December 13, 2017

C. R. Bard, Inc.
Aaron Conovaloff
Regulatory Affairs Specialist
1625 West 3rd Street
Tempe, Arizona 85281

Re: K172932
Trade/Device Name: True Flow Valvuloplasty Perfusion Catheter
Regulation Number: 21 CFR 870.1255
Regulation Name: Balloon Aortic Valvuloplasty Catheter
Regulatory Class: Class II
Product Code: OZT
Dated: September 25, 2017
Received: September 26, 2017

Dear Mr. 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.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Nicole G. Ibrahim -S

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K172932

Device Name
True® Flow Valvuloplasty Perfusion Catheter

Indications for Use *(Describe)*
The True® Flow Valvuloplasty Perfusion Catheter is indicated for balloon aortic valvuloplasty.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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True® Flow Valvuloplasty Perfusion Catheter

510(k) Summary
21 CFR 807.92

Submitter Information:

Bard Peripheral Vascular, Inc.
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Contact Person: Aaron Conovaloff, Regulatory Affairs Specialist
Date of Submission: September 25, 2017

Subject Device Name:

Name of Device:	True® Flow Valvuloplasty Perfusion Catheter
Common or Usual Name:	Balloon Aortic Valvuloplasty
Classification Name:	Balloon Aortic Valvuloplasty
Regulatory Class:	II
Regulation Number:	21 CFR 870.1255

Predicate Device:

Name of Device:	True® Flow Valvuloplasty Perfusion Catheter (K152613)
Common or Usual Name:	Balloon Aortic Valvuloplasty
Classification Name:	Balloon Aortic Valvuloplasty
Regulatory Class:	II
Regulation Number:	21 CFR 870.1255

Device Description:

The True® Flow Valvuloplasty Perfusion Catheter is an over-the-wire co-axial catheter with a balloon fixed at the tip. The balloon enables continuous hemodynamic flow through its central orifice. The catheter is 110 cm long and has two lumens: one lumen is used to inflate and deflate the balloon and the other permits the use of a guidewire to position the catheter. The balloon inflation luer-lock hub (angled) connects to a syringe inflation device to deliver radiopaque contrast media for inflation. The guidewire luer-lock hub (straight) connects to the guidewire lumen. The balloon is non-compliant and is designed to reach a known diameter and length when inflated within the specified pressure range. Two radiopaque markers are located

on the guidewire lumen. These bands are positioned at the proximal and distal balloon shoulders. These markers are provided for fluoroscopic positioning of the device across the aortic valve. Balloon catheter dimensions, nominal pressure, maximum inflation pressure, recommended introducer size, and maximum guidewire size are indicated on the package label.

Attribute	True® Flow Valvuloplasty Perfusion Catheter Product Offering
Balloon Diameter (mm)	18, 20, 22, 24, 26
Balloon Length (cm)	3.5
Catheter Shaft Length (cm)	110
Introducer Sheath Compatibility by Balloon Diameter (mm)	11F: 18 mm, 20 mm 12F: 22 mm 14F: 24 mm 16F: 26 mm

Indications for Use of Device:

The True® Flow Valvuloplasty Perfusion Catheter is indicated for balloon aortic valvuloplasty.

Technological Comparison to Predicate Devices:

The True® Flow Valvuloplasty Perfusion Catheter has the following similarities to the predicate device, the True® Flow Valvuloplasty Perfusion Catheter (clearance to market via K152613 on January 19, 2016):

- 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

It should be noted that the subject True® Flow Valvuloplasty Perfusion Catheter is identical to the predicate device with respect to manufacturing and design. The only difference between the subject and predicate devices is an update to the Instructions for Use to provide results from clinical experience with the device.

Performance Data:

Subsequent to clearance of K152613, a post-market clinical study (the TRUE-FLOW study) was conducted on the predicate True® Flow Valvuloplasty Perfusion Catheter. Twenty- five subjects were enrolled, of which all were successfully treated with the study device. One subject withdrew consent following all study procedures and hospital discharge, and is thus not included in the Analysis Population (n = 24). Subjects eligible to be enrolled in this study were adult male and non-pregnant females scheduled to undergo Transcatheter Aortic Valve Implantation (TAVI) for the treatment of aortic stenosis who had an annulus diameter that could be treated with the available sizes of the study device, in accordance with the IFU. The primary performance endpoint was successful dilatation of the aortic valve using the True® Flow Valvuloplasty Perfusion Catheter. The primary safety endpoint was freedom from device-related or procedure-related death, stroke, annulus rupture, coronary occlusion, ventricular perforation, during the pre-dilatation procedure. In 21 (87.5%) cases the True® Flow catheter successfully dilated the aortic annulus without clinically significant movement. For one subject these data were not recorded. No device related serious adverse events were reported during the study. The results of the TRUE-FLOW prospective, observational study indicated that the design of the True® Flow Valvuloplasty Perfusion Catheter allowed adequate blood flow through the device's central orifice to perform complete dilation of a stenotic aortic valve prior to TAVI without the need for rapid pacing.

Conclusions:

As the only difference between the subject and predicate devices is the addition of the above clinical experience to the IFU, there is no change to the intended use or indications for use, or any design specifications or manufacturing. Therefore the subject True® Flow Valvuloplasty Perfusion Catheter is substantially equivalent to the legally marketed predicate device, the True® Flow Valvuloplasty Perfusion Catheter.