technological characteristics are very similar, differences between vendors and manufacturing techniques necessitate bench testing to confirm equivalence.

5. **Are Performance Data Available to Assess Equivalence?**

Yes. The Viking catheter was tested for safety and performance based on the required characteristics of electrode recording catheters. Tests were chosen and developed based on the March, 1995 Draft Version of the "Electrode Recording Catheter Preliminary Guidance, Data to be Submitted to the Food and Drug Administration in Support of Premarket Notifications." Where appropriate, comparative testing was done using the Cordis Webster catheter and/or a Bard Woven electrode catheter. In addition, as previously mentioned, the Viking catheter was subjected to biocompatibility testing.

6. **Do Performance Data Demonstrate Equivalence?**

Yes. The performance of the Viking catheter was found to meet all testing acceptance criteria and was therefore clinically acceptable. Where comparative testing was conducted, the Viking catheter performance was equivalent to, better than, or between the performances of the Cordis Webster and Bard Woven electrode catheters or the performance was determined to be clinically acceptable in every case. The Viking catheter passed all tests of biocompatibility.

SUBSTANTIALLY EQUIVALENT DETERMINATION:

The Viking Catheter is substantially equivalent to currently sold electrode recording catheters.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20856

OCT 23 1997

Mr. Douglas E. Ferguson
C. R. Bard, Inc.
129 Concord Road
P.O. Box 566
Billerica, Massachusetts 01821

Re: K971265
Trade Name: Viking Diagnostic Electrode Catheters (38 models) and SureLink Extension Cables (8 models)
Regulatory Class: II
Product Code: 74DRF
Dated: July 24, 1997
Received: July 28, 1997

Dear Mr. Ferguson:

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 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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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" (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,

Thomas J. Callahan

Thomas J. Callahan, Ph.D.
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: Viking Diagnostic Electrode Catheter

Indications for Use:

Bard Electrophysiology's fixed curve 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.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Summerour for Tom Callahan

(Division Sign-Off)
Division of Cardiovascular, Respiratory, and Neurological Devices
510(k) Number K971265

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Division o
and Neurological
510(k) Number

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