April 7, 2020

Bard Access Systems, Inc. (Bard has joined BD)
Breanna Casados
Regulatory Affairs Specialist
605 North 5600 West
Salt Lake City, Utah 84116

Re: K200266
Trade/Device Name: BD CentroVena™ Acute Central Line (7 French Dual Lumen)
Regulation Number: 21 CFR 880.5200
Regulation Name: Intravascular Catheter
Regulatory Class: Class II
Product Code: FOZ
Dated: March 6, 2020
Received: March 9, 2020

Dear Breanna Casados:

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 Tina Kiang, Ph.D.
Director
DHT3C: Division of Drug Delivery and
General Hospital Devices,
and Human Factors
OHT3: Office of Gastrorenal, ObGyn,
General Hospital and Urology 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: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*
K200266

Device Name
BD CentroVena™ Acute Central Line (7 French Dual Lumen)

Indications for Use *(Describe)*
Acute central venous catheters are indicated to provide short-term access (<30 days) to the central venous system. They are designed for administering I.V. fluids, blood products, drugs and parenteral nutrition solutions, as well as blood withdrawal, central venous pressure monitoring, and power injection of contrast media.

| Catheter Length | Lumen(s) | Power Injection Flow Rate | Maximum Power Injector Pressure Setting |
|---|---|---|---|
| 16 cm and 20 cm | Distal | 10 mL/sec | 325 psi |
| | Proximal | 10 mL/sec | |

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.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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*PRAStaff@fda.hhs.gov*

*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

## 510(k) Summary for BD CentroVena™ Acute Central Line

### 21 CFR 807.92(a)

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 on is presented in the following table:

| | | |
|---|---|---|
| **General Provisions** | Submitter Name: | Bard Access Systems, Inc. (Bard has joined BD) |
| | Submitter Address: | 605 North 5600 West<br>Salt Lake City, UT 84116 |
| | Contact Person: | Breanna Casados<br>Regulatory Affairs Specialist |
| | Telephone Number: | 801.522.5243 |
| | Fax Number: | 801.522.5425 |
| | Date of Preparation: | 4/6/2020 |
| **Subject Device** | Trade Name(s): | BD CentroVena™ Acute Central Line (7 French Dual Lumen) |
| | Common Name: | Acute Central Line |
| | Classification Name: | Catheter, Intravascular, Therapeutic, Short-Term Less than 30 days |
| | Class: | 2 |
| | Regulation Number: | 21 CFR 880.5200 |
| | Product Code: | FOZ |
| | Classification Panel | General Hospital |
| **Predicate Device** | Predicate Trade Name: | BD Acute Central Line (7 French Triple Lumen) |
| | Classification Name: | Catheter, Intravascular, Therapeutic, Short-Term Less than 30 days |
| | Class: | 2 |
| | Product Code: | FOZ |
| | Regulation Number: | 21 CFR 880.5200 |

<table>
<tr><td></td><td>Premarket Notification #: K190855<br>Manufacturer: Bard Access Systems, Inc. (wholly owned subsidiary of BD)<br>Classification Panel General Hospital</td></tr>
<tr><td>Reference Device</td><td>Reference Trade Name: PowerPICC Provena<br>Classification Name: Percutaneous, Implanted, Long-term Intravascular Catheter<br>Class: II<br>Product Code: LJS<br>Regulation Number: 21 CFR 880.5970<br>Premarket Notification #: K162443<br>Manufacturer: Bard Access Systems, Inc.</td></tr>
<tr><td>Device Description</td><td>A family of power injectable central venous catheters constructed of medical grade polyurethane and is designed for insertion into the central venous system. BD power injectable acute central lines are radiopaque and have a soft tip that is more pliable than the catheter body. Each catheter is provided in a sterile package with applicable insertion kit accessories. The maximum pressure injector settings and maximum power injection flow rate are specified in the table below:
<table>
<tr><th>Catheter Length</th><th>Lumen(s)</th><th>Power Injection Flow Rate</th><th>Maximum Power Injector Pressure Setting</th></tr>
<tr><td rowspan="2">16 cm and 20 cm</td><td>Distal</td><td>10 mL/sec</td><td rowspan="2">325 psi</td></tr>
<tr><td>Proximal</td><td>10 mL/sec</td></tr>
</table></td></tr>
<tr><td>Intended Use</td><td>BD Acute Central Lines are intended for short-term access to the central venous system for intravenous therapy and blood sampling.</td></tr>
</table>

**Indications for Use**

Acute central venous catheters are indicated to provide short-term access (<30 days) to the central venous system. They are designed for administering I.V. fluids, blood products, drugs and parenteral nutrition solutions, as well as blood withdrawal, central venous pressure monitoring, and power injection of contrast media.

| Catheter Length | Lumen(s) | Power Injection Flow Rate | Maximum Power Injector Pressure Setting |
|---|---|---|---|
| 16 cm and 20 cm | Distal | 10 mL/sec | 325 psi |
| | Proximal | 10 mL/sec | |

**Technological Characteristics**

Technological characteristics of the subject BD CentroVena™ Acute Central Line are substantially equivalent with respect to basic design, function and fundamental scientific technology to those of the cited predicate device.

