May 4, 2022

C.R. Bard, Inc
Arieona Boyle
Regulatory Affairs Specialist
1625 W Third Street
Tempe, Arizona 85281

Re: K212588
Trade/Device Name: Conquest 40 PTA Dilatation Catheter, Atlas Gold PTA Dilatation Catheter, Vida PTV Dilatation Catheter, Vida BAV Balloon Valvuloplasty Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous catheter
Regulatory Class: Class II
Product Code: LIT, OMZ, OZT
Dated: April 1, 2022
Received: April 4, 2022

Dear Arieona Boyle:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For

Gregory O'Connell
Assistant Director
DHT2C: Division of Coronary
and Peripheral Intervention Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K212588

Device Name
Conquest™ 40 PTA Dilatation Catheter

Indications for Use *(Describe)*
The Conquest™ 40 PTA Dilatation Catheter is recommended for use in Percutaneous Transluminal Angioplasty of the femoral, iliac, and renal arteries and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. This device is also recommended 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K212588

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)

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K212588

Device Name
Vida™ PTV Dilatation Catheter

Indications for Use *(Describe)*
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.

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)

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K212588

Device Name
Vida™ BAV Balloon Valvuloplasty Catheter

Indications for Use *(Describe)*
The Vida™ BAV Balloon Valvuloplasty 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)

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Conquest™ 40 PTA Dilatation Catheter
Atlas™ Gold PTA Dilatation Catheter
Vida™ PTV Dilatation Catheter
Vida™ BAV Balloon Valvuloplasty 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:

Applicant:	Bard Peripheral Vascular, Inc 1625 West 3rd Street Tempe, Arizona 85281
Phone:	602-830-5603
Fax:	312-949-0436
Contact:	Arieona Boyle, Senior Regulatory Affairs Specialist
Date	April 29, 2022

Subject Device Name #1:

Device Trade Name:	**Conquest™ 40 PTA Dilatation Catheters**
Common or Usual Name:	Catheter, Angioplasty, Peripheral, Transluminal/ Catheter, Percutaneous
Product Code:	DQY, LIT
Classification:	Class II
Review Panel:	Cardiovascular
Regulation Number:	21 CFR 870.1250

Predicate Device #1:

- Conquest™ 40 PTA Dilatation Catheter (K120660; cleared March 15, 2012)

Reference Device:

- True™ Dilatation Balloon Valvuloplasty Catheter (K150667; cleared June 17, 2015)

Conquest™ 40 Device Description:

The Conquest™ 40 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 ultra 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 0.035" guidewires and is available in 50cm and 75cm 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. A stylet is placed into the tip of the catheter to aid in re-wrap/refolding of the balloon. This product is not manufactured with any latex.

<table>
<tr><th>Attribute</th><th colspan="3">Conquest™ 40 PTA Dilatation Catheter Product Offerings</th></tr>
<tr><td>Balloon Diameter (mm)</td><td colspan="3">4, 5, 6, 7, 8, 9, 10, 12</td></tr>
<tr><td>Balloon Length (cm)</td><td colspan="3">2, 3, 4, 6, 8, 10</td></tr>
<tr><td>Catheter Shaft Lengths (cm)</td><td colspan="3">50, 75</td></tr>
<tr><td rowspan="8">Introducer Sheath Compatibility</td><td>Recommended Introducer (Fr)</td><td>Balloon Diameter (mm)</td><td>Balloon Length (cm)</td></tr>
<tr><td rowspan="5">6</td><td>4</td><td>2, 4, 6, 8, 10</td></tr>
<tr><td>5</td><td>2, 4, 6, 8, 10</td></tr>
<tr><td>6</td><td>2, 4, 6, 8, 10</td></tr>
<tr><td>7</td><td>2, 4, 6, 8, 10</td></tr>
<tr><td>8</td><td>2, 3, 4, 6, 8, 10</td></tr>
<tr><td rowspan="2">7</td><td>9</td><td>2, 4, 8</td></tr>
<tr><td>10</td><td>2, 4, 8</td></tr>
</table>

Attribute	Conquest™ 40 PTA Dilatation Catheter Product Offerings		
	8	12	2, 4

Conquest™ 40 Indications for Use of Device:

The Conquest™ 40 PTA Dilatation Catheter is recommended for use in Percutaneous Transluminal Angioplasty of the femoral, iliac, and renal arteries and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. This device is also recommended for post-dilatation of stents and stent grafts in the peripheral vasculature. This catheter is not for use in coronary arteries.

