August 3, 2018

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

Re: K181323
Trade/Device Name: Atlas® Gold PTA Dilatation Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: LIT, DQY
Dated: May 17, 2018
Received: May 18, 2018

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.

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 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,

Gregory O'Connell
For 2018.08.03 12:06:15 -04'00'

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K181323

Device Name
Atlas® Gold PTA Dilatation Catheter

Indications for Use *(Describe)*
The Atlas® Gold PTA Dilatation Catheter is indicated for use in Percutaneous Transluminal Angioplasty of the peripheral vasculature, including the iliac arteries and iliac and femoral veins, and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. This device is also indicated for post-dilatation of stents and stent grafts in the peripheral vasculature. This catheter is not for use in coronary arteries.

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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Atlas® Gold PTA Dilatation Catheter

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:

Bard Peripheral Vascular, Inc.
1625 West Third St.
Tempe, AZ 85281

Phone: (480) 350-6012
Fax: (480) 449-2546

Contact Person: Aaron Conovaloff, Regulatory Affairs Specialist
Date of Submission: May 17, 2018

Subject Device Name:

Name of Device:	Atlas® Gold PTA Dilatation Catheter
Common or Usual Name:	Percutaneous Catheter
Classification Name:	Catheter, Angioplasty, Peripheral, Transluminal/Percutaneous catheter
Product Code:	LIT, DQY
Regulatory Class:	II
Regulation Number:	21 CFR 870.1250

Predicate Device:

Name of Device:	Atlas® Gold PTA Dilatation Catheter
Common or Usual Name:	Percutaneous Catheter
Classification Name:	Catheter, Angioplasty, Peripheral, Transluminal/Percutaneous catheter
Product Code:	LIT, DQY
Regulatory Class:	II
Regulation Number:	21 CFR 870.1250

Device Description:

The Atlas® Gold PTA 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 a tapered atraumatic tip to facilitate advancement of the catheter to and through the stenosis. 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. The over-the-wire catheter is compatible with .035" guidewire and is available in 80 cm and 120 cm working lengths. 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 to aid in re-wrap/refolding of the balloon. This product is not manufactured with any natural rubber latex.

<table>
<tr><th>Attribute</th><th colspan="3">Atlas® Gold PTA Dilatation Catheter Product Offering</th></tr>
<tr><td>Balloon Diameter (mm)</td><td colspan="3">12, 14, 16, 18, 20, 22, 24, 26</td></tr>
<tr><td>Balloon Length (cm)</td><td colspan="3">2, 4, 6</td></tr>
<tr><td>Catheter Shaft Lengths (cm)</td><td colspan="3">80, 120</td></tr>
<tr><td rowspan="13">Introducer Sheath Compatibility</td><td>Recommended Introducer (Fr)</td><td>Balloon Diameter (mm)</td><td>Balloon Length (cm)</td></tr>
<tr><td rowspan="2">7</td><td>12</td><td>2, 4, 6</td></tr>
<tr><td>14</td><td>2, 4</td></tr>
<tr><td rowspan="3">8</td><td>14</td><td>6</td></tr>
<tr><td>16</td><td>2, 4, 6</td></tr>
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<tr><td rowspan="2">9</td><td>18</td><td>6</td></tr>
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<tr><td>24</td><td>2, 4</td></tr>
<tr><td>12</td><td>26</td><td>2, 4</td></tr>
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Indications for Use of Device:

The Atlas® Gold PTA Dilatation Catheter is indicated for use in Percutaneous Transluminal Angioplasty of the peripheral vasculature, including the iliac arteries and iliac and femoral veins, and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. This device is also indicated for post-dilatation of stents and stent grafts in the peripheral vasculature. This catheter is not for use in coronary arteries.

Technological Comparison to Predicate Devices:

The Atlas® Gold PTA 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 intended 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 Atlas® Gold PTA Dilatation Catheter is identical to the predicate device with respect to manufacturing and design. The only differences between the subject and predicate devices are an expanded indications for use statement to include use in the venous system, and the inclusion of a summary of the results of a retrospective, investigator-sponsored clinical study describing experience using the Atlas® Gold PTA Dilatation Catheter in the venous system in the labeling.

Performance Data:

A retrospective, investigator-sponsored clinical study providing patient-level data using the Atlas® Gold PTA Dilatation Catheter in venous stenting procedures was conducted. The Atlas® Gold PTA Dilatation Catheter was used for post-stent dilatation in 61 patients, and for pre-dilatation in 20 patients. All patients were successfully treated with the study device. Subjects included had undergone iliofemoral vein compression treatment between September 1, 2013 and May 30, 2017. The primary safety endpoint was intra-procedural freedom from major adverse events defined as acute thrombosis, perforation, or device-related complications (rupture, balloon getting stuck on stent, stent disruption or dislodgement with balloon insertion or removal). This analysis demonstrated that the Atlas® Gold PTA Dilatation Catheter met 100%

freedom from intraprocedural adverse events related to the study device, and exceeded the 95% benchmark for the primary safety endpoint. No balloon perforation, vessel laceration/perforation, or balloon-related intravascular events occurred. IVUS imaging showed that the minimal luminal area (MLA) was improved post stenting and balloon expansion of the stent, with the mean luminal area increasing from 72 to 218.8 mm^2.

Reviews of published clinical literature describing the use of PTA balloons in the venous system were conducted. These reviews of relevant clinical literature from 46 articles with over 4000 patients demonstrate that PTA catheters are safe for use in the treatment of stenosis or thrombosis in native iliac or femoral veins, and the rates of reported safety events are low and are known events associated with PTA procedures.

Conclusions:

The subject and predicate devices are identical with respect to manufacturing and design. The only differences between the subject and predicate devices are an expanded indications for use statement to include use in the venous system, and the inclusion of a summary of the results of a retrospective, investigator-sponsored clinical study describing experience using the Atlas® Gold PTA Dilatation Catheter in the venous system in the labeling; the clinical data obtained using the Atlas® Gold PTA Dilatation Catheter demonstrated that there are no new questions of safety and effectiveness raised by the expanded indication for use. Therefore the subject Atlas® Gold PTA Dilatation Catheter is substantially equivalent to the legally marketed predicate device, the Atlas® Gold PTA Dilatation Catheter.