Key differences in the subject device when compared to the predicate device are as follows:

- The subject device has 2 lumens and the predicate device has 3 lumens
- The lumen geometry
- The strain relief at the joint between the extension legs and the luer hubs

The following table provides a comparison between the subject and predicate devices.

| Attribute | Subject Device – BD CentroVena™ Acute Central Line (7 French Dual Lumen) | Predicate Device – BD Acute Central Line (7 French Triple Lumen) |
|---|---|---|
| **Owner** | Bard Access Systems, Inc. | Bard Access Systems, Inc. |
| **Classification** | Same | FOZ – 21 CFR 880.5200<br>Short-term Intravascular Catheter |
| **510(k) Status** | Subject of this Premarket Notification | K190855 – Concurrence date Nov. 1, 2019 |
| **Indications for Use** | Acute central venous catheters are indicated to provide short-term access (< 30 days) to the central venous system. They are designed for administering I.V. fluids, blood products, drugs and parenteral nutrition solutions, as well as blood withdrawal, central venous pressure | Acute central venous catheters are indicated to provide short-term access (< 30 days) to the central venous system. They are designed for administering I.V. fluids, blood products, drugs and parenteral nutrition solutions, as well as blood withdrawal, central venous pressure |

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<tr><td></td><td>Commercial Name</td><td>BD CentroVena™ Acute Central Line</td><td>BD Acute Central Line</td></tr>
<tr><td></td><td>Catheter Dimensions</td><td>7 Fr Dual Lumen x 16 cm<br>7 Fr Dual Lumen x 20 cm</td><td>7 Fr Triple Lumen x 16 cm<br>7 Fr Triple Lumen x 20 cm<br>7 Fr Triple Lumen x 30 cm</td></tr>
<tr><td></td><td>Luer Hub Dimensions</td><td>Compliant to ISO 80369-7</td><td>Compliant to ISO 594-1 and 594-2</td></tr>
<tr><td></td><td>Lumen Shape</td><td>Two “D” shaped lumens: one 15 Ga and one 17 Ga</td><td>Three wedge-shaped lumens: two 18 Ga and one 17 Ga</td></tr>
<tr><td></td><td>Duration of Use</td><td>Same</td><td>Short term (<30 days)</td></tr>
<tr><td></td><td>Means of insertion</td><td>Same</td><td>Percutaneous</td></tr>
<tr><td></td><td>Insertion Site</td><td>Same</td><td>Jugular, subclavian, or femoral</td></tr>
<tr><td></td><td>Primary Device Materials</td><td>Catheter Base Materials<br><u>Shaft Tubing:</u><br>Same</td><td>Catheter Base Materials<br><u>Shaft Tubing:</u><br>Polyurethane</td></tr>
</table>

| | | | |
|---|---|---|---|
| | | Luer Connector:<br>Same<br><br>Extension Legs:<br>Same<br><br>Junction:<br>Same<br><br>Strain Relief:<br>Polyurethane | Luer Connector:<br>Polyurethane<br><br>Extension Legs:<br>Polyurethane<br><br>Junction:<br>Polyurethane<br><br>Strain Relief:<br>N/A |
| | **Number of Lumens** | Two (2) | Three (3) |
| | **Power Injection Maximum Flow Rate** | 16 and 20 cm length:<br>• Distal (15 Ga.) – 10 mL/sec<br>• Proximal (17 Ga.) – 10 mL/sec | 16 and 20 cm length:<br>• Distal (16 Ga.) – 10 mL/sec<br>• Medial (18 Ga.) – 9 mL/sec<br>• Proximal (18 Ga.) – 9 mL/sec<br>30 cm length:<br>• Distal (16 Ga.) – 9 mL/sec<br>• Medial (18 Ga.) – 7 mL/sec<br>• Proximal (18 Ga.) – 7 mL/sec |
| | **Sterility** | Same | Provided Sterile |
| | The Power Injection Maximum Flow Rates as indicated in the IFU statement differ in that the Proximal flow rate of the subject device is 10 mL/sec, whereas the flow rate of the Proximal of the predicate device is 9 mL/sec. The technological differences listed above were evaluated using industry consensus standards, and as defined in the Risk Assessment. A risk analysis was performed for the modifications done to the subject device, in accordance to ISO 14971, Medical Devices – Applications of Risk Management to Medical Devices. BAS has identified and evaluated the risks associated with the changes; these risks were adequately mitigated through verification and validation testing. Therefore, these differences in technological characteristics between the subject and predicate devices do not raise new or different questions of safety or effectiveness. | | |
| **Safety & Performance Tests** | The following performance tests were conducted or adopted from the predicate device to establish the performance of the BD CentroVena™ Acute Central Line, and in determining substantial equivalence to the predicate BD Acute Central Line (7F Triple Lumen). All testing passed the predetermined acceptance criteria. | | |

