November 1, 2019

Bard Access Systems, Inc. (Bard has joined BD)
% Dave Yungvirt
CEO
Third Party Review Group, LLC
25 Independence Blvd
Warren, New Jersey 07059

Re: K190855
Trade/Device Name: BD Acute Central Line
Regulation Number: 21 CFR 880.5200
Regulation Name: Intravascular catheter
Regulatory Class: Class II
Product Code: FOZ
Dated: October 3, 2019
Received: October 7, 2019

Dear Dave Yungvirt:

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,

Geeta Pamidimukkala
Acting Assistant 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)*
K190855

Device Name
BD Acute Central Line

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
	Medial / Proximal	9 mL/sec	
30 cm	Distal	9 mL/sec	
	Medial/ Proximal	7 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.

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Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
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."

K190855 510(k) Summary for BD Acute Central Line

<table>
<tr><td>General Provisions</td><td>Submitter Name:
Submitter Address:

Contact Person:

Telephone Number:
Fax Number:
Date of Preparation:</td><td>Bard Access Systems, Inc. (Bard has joined BD)
605 North 5600 West
Salt Lake City, UT 84116
Sean Loring
Regulatory Affairs Specialist
801.522.5634
801.522.5425
10/31/2019</td></tr>
<tr><td>Subject Device</td><td>Trade Name(s):
Common Name:
Classification Name:
Class:
Regulation Number:
Product Code:
Classification Panel</td><td>BD Acute Central Line
Acute Central Line
Catheter, Intravascular, Therapeutic, Short-Term Less than 30 days
2
21 CFR 880.5200
FOZ
General Hospital</td></tr>
<tr><td>Predicate Device</td><td>Predicate Trade Name:
Classification Name:
Class:
Product Code:
Regulation Number:
Premarket Notification #:
Manufacturer:
Classification Panel</td><td>Arrow Central Venous Catheter
Catheter, Intravascular, Therapeutic, Short-Term Less than 30 days
2
FOZ
21 CFR 880.5200
K071538
Arrow
General Hospital</td></tr>
<tr><td>Device Description</td><td colspan="2">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="4">325 psi</td></tr>
<tr><td>Medial / Proximal</td><td>9 mL/sec</td></tr>
<tr><td rowspan="2">30 cm</td><td>Distal</td><td>9 mL/sec</td></tr>
<tr><td>Medial/ Proximal</td><td>7 mL/sec</td></tr>
</table></td></tr>
<tr><td>Intended Use</td><td colspan="2">BD Acute Central Lines are intended for short-term access to the central venous system for intravenous therapy and blood sampling.</td></tr>
<tr><td>Indications for Use</td><td colspan="2">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</td></tr>
</table>

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
	Medial / Proximal	9 mL/sec	
30 cm	Distal	9 mL/sec	
	Medial/ Proximal	7 mL/sec	

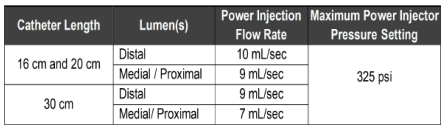
Technological Characteristics

Technological characteristics of the subject BD 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:

- Lumen geometry
- Offering of a 7 Fr x 30 cm length in subject device (BD Acute Central Line)

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

Attribute	Subject Device – BD Acute Central Line	Predicate Device – Arrow Central Venous Catheter	Discussion of Characteristics between subject and predicate
Owner	Bard Access Systems, Inc.	Arrow	
Classification	Same	FOZ – 21 CFR 880.5200	Classification of subject device is the same as the predicate
510(k) Status	Subject of this Premarket Notification	K071538 – Concurrence date August 30, 2007	
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; Medial / Proximal 9 mL/sec 30 cm: Distal 9 mL/sec; Medial/ Proximal 7 mL/sec 325 psi	The Arrow CVC is intended to provide short-term (<30 days) central venous access for treatment of diseases or conditions requiring central venous access, including, but not limited to the following: • Lack of usable peripheral IV sites • Central venous pressure monitoring • Total parenteral nutrition (TPN) • Infusions of fluids, medications, or chemotherapy • Frequent blood sampling or receiving blood transfusions/blood products	Indications for use between the subject and predicate devices are substantially equivalent.
Commercial Name	BD Acute Central Line	Arrow Central Venous Catheter	

	Catheter Dimensions	7 Fr Triple Lumen x 16 cm 7 Fr Triple Lumen x 20 cm 7 Fr Triple Lumen x 30 cm	7 Fr Triple Lumen x 16 cm 7 Fr Triple Lumen x 20 cm	Additional catheter length of 30 cm does not raise new or different questions of safety or effectiveness and a risk assessment did not identify any new or significantly modified risks.
	Duration of Use	Same	Short term (<30 days)	Both the subject and predicate devices are indicated for use for less than 30 days.
	Means of insertion	Same	Percutaneous	Means of insertion is identical between the subject and predicate devices.
	Insertion Site	Same	Jugular, subclavian, or femoral veins	Insertion sites for the subject and predicate devices are identical.
	Primary Device Materials	*Catheter Base Materials* Shaft Tubing: Polyurethane Luer Connector: Polyurethane Extension Legs: Polyurethane Junction: Polyurethane	*Catheter Base Materials* Shaft Tubing: Polyurethane Luer Connector: Polyurethane Extension Legs: Polyurethane Junction: Polyurethane	Catheter base materials for the predicate device are proprietary.
	Catheter Proximal Configuration	Same	Side-hole skive	Lumen configurations are substantially equivalent between the subject and predicate devices.
	Catheter Medial Configuration	Same	Side-hole skive	Lumen configurations are substantially equivalent between the subject and

