

Vida PTV Dilatation Catheter

JUL 02 2013

510(k) Summary
21 CFR 807.92

As required by the Safe Medical Devices Act of 1990, coded under Section 513, Part (l)(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: 480-350-6012

Fax: 480-449-2546

Contact: Aaron Conovaloff, Regulatory Affairs Associate

Date April 9, 2013

Subject Device Name:

Device Trade Name: **Vida 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:

- Bard PTV Dilatation Catheter (K122367; cleared November 2, 2012)
- Atlas Gold PTA Dilatation Catheter (K122984, cleared October 22, 2012)

Device Description:

The Vida 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 .035" guidewire and is available in 100 cm working length. 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. Packaged with every product is a profile reducing sheath that is positioned over the balloon for protection before use. A re-wrapping tool is also provided on the catheter shaft. This product is not manufactured with any latex.

Attribute	Vida PTV Dilatation Catheter Product Offering
Balloon Diameter (mm)	12, 14, 16, 18, 20, 22, 24, 26
Balloon Length (cm)	2, 4, 6
Catheter Shaft Length (cm)	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 Vida PTV Dilatation Catheter is recommended for Percutaneous Transluminal Valvuloplasty (PTV) of the pulmonary valve in the following:

- A patient with isolated pulmonary valve 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 indications for use statement for the Vida 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 Vida PTV Dilatation Catheter, is substantially equivalent to the predicate devices.

Technological Comparison to Predicate Devices:

The Vida PTV Dilatation Catheter has the following similarities to the predicate device, the Bard PTV Dilatation Catheter (clearance to market via K122367 on November 2, 2012):

- Same intended use
- Same indications for use
- Same target population
- Same operating principle
- Same fundamental scientific technology
- Same sterility assurance level and method of sterilization

The Vida PTV Dilatation Catheter has the following similarities to the predicate device, the Atlas Gold PTA Dilatation Catheter (clearance to market via K122984, on October 22, 2012):

- Same operating principle
- Same fundamental scientific technology
- Same packaging materials and configurations
- Same sterility assurance level and method of sterilization

Performance Data:

To demonstrate substantial equivalence of the subject device to the predicate devices, its technological characteristics and performance criteria 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:

- Visual Inspection

- Media Interaction (i.e. Balloon Preparation Test)
- Catheter Shaft Length
- Trackability
- Inflation/Deflation Time (i.e. Balloon Inflation/Deflation Test, and Balloon Inflatability Test)

The following *in vitro* tests were leveraged from the predicate Atlas Gold PTA Dilatation Catheter:

- Tip Length
- Balloon Outer Diameter (i.e. Diameter and Profile Test)
- Balloon Working Length
- Catheter Shaft Outer Diameter
- Catheter Shaft Inner Diameter
- Tip Visibility
- Catheter Shaft Visibility
- Marker Band Visibility
- Tip Morphology
- Tip Tensile (i.e. Tip Pull and Torque Test, and Bond Strength Test)
- Balloon to Shaft Tensile
- Hub to Shaft Tensile
- Catheter Shaft Elongation
- Balloon Nominal (Operating) Pressure
- Rated Burst Pressure (i.e. Balloon Minimum Burst Strength)
- Balloon Burst Mode
- Fatigue (i.e. Repeated Balloon Inflation)
- Catheter Shaft Leaks (i.e. Catheter Body Maximum Pressure Test)
- Catheter Shaft Burst (i.e. Catheter Body Maximum Pressure Test)
- Balloon Distensibility
- Marker Band Alignment
- Sheath Compatibility
- Equipment Interface
- Visual Inspection of Packaging
- Dye Penetration

- Pouch Tensile Strength

The results from these tests demonstrate that the technological characteristics and performance criteria of the Vida 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 same intended use. The following table provides a detailed summary of performance testing completed on the subject device.

Summary of Performance Testing

Test Performed	Acceptance Criteria		Vida
Visual Inspection	The catheters shall be free from contamination, discoloration, and any form of damage that could impact the proper functioning of the device.		
Media Interaction (i.e. Balloon Preparation Test)	Each catheter shall be prepped per the procedure without any functional difficulties or anomalies. Guidewire lumen must be flushable (saline appears at distal end when injected from proximal end) with 5 ml of saline utilizing a 10-ml syringe or equivalent.		
Catheter Shaft Length	100 ± 3 cm		
Trackability	Using the IDTE, the trackability into an appropriately-sized 23-cm Cordis Avanti introducer or B.Braun Intradyn 23-cm (sheath sizes ≥ 12 Fr.) and through a worst-case pulmonary valve model should have forces ≤ 700 gF.		
Inflation/Deflation Time (i.e. Balloon Inflation/Deflation Test, and Balloon Inflatability Test)	Inflation Time	Inflation achieved ≤ 20 seconds using 25:75 contrast:saline ratio.	
	Simulated Use Deflation Time	Deflation achieved ≤ 20 seconds using 25:75 contrast:saline ratio.	
	Removal Deflation Time	Deflation time ≤ 90 seconds with 25:75 contrast:saline ratio.	

Conclusions:

The subject device, the Vida 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 Vida PTV Dilatation Catheter is substantially equivalent to the legally marketed predicate devices, the Bard PTV Dilatation Catheter and the Atlas Gold PTA Dilatation Catheter.



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

July 2, 2013

Aaron Conovaloff, Ph.D.
Regulatory Affairs Associate
Bard Peripheral Vascular, Inc.
1625 West 3rd Street
Tempe, AZ 85281

Re: K131002

Trade/Device Name: Vida™ PTV Dilatation Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Pulmonary Valvuloplasty Catheters
Regulatory Class: Class II
Product Code: OMZ
Dated: April 26, 2013
Received: April 29, 2013

Dear Dr. Conovaloff:

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 contact 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>. 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,



for
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): K131002

Device Name: Vida PTV Dilatation Catheter

Indications for Use: The Vida PTV Dilatation Catheter is recommended for Percutaneous Transluminal Valvuloplasty (PTV) of the pulmonary valve in the following:

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

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

M. G. Hillebrunn