September 18, 2019

C.R. Bard, Inc.
Mona Shahrebani
Regulatory Affairs Specialist
605 North 5600 West
Salt Lake City, Utah 84116

Re: K191232
Trade/Device Name: AccuCath Ace™ Intravascular Catheter
Regulation Number: 21 CFR 880.5200
Regulation Name: Intravascular Catheter
Regulatory Class: Class II
Product Code: FOZ
Dated: August 16, 2019
Received: August 19, 2019

Dear Mona Shahrebani:

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 Nikhil Thakur
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)*
K191232

Device Name
AccuCath Ace™ Intravascular Catheter

Indications for Use *(Describe)*
The AccuCath Ace™ Intravascular Catheter is indicated for vascular access, including both the external and internal jugular veins, to sample blood, monitor blood pressure, or administer fluids intravenously. This device may be used with consideration given to adequacy of vascular anatomy, appropriateness of the solution being infused, and duration of therapy. The AccuCath Ace™ IV Catheter is suitable for use with power injectors.

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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510(k) Summary for AccuCath Ace™ Intravascular Catheter

K191232

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 Salt Lake City, UT 84116
	Contact Person:	Mona Shahrebani Regulatory Affairs Specialist
	Telephone Number:	801.522.5967
	Fax Number:	801.522.4907
	Date of Preparation:	9/18/2019
Subject Device	Trade Name(s):	AccuCath Ace™ Intravascular Catheter
	Common Name:	Catheter, Intravascular, Therapeutic, Short-Term Less than 30 days
	Regulation Name:	Intravascular Catheter
	Class:	2
	Regulation Number:	21 CFR 880.5200
	Product Code:	FOZ
	Classification Panel	General Hospital

Predicate Device	Predicate Trade Name: Regulation Name: Class: Product Code: Regulation Number: Premarket Notification #: Manufacturer: Classification Panel	AccuCath™ Intravascular Catheter Intravascular Catheter 2 FOZ 21 CFR 880.5200 K162894 Bard Access Systems, Inc. General Hospital
Reference Device	Reference Trade Name: Classification Name: Class: Product Code: Regulation Number: Premarket Notification #: Manufacturer: Classification Panel	PowerGlide Pro™ Midline Catheter Catheter, Intravascular, Therapeutic, Short-Term Less than 30 days 2 FOZ 21 CFR 880.5200 K153280 Bard Access Systems, Inc. General Hospital
Device Description	The AccuCath Ace™ Intravascular Catheter consists of a radiopaque catheter with a valve mechanism delivered over a guidewire with an atraumatic tip design; a flashback chamber to enhance flashback visualization, and a safety container that prevents sharp injuries. The AccuCath Ace™ Intravascular Catheter is designed to reduce blood exposure during insertion. The devices are single use, sterile, intravascular catheters offered in 18, 20, and 22 gauge configurations. All lumens are power injectable at their labeled flow rate. The AccuCath Ace™ Intravascular Catheter is offered in Emergent Access Kit configurations with various components provided for the convenience of the end user.	
Intended Use	The AccuCath Ace™ Intravascular Catheter is intended to be inserted in the patient's vascular system for short term use to sample blood, monitor blood pressure, or administer fluids intravenously.	
Indications for Use	The AccuCath Ace™ Intravascular Catheter is indicated for vascular access, including both the external and internal jugular veins, to sample blood, monitor blood pressure, or administer fluids intravenously. This device may be used with consideration given to adequacy of vascular anatomy, appropriateness of the solution being infused, and duration of therapy. The AccuCath	

<table>
<tr><td></td><td>Ace™ IV Catheter is suitable for use with power injectors.</td></tr>
<tr><td>Technological Characteristics</td><td>
Technological characteristics of the subject AccuCath Ace™ Intravascular Catheter are substantially equivalent with respect to basic design, function and fundamental scientific technology to those of the cited predicate device.