Conquest™ 40 Comparison of Indications for Use to Predicate Device:

The indications for use statement for the subject device, the Conquest™ 40 PTA Dilatation Catheter, is the same as compared to the predicate device. Therefore, the subject device, the Conquest™ 40 PTA Dilatation Catheter, is substantially equivalent to the predicate device.

Subject Device Name #2:

Device Trade Name:	**Atlas™ Gold PTA Dilatation Catheters**
Common or Usual Name:	Catheter, Angioplasty, Peripheral, Transluminal/ Catheter, Percutaneous
Product Code:	DQY, LIT
Classification:	Class II
Review Panel:	Cardiovascular
Regulation Number:	21 CFR 870.1250

Predicate Device #2:

- Atlas™ Gold PTA Dilatation Catheter (K181323; cleared August 03, 2018)

Reference Device:

- True™ Dilatation Balloon Valvuloplasty Catheter (K150667; cleared June 17, 2015)

Atlas Gold 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.

Attribute	Atlas™ Gold PTA 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)	80, 120		
Introducer Sheath Compatibility	Recommended Introducer (Fr)	Balloon Diameter (mm)	Balloon Length (cm)
	7	12	2, 4, 6
		14	2, 4
	8	14	6
		16	2, 4, 6
		18	2, 4
	9	18	6
		20	2, 4
	10	22	2, 4
		24	2, 4
	12	26	2, 4

Atlas™ Gold 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.

Atlas™ Gold Comparison of Indications for Use to Predicate Device:

The indications for use statement for the subject device, the Atlas Gold PTA Dilatation Catheter, is the same as compared to the predicate device. Therefore, the subject device, the Atlas Gold PTA Dilatation Catheter, is substantially equivalent to the predicate device.

Subject Device Name #3:

Device Trade Name:	**Vida™ PTV Dilatation Catheters**
Common or Usual Name:	Pulmonary Valvuloplasty Catheter
Product Code:	OMZ
Classification:	Class II
Review Panel:	Cardiovascular
Regulation Number:	21 CFR 870.1250

Predicate Device #3:

- Vida™ PTV Dilatation Catheter (K131002; cleared July 02, 2013)

Reference Device:

- True™ Dilatation Balloon Valvuloplasty Catheter (K150667; cleared June 17, 2015)

Vida™ PTV 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.

<table>
<tr><th>Attribute</th><th colspan="3">Vida™ PTV 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">100</td></tr>
<tr><td rowspan="11">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>
<tr><td>18</td><td>2, 4</td></tr>
<tr><td rowspan="2">9</td><td>18</td><td>6</td></tr>
<tr><td>20</td><td>2, 4</td></tr>
<tr><td rowspan="2">10</td><td>22</td><td>2, 4</td></tr>
<tr><td>24</td><td>2, 4</td></tr>
<tr><td>12</td><td>26</td><td>2, 4</td></tr>
</table>

Vida™ PTV 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.

Vida™ PTV Comparison of Indications for Use to Predicate Device:

The indications for use statement for the subject device, the Vida™ PTV Dilatation Catheter, is the same as compared to the predicate device. Therefore, the subject device, the Vida™ PTV Dilatation Catheter, is substantially equivalent to the predicate device.

Subject Device Name #4:

Device Trade Name:	**Vida™ BAV Balloon Valvuloplasty Catheters**
Common or Usual Name:	Balloon Aortic Valvuloplasty
Product Code:	OZT
Classification:	Class II
Review Panel:	Cardiovascular
Regulation Number:	21 CFR 870.1255

Predicate Device #4:

- True™ BAV Balloon Valvuloplasty Catheter (K141985; cleared September 18, 2014)

Reference Device:

- True™ Dilatation Balloon Valvuloplasty Catheter (K150667; cleared June 17, 2015)

Vida™ BAV Device Description:

The Vida™ BAV Balloon Valvuloplasty 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. 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.

<table>
<tr><th>Attribute</th><th colspan="3">Vida™ BAV Balloon Valvuloplasty Catheter
Product Offering</th></tr>
<tr><td>Balloon Diameter (mm)</td><td colspan="3">18, 20, 22, 24, 26</td></tr>
<tr><td>Balloon Length (cm)</td><td colspan="3">4</td></tr>
<tr><td>Catheter Shaft Lengths (cm)</td><td colspan="3">100</td></tr>
<tr><td rowspan="6">Introducer Sheath Compatibility</td><td>Recommended Introducer (Fr)</td><td>Balloon Diameter (mm)</td><td>Balloon Length (cm)</td></tr>
<tr><td>8</td><td>18</td><td>4</td></tr>
<tr><td>9</td><td>20</td><td>4</td></tr>
<tr><td rowspan="2">10</td><td>22</td><td>4</td></tr>
<tr><td>24</td><td>4</td></tr>
<tr><td>12</td><td>26</td><td>4</td></tr>
</table>

Vida™ BAV Indications for Use of Device:

The Vida™ BAV Balloon Valvuloplasty Catheter is indicated for balloon aortic valvuloplasty.

