K122367

Bard PTV Dilatation Catheter

NOV 2 2012

510(k) Summary
21 CFR 807.92

As required by the Safe Medical Devices Act of 1990, coded under Section 513, Part (I)(3)(A) of the Food, Drug and Cosmetic Act, a 510(k) summary upon which substantial equivalence determination is based is as follows:

Submitter Information:

Applicant:	Bard Peripheral Vascular, Inc 1625 West 3rd Street Tempe, Arizona 85281
Phone:	480-379-2841
Fax:	480-449-2546
Contact:	Erin Fox, Regulatory Affairs Specialist II
Date	August 1, 2012

Subject Device Name:

Device Trade Name:	**Bard PTV Dilatation Catheter**
Common or Usual Name:	Pulmonary (Pulmonic) Valvuloplasty Catheters/Percutaneous Valvuloplasty Catheter (21 CFR 870.1250, Product Code OMZ)
Classification:	Class II
Classification Panel:	Cardiovascular

Predicate Devices:

- Mullins-X PTV Catheter (K102473; cleared December 9, 2010)
- Atlas® PTA Balloon Dilatation Catheter (K120971, cleared April 19, 2012)

Device Description:

The Bard PTV Dilatation Catheter is a high performance balloon catheter consisting of an over the wire catheter with a balloon fixed at the distal tip. The proprietary non-compliant, low profile balloon is designed to provide consistent balloon diameters and lengths even at high pressures. Two radiopaque markers delineate the working length of the balloon and aid in balloon placement. The coaxial catheter includes an atraumatic tip to facilitate advancement of the catheter to and through the valve. The over the wire catheter is compatible with 0.035" guidewire and is available in 75 and 100 cm working lengths. The proximal portion of the catheter includes a female luer lock hub connected to the inflation lumen, and a female luer-lock hub connected to the guidewire lumen.

Attribute	Bard PTV Dilatation Catheter Product Offering
Balloon Diameter (mm)	12, 14, 16, 18, 20, 22, 24, 26
Balloon Length (cm)	2, 4, 6
Catheter Shaft Lengths (cm)	75, 100
Introducer Sheath Compatibility (compatible balloon sizes, diameter (mm) x length (cm))	7F: (12x 2,4,6; 14x 2,4) 8F: (14x 6; 16x 2,4,6; 18x 2,4) 9F: (18x 6; 20x 2,4) 10F: (22x 2,4; 24x 2,4) 12F: (26x 2,4)

Indications for Use of Device:

The Bard PTV Dilatation Catheters are recommended for Percutaneous Transluminal Valvuloplasty (PTV) of the pulmonary valve.

- A patient with isolated pulmonary stenosis
- A patient with valvular pulmonary stenosis with other minor congenital heart disease that does not require surgical intervention.

Comparison of Indications for Use to Predicate Devices:

The indication for use statement for the Bard PTV Dilatation Catheter does not raise any new issues of safety and effectiveness as demonstrated through the risk analysis process based on the proposed indications for use statement as compared to the predicate devices. Therefore, the subject device, the Bard PTV Dilatation Catheter, is substantially equivalent to the predicate device.

Technological Comparison to Predicate Devices:

The Bard PTV Dilatation Catheter has the following similarities to the predicate devices:

- Same intended use (Mullins-X PTV Catheter)
- Same indications for use (Mullins-X PTV Catheter)
- Same target population (Mullins-X PTV Catheter)
- Same fundamental scientific technology (both predicates)
- Same operating principle (both predicates)
- Same packaging materials and configuration (Atlas® PTA Balloon Dilatation Catheter)
- Same sterility assurance level and method of sterilization (Atlas® PTA Balloon Dilatation Catheter)

Performance Data:

To demonstrate substantial equivalence of the subject device, the Bard PTV Dilatation Catheter, to the predicate devices, the technological characteristics and performance criterion were evaluated. Using FDA Guidance Documents on non-clinical testing of medical devices and internal Risk Assessment procedures, the following *in vitro* tests were performed on the subject device:

- Catheter Shaft Length
- Inflation Time
- Simulated Use Deflation Time
- Removal Deflation Time
- Trackability

The following *in vitro* tests were leveraged from the predicate device, the Atlas® PTA Balloon Dilatation Catheter:

- Tip Length
- Balloon Outer Diameter
- Balloon Working Length
- Catheter Shaft Outer Diameter
- Catheter Shaft Inner Diameter
- Tip Visibility
- Catheter Shaft Visibility
- Marker Band Visibility
- Tip Morphology
- Tip Tensile
- Joint Tensile
- Catheter Elongation
- Nominal (Operating) Pressure
- Rated Burst Pressure
- Balloon Burst Mode
- Fatigue
- Catheter Shaft Leaks
- Catheter Shaft Burst
- Balloon Distensibility
- Marker Band Alignment
- Sheath Compatibility
- Equipment Interface
- Media Interaction
- Pouch Tensile Strength

The results from these tests demonstrate that the technological characteristics and performance criteria of the Bard PTV Dilatation Catheter are substantially equivalent to the predicate devices and that it can perform in a manner equivalent to devices currently on the market for the similar intended use. The following table provides a detailed summary of performance testing completed on the subject device, as compared to the corresponding performance testing completed on the predicate Mullins-X PTV Catheter.