The following table provides a comparison between the subject and predicate devices.
<table>
<tr><th>Attribute</th><th>Subject Device – AccuCath Ace™ Intravascular Catheter</th><th>Predicate Device – AccuCath Intravascular Catheter</th></tr>
<tr><td>Owner</td><td>Same as predicate</td><td>Bard Access Systems</td></tr>
<tr><td>Classification</td><td>Same as predicate</td><td>FOZ – 21 CFR 880.5200</td></tr>
<tr><td>510(k) Status</td><td>Subject of this Premarket Notification</td><td>K162894 – Concurrence date November 15, 2016</td></tr>
<tr><td>Indications for Use</td><td>The AccuCath Ace™ Intravascular Catheter is indicated for vascular access, including both the external and internal jugular veins, to sample blood, monitor blood pressure, or administer fluids intravenously. This device may be used with consideration given to adequacy of vascular anatomy, appropriateness of the solution being infused, and duration of therapy. The AccuCath Ace™ IV Catheter is suitable for use with power injectors.</td><td>The AccuCath™ Intravascular Catheter is inserted into a patient's vascular system to sample blood, monitor blood pressure, or administer fluids intravenously. This device may be used with consideration given to adequacy of vascular anatomy, appropriateness of the solution being infused, and duration of therapy. The AccuCath™ IV Catheter is suitable for use with power injectors.</td></tr>
<tr><td>Commercial Name</td><td>AccuCath Ace™ Intravascular Catheter Emergent Access Kits</td><td>AccuCath™ Intravascular Catheter</td></tr>
<tr><td>Catheter Dimensions</td><td>Same as predicate</td><td>Gauge / Length
18 gauge, 1.25 & 2.25 inches
20 gauge, 1.25 & 2.25 inches
22 gauge, 1.25 inches</td></tr>
<tr><td>Duration of Use</td><td>Same as predicate</td><td>Short term (<30 days)</td></tr>
<tr><td>Means of</td><td>Same as predicate</td><td>Percutaneous, over a Guidewire</td></tr>
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	insertion		
	Insertion Site	Central, peripheral	peripheral
	Primary Device Materials	Same as predicate	**Catheter Base Materials:** • Shaft Tubing: Polyurethane • Luer Connector: Polyurethane **Needle:** • Stainless Steel **Guidewire:** • Nitinol
	Catheter Proximal Configuration	Same as predicate	Luer connection
	Catheter Distal Configuration	Same as predicate	Open ended
	Number of Lumens	Same as predicate	Single Lumen
	Power Injection Maximum Flow Rate	Same as predicate	6 mL/s
	Sterility	Same as predicate	Provided Sterile
	The technological characteristics listed above were evaluated using industry consensus standards, and as defined in the Risk Assessment. The change in insertion site reflects the use of the device in emergent situations where central access is necessary. A risk analysis was performed to assessed the changes and there were no new or different questions of safety and effectiveness. Therefore, these technological characteristics substantially equivalent to the predicate device and do not raise new or different questions of safety or effectiveness.		
Safety & Performance Tests	The following performance tests were conducted in determining substantial equivalence of the AccuCath Ace™ Intravascular Catheter to the predicate AccuCath™ Intravascular Catheter: • Biocompatibility per ISO 10993-1		

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Biocompatibility was leveraged from the sponsor's own devices-Predicate device (K162894) and Reference device (K153280)

Sterility per AAMI/ANSI/ISO 11135:2014, Sterilization of health care products – Ethylene oxide – Requirements for development, validation and routine control of a sterilization process for medical devices.
Risk Analysis per ISO 14971

<table>
<tr><th colspan="2">Reference Standard: ISO 10555-1:2013 – Sterile Single-Use Intravascular Catheters – Part 1: General requirements</th></tr>
<tr><td>Power Injection Conditioning</td><td>Test to confirm the catheter does not leak or burst as a result of power injections at maximum indicated flow rate.</td></tr>
<tr><td>Hydraulic Catheter Burst Test</td><td>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.</td></tr>
<tr><td>Shaft Tensile Test</td><td>Test to demonstrate the peak tensile force of each test piece exceeds the minimum peak tensile force.</td></tr>
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</td></tr>
<tr><td>Technological Comparison to Predicate Device</td><td>Technological characteristics of the subject AccuCath Ace™ Intravascular Catheter are substantially equivalent with regard to the basic design and function of the predicate device, AccuCath™ Intravascular Catheter (K162894). All changes to materials are determined to be biologically safe for use, and the changes in design are considered substantially equivalent to the predicate device.</td></tr>
<tr><td>Summary of Substantial Equivalence</td><td>The modifications to the indications for use and product instructions for use has no impact on the intended use or the technological characteristics of the device. The results of the risk analysis as well as functional performance testing determined that the subject AccuCath Ace™ Intravascular Catheter has demonstrated to be substantially equivalent to the cited predicate device.</td></tr>
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