Bard Electrophysiology
C.R. Bard, Inc.
55 Technology Drive
Lowell, MA 01851
(978) 441-6202
www.BardEP.com

K082094

BARD

DEC 17 2008

5. 510(k) Summary or 510(k) Statement

510(k) SUMMARY

This 510(k) Summary is provided per the requirements of section 807.92(c).

Owner Name: Bard Electrophysiology Division of C.R. Bard, Inc.

Address: 55 Technology Drive
Lowell, MA 01851

Phone Number: 978-323-2216

Fax Number: 978-323-2222

Contact Person: Deborah L. Herrington
Manager, Regulatory Affairs
Email address: deborah.herrington@crbard.com

Alternate Contact: Julie Broderick
Vice President, RA/CA
PH: 978-323-2220
FX: 978-323-2222
Email address: julie.broderick@crbard.com

Date of Summary: July 22, 2008

Device Trade Name: PTFE (Teflon®) Coated Guide Wires

Device Common Name: Guide Wires

K082094

Classification Name: Class II, Catheter, Guide Wire (21 CFR 870.1330, Product Code DQX)

Predicate Device(s): Bard Preamendment Guide Wires

Bard (U.S.C.I.) TRC Stainless Steel Safety Spring Guides K772021

Bard (U.S.C.I.) TRC Teflon Coated Safety Spring Guides K780438

The Bard PTFE (Teflon®) Coated Guide Wires, covered under this 510(k) Premarket Notification are substantially equivalent, in terms of intended use, materials of construction, technological characteristics, and principles of operation, to the predicate devices for facilitating the delivery of other devices per the indications for use included in this 510(k).

Device Description: The Bard PTFE (Teflon®) coated guide wires, subject of this 510(k), like their predicate device counterparts, are manufactured from stainless steel wire, tin/silver solder, and PTFE (Teflon®) coating, or Benzalkonium Heparin (BH) coating applied over the PTFE (Teflon®) coating. The guide wire construction consists of a safety wire, a core wire, and a wound spring for flexibility. The features that distinguish individual wires consist of the core type (fixed or moveable), a straight or "J" tip configuration, diameters, lengths, and coating types. Each guide wire is subsequently packaged, labeled, and sterilized.

There is no change between the Bard PTFE (Teflon®) Coated Guide Wires, subject of this 510(k), and their predicate device counterparts with respect to: materials of construction, manufacturing, packaging, labeling, or sterilization. The only difference is the suppliers process change relating to environmental concerns to perfluorooctanoic acid (PFOA), a substance used as a processing aid in the manufacture of Teflon®. There is no change to the actual Teflon® material itself.

Substantial Equivalence: The Bard PTFE (Teflon®) Coated Guide Wires, subject of this 510(k), are substantially equivalent to the predicate devices. There is no change to the indications for use, no change to the principles of operation, no change to the materials of construction (only a reduction in residual PFOA and a change to the surfactant of the PTFE coating, both of which are both burned off during the furnace cure, and therefore, not part of the Bard finished guide wires), and technological characteristics of the guide wires support a determination of substantial equivalence.

Technological Characteristics: The Bard PTFE (Teflon®) coated guide wires, subject of this 510(k), are substantially equivalent to the Predicate Devices. The only difference is the supplier's process change relating to environmental concerns to perfluorooctanoic acid (PFOA), a substance used as a processing aid in the manufacture of Teflon® (consisting of a reduction in residual PFOA and a change to the surfactant, both of which are both burned off during the furnace cure, and therefore, not part of the Bard finished guide wires). As stated above, there is no change to the actual Teflon® material itself. Therefore, the technological characteristics of the guide wires subject of this 510(k), are the same as their predicate devices.

The Bard process for applying and curing the PTFE coating remains unchanged. The performance specifications for the Bard guide wires, subject of this 510(k), remain the same as their Predicate Device counterparts.

Intended Use of Device: See individual indications for use statements below.

Device Name: Bard PTFE (Teflon®) Coated Guide Wires

Indications for Use:
Bard Guide Wires Indication: Bard PTFE Coated Guide Wires are indicated for percutaneous entry of a guiding catheter into a vessel using standard percutaneous methods (Seldinger's Technique). Generally, Guide Wires which are 100cm or longer are indicated for use with vascular catheters and balloon dilatation catheters in angiographic or interventional procedures. The guide wire may be inserted through an

[18g] needle, introducer, or catheter. A guide wire with an outer diameter of .018" or smaller may be used with open ended guide wires.

Guide wires which are shorter than 100cm are generally indicated for non-vascular use. Guide wires with an outer diameter of .018" or smaller may be inserted into the target organ through a [22g] needle or an open-ended guide wire (60cm or shorter), Larger guide wires may be inserted through larger gauge needles or an introducer for placement of dilators and/or drainage catheters.

Principles of Operation: A guide wire may be pre-loaded into a catheter to facilitate atraumatic insertion into and advancement through a vein or artery, or for other percutaneous access. A guide wire may also be used at the site of initial introduction into the vasculature through a needle.