Summary of Performance Testing

Predicate Mullins-X Test	Predicate Mullins-X Acceptance Criteria	Test Performed on Subject Device?	Subject Bard PTV Dilatation Catheter Acceptance Criteria	Test Result
Visual Inspection	The catheters shall be free from contamination, discoloration, and any form of damage that could impact the proper functioning of the device.	YES	Inspection of the device for damage is completed prior to any testing for informational purposes. Contamination of the device is covered in biocompatibility section 15. During testing no abnormalities were observed, which was confirmed through functional testing of the device (described below).	PASS
Balloon Preparation Test	Each catheter shall be prepped per the procedure without functional difficulties or anomalies.	YES	**Media Interaction** (as stated in Table 7) The specification for the subject device states that the catheter's guidewire lumen must be flushable with saline utilizing a 10mL syringe or equivalent. Though worded differently, the specification of the subject device is similar to the Mullins-X predicate device, as they both ensure no anomalies are noted during simulated use. All results showed the subject device passed the specified criteria.	PASS
Diameter and Profile Test	The balloon diameter at rated burst pressure shall be within +/- 10% of the labeled balloon diameter and the samples should fit through the selected introducer with no problems.	YES	**Balloon Outer Diameter** (as stated in Table 7) The specification for the subject device is +.04/-.03mm across all diameters. When calculated for the smallest balloon size (12mm) a +/- 10% change in labeled diameter equates to +/-1.2mm. All results showed the subject device passed the specified criteria, which is more robust than the Mullins-X predicate device criteria.	PASS

Balloon Distensibility	The results must demonstrate that the balloon diameter is within +/- 10% of the labeled diameter at the RBP and will not be significantly increased at increasingly higher pressures.	YES	**Balloon Distensibility** (as stated in Table 7) The specification for the subject device is ≤ 5% across all diameters. All results showed the subject device passed the specified criteria which is more robust than the Mullins-X predicate device criteria.	PASS
Repeated Balloon Inflation (Balloon Fatigue Test)	No breaks allowed	YES	**Fatigue** (as stated in Table 7) The specification for the subject device states that the catheter must be capable of withstanding 20 cycles of inflation to ≥ labeled rated burst pressure. All results showed the subject device passed the specified criteria, and no breaks were seen.	PASS
Balloon Minimum Burst Strength	The results must show statistically that with at least 95% confidence, 99.9% of the balloons will not burst at or below the maximum recommended rated burst pressure.	YES	**Rated Burst Pressure** (as stated in Table 7) The specification for the subject device states that the catheter must meet the labeled burst pressure at a 95% confidence/ 99.9% reliability. The labeled rated burst pressure is greater than the Mullins-X predicate device. All results showed the subject device passed the specified criteria, which is more robust than the Mullins-X predicate device criteria, because the labeled rated burst pressures are higher.	PASS
Balloon Inflation/ Deflation Test	Inflation achieved in less than 12 seconds and deflation achieved in less than 20 seconds	YES	**Inflation** and **Deflation** (as stated in Table 7) All results showed the subject device passed the specified criteria.	PASS

Balloon Inflatability Test	There should be no interference with balloon deflation	YES	**Deflation** (as stated in Table 7) The balloon's ability to deflate is evaluated during deflation testing as mentioned above. Any abnormalities during testing are documented. During testing no abnormalities during deflation were observed and all samples were able to be fully deflated.	PASS
Tip Pull and Torque Test	Must withstand at least 10 turns without breaking	YES	**Tip Tensile** (as stated in Table 7) The tip specification for the subject device is different than the Mullins-X predicate device in that it follows ISO10555-1; specifically, the tip is tested for tensile strength. The tip tensile specification for the subject device states that the catheter must withstand a minimum tensile force of 2 pounds-force. All results showed the subject device passed the specified criteria from the ISO standard.	PASS
Bond Strength Test	All bonds must withstand at least 3 lbs of pull strength.	YES	**Joint Tensile** (as stated in Table 7) The bond strength specification for the subject device states that the catheter must withstand a minimum tensile force of 5 pounds-force. All results showed the subject device passed the specified criteria, which is more robust than the Mullins-X predicate device criteria.	PASS

Catheter Body Maximum Pressure Test	All samples must withstand 30 ATM (400psi).	YES	**Catheter Shaft Leak and Catheter Shaft Burst** (as stated in Table 7) The highest rated burst pressure for Atlas Gold is 18atm, and as a safety factor the proposed specification was set to +5atm above the highest rated burst pressure (23atm minimum). Though the value is less than the Mullins-X specification, it is adequate for the labeled burst pressure of the subject device. All results showed the subject device passed the specified criteria.	PASS

Conclusions:

The subject device, the Bard PTV Dilatation Catheter, met all predetermined acceptance criteria of design verification and validation as specified by applicable standards, guidance, test protocols and/or customer inputs. The Bard PTV Dilatation Catheter is substantially equivalent to the legally marketed predicate devices, the Mullins-X PTV Catheter and the Atlas® PTA Balloon Dilatation Catheter.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

NOV 2 2012

Bard Peripheral Vascular, Inc.
c/o Ms. Erin Fox
Regulatory Affairs Specialist
C. R. Bard
1625 West Third Street
Tempe, AZ 85281

Re: K122367
Trade/Device Name: Bard PTV Dilatation Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Pulmonary Valvuloplasty Catheter
Regulatory Class: Class II
Product Code: OMZ
Dated: August 2, 2012
Received: August 5, 2012

Dear Ms. Fox:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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 (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K122367

Device Name: Bard PTV Dilatation Catheter

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Prescription Use X AND/OR Over-The-Counter Use_____
(Part21 CFR 801 Subpart D) (21CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K122367