

OCT 14 1998

C.R. Bard, Inc.
Regulatory Affairs
129 Concord Road
P.O. Box 566
Billerica, MA 01821
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K974713



SECTION 6.0 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

As required under Section 12, part (a)(I)(3A) of the Safe Medical Device Act of 1990, an adequate summary of any information respecting safety and effectiveness follows.

General Information

- ◆ **Submitter Information:**
 - Name: C.R. Bard, Inc.
 - Address: 129 Concord Road, Billerica, MA 01821
 - Phone: (978) 667-2511 extension 4131
 - Fax: (978) 667-8594

- ◆ **Contact:**
 - Fred Boucher
 - Regulatory Affairs Manager

- ◆ **Date of Summary:**
 - December 16, 1997

- ◆ **Name of Device:**
 - Bard® Hydrophilic Coated Guide Wire

- ◆ **Common/Usual Name of Device:**
 - Catheter Guide Wire

- ◆ **Device Classification:**
 - 21 CFR 870.1330

- ◆ **Predicate Device(s):**
 - Bard® Preamendment Angiographic Guide Wires
 - Bard® PTCA Steerable Standard Guide Wire
 - Bard® Silk™ Guide Wire
 - Terumo Glidewire™

- ◆ **Description and Intended Use of Device:**

The Bard Hydrophilic Coated Guide Wire is a guide wire that is designed to fit inside a percutaneous catheter for the purpose of directing the catheter through a blood vessel. They may be used for the introduction and placement of diagnostic or interventional devices in the coronary and peripheral vasculature and may be used to reach and cross a target lesion.

Hydrophilic Coated Angiography Guide Wires are indicated for use for percutaneous entry into a vessel using the Seldinger technique. Hydrophilic Coated Angioplasty (PTCA) Guide Wires are steerable guidewires that are used for the introduction and placement of diagnostic or interventional devices in the coronary and peripheral vasculature and may be used to reach and cross a target lesion.

- ◆ **Technological Characteristics Summary:**

The Bard Hydrophilic Coated Guide Wire is similar to the Terumo Glidewire regarding materials and construction, and is similar to Bard Silk Guide Wires, Bard Angiography Guide Wires and Bard PTCA Steerable Standard Guide Wire regarding materials and construction, packaging and sterilization. The indications for use are similar to both Terumo Glidewire and the Bard Guide Wires. They are all indicated for the introduction and placement of diagnostic or interventional devices in the coronary and peripheral vasculature and may be used to reach and cross a target lesion.

- ◆ **Performance Data:**

Safety and performance testing was performed to demonstrate that the Bard Hydrophilic Coated Guide Wire is substantially equivalent to the predicate devices.



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Fred L. Boucher
Regulatory Affairs Manager
Bard Cardiology Division
C.R. Bard, Inc.
129 Concord Road
P.O. Box 566
Billerica, MA 01821

Re: K974713
Trade Name: Bard® Hydrophilic Coated Guide Wires
Regulatory Class: II
Product Code: DQX
Dated: July 16, 1998
Received: July 16, 1998

Dear Mr. Boucher:

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.

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) 594-4586. 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,



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

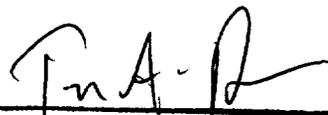
Device Name: Hydrophilic Coated Guide Wire

Indications for Use: Hydrophilic Coated Angiography Guide Wires are indicated for use for percutaneous entry into a vessel using the Seldinger technique.

Hydrophilic Coated Angioplasty (PTCA) Guide Wires are steerable guidewires that are used for the introduction and placement of diagnostic or interventional devices in the coronary and peripheral vasculature and may be used to reach and cross a target lesion.

Contraindications: None

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K974713

Prescription Use X
(Per 21 CFR 801.109)

OR Over-the Counter Use _____