Test Data: The Bard PTFE (Teflon®) Coated Guide Wires were subjected to the following testing:

1. Biocompatibility Testing – The modified PTFE coating was anticipated to have no effect on the biocompatibility profile of the final guide wires. However, to ensure that these guide wires meet the current biocompatibility requirements, testing of the Bard PTFE (Teflon®) coated guide wires was performed according to the requirements of the International Standard ISO 10993, "Biological Evaluation of Medical Devices Part-1: Evaluation and Testing" and the FDA-modified testing matrix included in the ODE May 1, 1995 General Program Memorandum #G95-1. Testing categories included: cytotoxicity, sensitization, intracutaneous reactivity, acute systemic toxicity, hemocompatibility, and material mediated pyrogen testing. The biocompatibility testing demonstrated that the Bard guide wires with the modified PTFE (Teflon®) coating process are nontoxic and biocompatible.
2. Inhibition/Enhancement Testing and Product Endotoxin Testing per the Gel Clot Method was conducted on representative samples manufactured with the "new" (replacement Teflon® material) coating and were found to be acceptable.
3. The replacement Teflon® Primer was inspected to the raw material (RM) specification, it was used to mix the Primer Spray, the Primer Spray was applied to representative products to confirm acceptable processing over the applicable

range of processing conditions and product constructions, and inspection and testing was conducted to demonstrate the coated products are acceptable.

4. Testing was conducted with representative guide wire items to demonstrate that the replacement material works acceptably for its intended function over the range of applicable processing conditions and product constructions with respect to the coating application itself and the appearance of the coating. The parameters selected for bench testing where chosen based on their impact on the coating process. As the parameters within the coating process portion of the device manufacture did not change (i.e., oven cure time and temperature), guide wire stiffness, tensile and torque are not affected. Testing consisted of comparing samples manufactured from the replacement coating to samples manufactured with the current coating and performing coefficient of friction (COF) testing pre and post lubricity testing. Coating durability was confirmed via "flex" and "fracture" testing.

5. In addition to the inspections and testing outlined above, a USP Physiochemical analysis and a FTIR analysis was conducted to compare the current PTFE (Teflon®) coating (850-604) to the replacement PTFE (Teflon®) coating (850N-604). The replacement material meets the requirements of the USP Physiochemical analysis testing and the FTIR analysis indicates no discernable difference in chemical identity of the proposed finished coating from the current finished coating.

Applicability of Performance Standards: Bard has determined that no mandatory performance standards have been established for the devices under Section 514 of the Medical Device Amendments to the Federal Food, Drug, and Cosmetic Act or by subsequent regulatory action. Bard has determined that there are no applicable voluntary standards.

Conclusion: The results of the testing outlined above, consisting of biocompatibility, inhibition/enhancement, and LAL testing; demonstrates that the Bard PTFE (Teflon®) Coated Guide Wires manufactured with the replacement Teflon® material are:

- biologically safe,
- non-pyrogenic,
- have no inhibition or enhancement effects upon the lysate reaction, and
- have no discernable difference in chemical identity

Additionally, evaluation of the coating application; inspection of the coated product; bench testing; and physiochemical and FTIR analysis demonstrates that the Bard PTFE (Teflon®) Coated Guide Wires manufactured with the replacement Teflon® material:

- met the performance requirements with respect to the parameters that would be impacted by the coating consisting of coefficient of friction pre and post lubricity testing, and
- coating durability as demonstrated through "flex" and "fracture" testing.

Therefore, the replacement Teflon® material used in the manufactured of the guide wires covered under this 510(k) is substantially equivalent to the Teflon® material used in the manufacture of the predicate devices. And, the Bard PTFE (Teflon®) Coated Guide Wires manufactured with the replacement Teflon® material, subject of this 510(k), are substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Bard Electrophysiology
c/o Ms. Deborah L. Herrington
Manager, Regulatory Affairs
55 Technology Drive
Lowell, MA 01851

DEC 17 2008

Re: K082094
Trade/Device Name: Bard PTFE (Teflon®) Coated Guide Wires
Common Name: Wire, Guide, Catheter
Regulation Number: 21 CFR 870.1330
Regulatory Class: II
Product Code: DQX
Dated: December 4, 2008
Received: December 5, 2008

Dear Ms. Herrington:

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

4. Indications for Use Statement

Indications for Use

510(k) Number (if known):

Device Name: Bard PTFE (Teflon®) Coated Guide Wires

Indications for Use:
Bard Guide Wires Indication: Bard PTFE Coated Guide Wires are indicated for percutaneous entry of a guiding catheter into a vessel using standard percutaneous methods (Seldinger's Technique). Generally, Guide Wires which are 100cm or longer are indicated for use with vascular catheters and balloon dilatation catheters in angiographic or interventional procedures. The guide wire may be inserted through an [18g] needle, introducer, or catheter. A guide wire with an outer diameter of .018" or smaller may be used with open ended guide wires.

Guide wires which are shorter than 100cm are generally indicated for non-vascular use. Guide wires with an outer diameter of .018" or smaller may be inserted into the target organ through a [22g] needle or an open-ended guide wire (60cm or shorter), Larger guide wires may be inserted through larger gauge needles or an introducer for placement of dilators and/or drainage catheters.

Contraindications: None

Prescription Use __X__ Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) AND/OR (21 CFR 801 Subpart C)
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K052094