April 19, 2024

Bard Access Systems, Inc. (C.R. Bard, Inc.)
Samira Saeed
Regulatory Affairs Specialist I
605 N 5600 W
Salt Lake City, Utah 84116

Re: K233106
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: April 4, 2024
Received: April 16, 2024

Dear Samira Saeed:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

David Wolloscheck, Ph.D.
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K233106

Device Name
AccuCath Ace™ Intravascular Catheter

Indications for Use *(Describe)*
The AccuCath Ace™ 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 for adult and pediatric patients, including those patients with difficult intravascular access who may have small, fragile, and/or non-palpable vessels, 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.

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K233106 - 510(k) Summary 21 CFR 807.92(a)

	Submitter Name:	Bard Access Systems, Inc. (Bard has joined BD)
General Provisions	Submitter Address:	605 North 5600 West Salt Lake City, Utah 84116
	Contact Person:	Samira Saeed Regulatory Affairs Specialist
	Telephone Number:	801.522.5000
	Date of Preparation:	April 19th 2024
	Trade Name:	AccuCath Ace™ Intravascular Catheter
Subject Device:	Common Name:	catheter, intravascular, therapeutic, short-term less than 30 days
	Classification Name:	Intravascular catheter
	Class:	Class II
	Regulation Number:	880.5200
	Product Code:	FOZ
	Classification Panel:	General Hospital
	Trade Name:	AccuCath™ Intravascular Catheter
Predicate Device	Common Name	catheter, intravascular, therapeutic, short-term less than 30 days
	Classification Name:	Intravascular catheter
	Class:	Class II
	Regulation Number:	880.5200
	Product Code:	FOZ
	Premarket Notification Number:	K162894
Device Description	The AccuCath Ace™ Intravascular Catheter system 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 IV Catheter is designed to reduce blood exposure during insertion, for use with ultrasound, and for use with the Cue Needle Tracking System.	
Indications for Use	The AccuCath Ace™ 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 **for adult and pediatric patients, including those patients with difficult intravascular access who may have small, fragile, and/or non-palpable vessels,** 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.	
Technological Characteristics	Technological characteristics of the subject AccuCath Ace™ Intravascular Catheter are substantially equivalent with respect to design and function to those of the cited predicate device.	

The following table provides a comparison between the subject and predicate device:

Attribute	Predicate Device AccuCath™ Intravascular Catheter (K162894)	Subject Device AccuCath Ace™ Intravascular Catheter	Comparison
Owner	Bard Access Systems, Inc.	Bard Access Systems, Inc.	Same
Classification	Class II	Class II	Same
510(k) Status	K162894	Subject of this Premarket Notification	-
Indications for Use	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.	The AccuCath Ace™ 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 **for adult and pediatric patients, including those patients with difficult intravascular access who may have small, fragile, and/or non-palpable vessels,** 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.	Different Added indication for patients with DIVA which is a subset of general use population - no effect on device safety or effectiveness or change in risk.
Commercial Name	AccuCath™ Intravascular Catheter	AccuCath **Ace**™ Intravascular Catheter	Different The minor name change has no effect on device safety or effectiveness

			and results in no new or modified risks
Catheter Dimensions	Length: 1.25 & 2.25 inches Diameter: 18, 20, 22 gauge	Length: 1.25 & 2.25 inches Diameter: 18, 20, 22 gauge	Same
Durations of Use	Short term (<30 days)	Short term (<30 days)	Same
Primary Device Components	Needle Guidewire Catheter	Needle Guidewire Catheter	Same
Means of Insertion	Percutaneous, over a guidewire	Percutaneous, over a guidewire	Same
Insertion Site	Peripheral	Peripheral	Same
Primary Device Materials	Catheter Base Materials: ▪ Shaft Tubing: Pebax® ▪ Luer Connector: Polyurethane Needle: Stainless Steel Guidewire: Nitinol	Catheter Base Materials: ▪ Shaft Tubing: Pebax® ▪ Luer Connector: Polyurethane Needle: Stainless Steel Guidewire: Nitinol	Same
Catheter Proximal Configuration	Luer Connection	Luer Connection	Same
Catheter Distal Configuration	Open Ended	Open Ended	Same
Number of Lumens	Single Lumen	Single Lumen	Same
Power Injection Maximum Flow Rate	6 mL/s	6 mL/s	Same
Sterility	Provided Sterile	Provided Sterile	Same
Available Configurations	Standalone Basic Kit	Standalone Basic Kit **Intermediate Kit**	Different The addition of the intermediate kit configuration has no effect

			on device safety or effectiveness and results in no new or modified risks.
Cue Needle Tracking System Compatibility	None	**2.25" AccuCath Ace IV Catheters**	Different The addition of Cue compatibility has no effect on device safety or effectiveness and results in no new or modified risks. Verification testing was carried out on all changed aspects: the needle, packaging, ultrasound system/Cue compatibility, tracking accuracy, and magnetization. All acceptance criteria was met.

The key modification made to the subject device when compared to the predicate device is the specification of a difficult intravascular access (DIVA) indication to the indications for use. As a result, the indications for use in the product instructions for use were updated to reflect the modification. Previously, several design, packaging, and labeling changes were made to the AccuCath Ace IV Catheter. These changes are currently implemented in the marketed predicate devices.

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Performance Tests	As part of Bard Access Systems, Inc.'s design controls, a risk analysis was conducted to assess the impact of the proposed subject device indications for use modifications. The results of the risk analysis determined that no verification or validation activities were required because the subject device modifications to the Indications for use and resulting modifications to the instructions for use and labeling do not include any changes to the design, materials, performance, or risk profile of the cited predicate device. Therefore, it is not necessary to conduct additional performance tests including verification and validation. Since clearance of the predicate, several additional changes were made to the device and documented via Letter to File. Verification, sterilization, biocompatibility, and packaging testing was carried out as necessary for each of these changes at the time of the change. In each case, the changed device was found to be as safe and as effective and introduced no new or modified risks. These historic changes are currently implemented in the marketed predicate devices.
Clinical Literature	There is a body of literary evidence demonstrating that the AccuCath Ace Intravascular Catheter has equivalent or better outcomes in DIVA patients compared to catheters with no guidewire. These outcomes include improved first attempt success, reduction of insertion complications, improved completion of therapy, increased dwell time of the catheter, and overall patient and clinician satisfaction. AccuCath Ace includes features that improve ease of insertion and limit vessel damage making the AccuCath Ace Intravascular Catheter an ideal option for DIVA patients.
Summary of Substantial Equivalence	The modification to the indications for use and resulting modifications to the product instructions for use and labeling has no impact on the intended use, technological characteristics, or risk profile of the subject device because there are no changes to the design or performance of the predicate device. Previous minor changes made to the device have been documented and the necessary testing carried out. The changes were found to have no impact on the safety and effectiveness of the device, nor did they introduce new risks or modify existing risks. Therefore, the subject AccuCath Ace™ Intravascular Catheter is substantially equivalent to the predicate AccuCath™ Intravascular Catheter.