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| | | **Reference Standard:** ***ISO 10993-1:2009 – Biological Evaluation of Medical Devices – Part 1: Evaluation and testing within a risk management process*** | | |
| | | **Biocompatibility Testing** | Biocompatibility tests were leveraged from the predicate BD Acute Central Line and reference device (K162443) to confirm that the catheter is free from biological hazard. | |
| | | **Reference Standard:** ***USP<788>Particulate Matter in Injections*** | | |
| | | **Particulate Matter Testing** | Particulate Matter Testing conducted on the predicate BD Acute Central Line was adopted by the subject device. | |
| | | **Reference Standard:** ***ISO 10555-1:2013 – Sterile Single-Use Intravascular Catheters – Part 1: General requirements*** | | |
| | | **Clamp Engagement** | Test to confirm that the catheter assembly will not leak when the clamp is engaged. | |
| | | **Leak Test** | Test to confirm that the catheter assembly will not leak when the distal end of the catheter is occluded. | |
| | | **Dimensional Test** | Test to measure OD and ID for single lumen catheters and OD and lumen area for dual lumen catheters to ensure compliance with dimensional specification. | |
| | | **Implantable Length** | Test to measure useful length for catheters to ensure compliance with dimensional specification. | |
| | | **Extension Leg Length** | Test to measure and confirm extension leg length compliance with dimensional specification. | |
| | | **Burst Test** | Burst pressure test to confirm the catheter burst pressure exceeds the peak pressure present in the catheter at maximum flow conditions when the distal end is occluded. | |
| | | **Hydraulic Catheter Burst Test** | Burst pressure test to confirm the catheter burst pressure exceeds the peak pressure present in the catheter at maximum flow conditions when the distal end is occluded. | |
| | | **Power Injection Conditioning** | Test to confirm the catheter does not leak or burst as a result of power injections at maximum indicated flow rate. | |
| | | **Gravity Flow** | Test to measure the gravity flow performance of a full-length catheter. | |
| | | **Luer to Extension Leg Tensile Test** | Test to demonstrate the peak tensile force of each test piece exceeds the minimum peak tensile force. | |

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|---|---|---|---|---|
| | | **Extension Leg to Trifurcation Tensile Test** | | |
| | | **Trifurcation to Shaft Tensile Test** | | |
| | | **Shaft Tensile Test** | | |
| | | **Reference Standard: *ASTM F640-12 – Standard Test Methods for Determining Radiopacity for Medical Use*** | | |
| | | **Radiopacity** | Test to demonstrate catheter radio-detectability. | |
| | | **Reference Standard: *ISO 10555-3:2013 – Intravascular catheters – Sterile and single-use catheters – Part 3: Central venous catheters*** | | |
| | | **Tip Tensile** | Test to demonstrate the peak tensile force of each test piece exceeds the minimum peak tensile force. | |
| | | **Reference Standard: FDA Guidance on *Premarket Notification [510(k)] Submission for Short-Term and Long-Term Intravascular Catheters, 1995*** | | |
| | | **Catheter Collapse Test** | Test to measure the flow rate of aspiration and demonstrate that the catheter will not collapse under a vacuum. | |
| | | **Shaft Tensile Test** | Test to evaluate the maximum catheter strain and modulus at break. | |
| | | **Suture Wing Integrity Test** | Test to measure the maximum force a catheter junction suture wing can withstand prior to break. | |
| | | **OD Swell** | Test to confirm that the catheter does not swell beyond twice the size of the labeled OD during power injection. | |
| | | **Tip Stability Test** | Test to confirm that the catheter tip remains in the same orientation during power injection (tip pointing in direction of venous flow) at the maximum indicated flow rate. | |
| | | **Guidewire Drag Test** | Test to ensure that the guidewire used to place the catheter can be removed without difficulty. | |
| | | **Reference Standard: *ISO 80369-7:2016 Small-bore connectors for liquids and gases in healthcare applications – Part 7: Connectors for intravascular or hypodermic applications*** | | |

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|---|---|---|---|---|
| | | **Luer Testing** | Testing to ensure that luer connectors meet requirements for Stress Cracking, Resistance to Separation from Axial Load, Resistance to Separation from Unscrew Torque, and Resistance to Overriding. | |
| | | **Dimensions** | Dimensional testing to characterize luer dimensions. | |
| | | **Leak Testing** | Sub-atmospheric Leak Testing and Luer Positive Pressure Leak | |
| **Technological Comparison to Predicate Device** | Technological characteristics of the subject BD CentroVena™ Acute Central Line are substantially equivalent with regard to the design and function of the predicate device, BD Acute Central Line (K190855). The subject device differs from the predicate in dimensional specifications including lumen geometry and number of lumens. However, these differences do not alter the intended use of the subject device, and do not raise any new or different questions regarding safety or effectiveness when compared to the predicate device. | | | |
| **Summary of Substantial Equivalence** | Based on the risk management activities and testing, the subject BD CentroVena™ Acute Central Line (7F Dual Lumen) is substantially equivalent to the cited predicate device. | | | |