

MAY 15 1998

K980575

C.R. Bard, Inc.
Regulatory Affairs
129 Concord Road
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Billerica, MA 01821
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VI. 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990.

A. Submitter Information:

Name: Bard Cardiology Div. of C.R. Bard, Inc.
Address: 129 Concord Road, Billerica, MA 01821
Phone: (978) 667-2511 extension 4490
Fax: (978) 667-8594
Contact Person: Victoria A. Brunelle
Regulatory Affairs Coordinator
Date of Preparation: February 13, 1998

B. Device Name

Trade Name: Bard® 4F SiteSeer™ Angiographic Cardiovascular Catheter
Common Name: Cardiovascular Angiographic Catheter
Classification Name: Diagnostic Intravascular Catheter/Percutaneous Catheter

C. Predicate Device Name(s):

1. Cordis Infiniti™ Angiographic Catheter
2. Cordis Super Torque™ Catheter
3. Bard Envision™ Catheter
4. Bard Pro-Flo™ Catheter
5. Namic Selector™ Catheter

D. Device Description

The 4F SiteSeer catheter is an intravascular diagnostic catheter for use in the cardiovascular system.

E. Intended Use

Intravascular diagnostic catheters are used to record intracardiac pressures, to sample blood, and to introduce substances into the heart and vessels.



VI. 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION (CONT.)

F. Technological Characteristics The Bard Cardiology 4F SiteSeer Angiographic Catheter is similar to the Envision Angiographic catheters regarding materials and construction, packaging, and sterilization.

The indications for use are similar to both the Cordis catheters and the Bard Cardiology Angiographic catheters. They are all indicated to deliver media or substances into the vascular system. The actual indications are listed below:

The Bard 4F SiteSeer is indicated for use in the cardiovascular system. Their primary function is to record intracardiac pressures, to sample blood, and to introduce substances into the heart and vessels.

The Cordis Infiniti indications are designed to deliver radiopaque contrast media to selected sites in the vascular system.

Similar to the Cordis catheters, the Bard SiteSeer catheter will be available in 4 French size, and will be offered in various curve styles.

G. Performance Data

Safety and performance testing was performed to demonstrate that the Bard SiteSeer Angiographic Catheter is substantially equivalent to the predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

MAY 15 1998

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Victoria Brunelle
Regulatory Affairs Coordinator
C.R. Bard, Inc.
Regulatory Affairs
129 Concord Road
P.O. Box 566
Billerica, MA 01821

Re: K980575
BARD® 4F SiteSeer™ Angiographic Catheter
Regulatory Class: II (Two)
Product Code: 74 DQO
Dated: February 13, 1998
Received: February 17, 1998

Dear Ms. Brunelle:

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 (Pre-market 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.

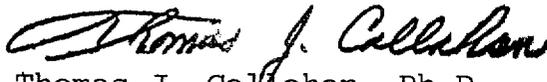
Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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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/dsma/dsmamain.html>."

Sincerely yours,



Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular, Respiratory,
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

D. INDICATIONS FOR USE

Device Name: BARD® 4F SiteSeer™ Angiographic Catheter

Indications for Use: An intravascular diagnostic catheter is a device used to record intracardiac pressure, to sample blood, and to introduce substances into the circulatory system.

Contraindications: None

Concurrence of CDRH, Office of Device Evaluation (ODE)

Tu A. R.

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K980575

Prescription Use X
(Per 21 CFR 801.109)

OR Over-the-Counter Use _____