Vida™ BAV Comparison of Indications for Use to Predicate Device:

The indications for use statement for the subject device, the Vida™ BAV Balloon Valvuloplasty Catheter, is the same as compared to the predicate device. Therefore, the subject device, the Vida™ BAV Balloon Valvuloplasty Catheter, is substantially equivalent to the predicate device.

Technological Comparison to Predicate Devices:

The subject devices, Conquest™ 40, Atlas™ Gold, Vida™ PTV and Vida™ BAV are identical to their previous approved clearances in the following aspects:

- Same intended use
- Same indications for use
- Same target population
- Same operating principle
- Same fundamental scientific technology
- Same packaging materials and configurations
- Same sterility assurance level and method of sterilization
- Similar materials
- Same design specifications (with the exception of sheath withdrawal)

The subject Conquest™ 40, Atlas™ Gold, Vida™ PTV and Vida™ BAV devices have the following differences as compared to their corresponding predicate devices:

- A Pebax Grade Material Change
- A Sheath Withdrawal Force Specification Change

The subject devices were also modified with the following minor changes that did not warrant a 510(k) submission:

- An Inner Shaft Formulation Change (Applicable to Atlas™ Gold, Vida™ PTV, and Vida™ BAV only)
- An Additional Qualified Sterilization Cycle

Performance Data:

To demonstrate substantial equivalence of the subject devices to their respective predicate devices, their 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 devices:

Conquest 40

- Trackability
- Minimum Balloon Burst Strength and Balloon Failure Mode
- Fatigue
- Fatigue in Stent (Puncture Resistance)
- Minimum Balloon Burst Strength and Balloon Failure Mode (Robustness)
- Sheath Compatibility

Atlas Gold/Vida PTV/Vida BAV

- Trackability
- Minimum Balloon Burst Strength and Balloon Failure Mode
- Fatigue
- Sheath Compatibility
- Distensibility
- Balloon to Shaft Tensile
- Hub to Shaft Tensile
- Catheter Elongation
- Tip to Shaft Tensile
- *Atlas Gold Only* - Fatigue in Stent (Puncture Resistance)
- *Atlas Gold Only* - Minimum Balloon Burst Strength and Balloon Failure Mode (Robustness)

The following *in vitro* biocompatibility testing was conducted in accordance with ISO 10993-1: 2018

Conquest 40

- Cytotoxicity
- Sensitization
- Irritation/Intracutaneous Toxicity
- Systemic Toxicity
- Hemocompatibility
    - Hemolysis - Direct
    - Partial Thromboplastin (PTT)
    - Platelet/Leukocyte Count (PLC)
    - SEM Surface Analysis
    - Complement Activation
- Material Mediated Pyrogenicity

Atlas Gold (applicable to Vida PTV/Vida BAV)

- Cytotoxicity
- Sensitization
- Irritation/Intracutaneous Toxicity
- Systemic Toxicity
- Hemocompatibility
    - Hemolysis – Direct/Indirect
    - Thrombogenicity
    - Partial Thromboplastin (PTT)
    - Platelet/Leukocyte Count (PLC)
    - SEM Surface Analysis
    - Complement Activation
- Material Mediated Pyrogenicity

Conclusions:

The subject devices, Conquest™ 40 PTA Dilatation Catheters, Atlas™ Gold PTA Dilatation Catheters, Vida™ PTV Dilatation Catheters, Vida™ BAV Balloon Valvuloplasty Catheters met all predetermined acceptance criteria of design verification and validation as specified by applicable standards, guidance, test protocols and/or customer inputs. The Conquest 40™ PTA Dilatation Catheters, Atlas™ Gold PTA Dilatation Catheters, Vida™ PTV Dilatation Catheters, Vida™ BAV Balloon Valvuloplasty Catheters are substantially equivalent to the legally marketed predicate devices, Conquest™ 40 PTA Dilatation Catheters, Atlas™ Gold PTA Dilatation Catheters, Vida™ PTV Dilatation Catheters, True™ BAV Balloon Valvuloplasty Catheters.