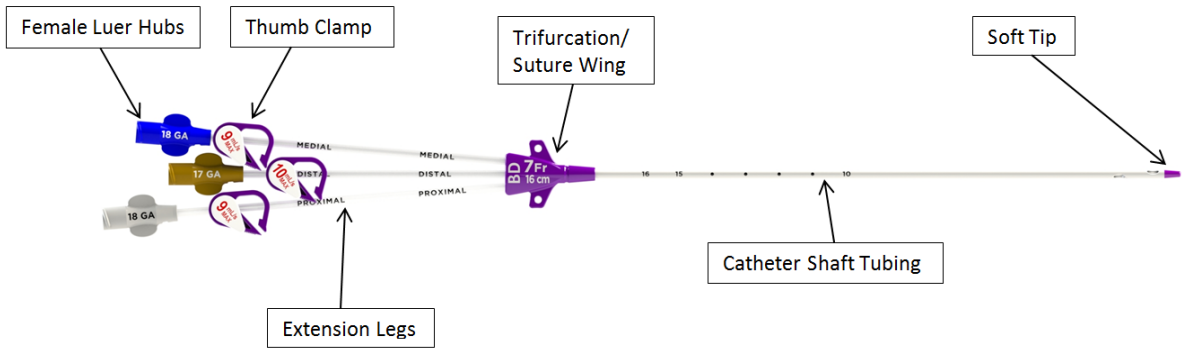
				predicate devices.
	Catheter Distal Configuration	Same	Formed tip	Tip configurations of the subject and the predicate device are substantially equivalent.
	Number of Lumens	Same	Triple Lumen	Same as predicate device.
	Power Injection Maximum Flow Rate	16 and 20 cm length: • Distal (17 Ga.) – 10 mL/sec • Medial (18 Ga.) – 9 mL/sec • Proximal (18 Ga.) – 9 mL/sec 30 cm length: • Distal (17 Ga.) – 9 mL/sec • Medial (18 Ga.) – 7 mL/sec • Proximal (18 Ga.) – 7 mL/sec	16 and 20 cm length: • Distal (16 Ga.) – 10 mL/sec • Medial (18 Ga.) – 5 mL/sec • Proximal (18 Ga.) – 5 mL/sec	Differences in power injection maximum flow rates do not raise additional questions of safety or effectiveness.
	Sterility	Same (10^{-6}) Ethylene Oxide AAMI 11135:2014	Provided Sterile	The subject and predicate devices are both provided sterile.
	The technological differences listed above were evaluated using industry consensus standards, and as defined in the Risk Assessment. 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 by or for BAS per guidance documents and standards in conjunction with in-house protocols to establish the performance of the BD Acute Central Line, and in determining substantial equivalence to the predicate Arrow Central Venous Catheter. All testing passed the predetermined acceptance criteria.

Reference Standard: *ISO 10993-1:2009 – Biological Evaluation of Medical Devices – Part 1: Evaluation and testing within a risk management process*	
Biocompatibility Testing	Tests to confirm that the catheter is free from biological hazard per testing. A health-based risk assessment per ISO 10993-1 was performed for determining the acceptability of the material for the intended purpose. Testing Performed includes: • Cytotoxicity • Sensitization • Irritation or Intracutaneous Reactivity • Acute Systemic Toxicity • Pyrogenicity • Subchronic Systemic Toxicity • Genotoxicity • Hemocompatibility • Implantation
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.
Extension Leg to Trifurcation Tensile Test	
Trifurcation to Shaft Tensile Test	
Shaft Tensile Test	
Reference Standard: *ASTM F640-12 – Standard Test Methods for Radiopacity of Plastics 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 Guidance: 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.
Priming Volume	Test to measure the volume required to prime a full-length catheter.
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.
	•

<table>
<tr><td></td><td>
<table>
<tr><td colspan="2">Reference Standards: ISO 594: Conical Fittings for a 6% (Luer) Taper for Syringes, Needles, and Certain Other Medical Equipment – Part 1: General Requirements and Part 2: Lock Fittings</td></tr>
<tr><td>Luer Testing</td><td>Testing to ensure that luer connectors meet requirements for
Leak
Leak Decay
Stress Cracking
Resistance to Separation from Axial Load
Resistance to Separation from Unscrewing
Resistance to Overriding
Gauging</td></tr>
<tr><td colspan="2">Reference Standard: USP<788>: Sizing and Counting Particulate Matter</td></tr>
<tr><td>Particulate Testing</td><td>Testing to ensure that particulate matter on the catheter post-manufacture is not exceeded for prescribed particle sizes.</td></tr>
<tr><td colspan="2">Reference Standard: FDA Guidance on Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR) Environment, 2014</td></tr>
<tr><td>MR Safety</td><td>Testing to demonstrate that the subject device is safe for use in an MR environment.</td></tr>
</table>
</td></tr>
<tr><td>Diagram</td><td> 
</td></tr>
<tr><td>Technological Comparison to Predicate Device</td><td>Technological characteristics of the subject BD Acute Central Line are substantially equivalent with regard to the basic design and function of the predicate device, Arrow Central Venous Catheter (K071538). The materials in the subject device, as well as the flow rates, lumen geometry, catheter use pressure and priming volumes, differ from the predicate device. 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.</td></tr>
<tr><td>Summary of Substantial Equivalence</td><td>Based on the risk management activities and testing, the subject BD Acute Central Line has been demonstrated to be substantially equivalent to the cited predicate device.</td></tr>
</table>

Conclusion: Based on the indications for use, technological characteristics, and results of performance testing, the subject BD Acute Central Line has been demonstrated to be substantially equivalent to the predicate devices.