March 1, 2024

Bard Access Systems, Inc.
% Samira Saeed
Regulatory Affairs Specialist I
605 N 5600 W
SALT LAKE CITY UT 84116

Re: K240146
Trade/Device Name: BD Prevue™ II Peripheral Vascular Access System
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic Pulsed Echo Imaging System
Regulatory Class: Class II
Product Code: IYO, IYX, LLZ

Dear Samira Saeed:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated February 18, 2014. Specifically, FDA is updating this SE Letter to include the correct IFU statement and 510(k) Summary, as an administrative correction.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Yanna Kang, OHT8: Office of Radiological Health, (301) 796-6704, Yanna.Kang@fda.hhs.gov.

Sincerely,

Yanna S. Kang -S

Yanna Kang, Ph.D.
Assistant Director
Mammography and Ultrasound Team
DHT8C: Division of Radiological Imaging
and Radiation Therapy Devices
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

February 18, 2024

Bard Access Systems, Inc.
% Samira Saeed
Regulatory Affairs Specialist I
605 N 5600 W
SALT LAKE CITY UT 84116

Re: K240146
Trade/Device Name: BD Prevue™ II Peripheral Vascular Access System
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic Pulsed Echo Imaging System
Regulatory Class: Class II
Product Code: IYO, IYX, LLZ
Dated: January 18, 2024
Received: January 19, 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,

Yanna S. Kang -S

Yanna Kang, Ph.D.
Assistant Director
Mammograph and Ultrasound Team
DHT8C: Division of Radiological Imaging
and Radiation Therapy Devices
OHT8: Office of Radiological Health
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)*
K240146

Device Name
BD Prevue™ II Peripheral Vascular Access System

Indications for Use *(Describe)*
BD Prevue™ II Peripheral Vascular Access System is indicated for Vascular and Vascular Access Imaging Applications performed by appropriately trained healthcare professionals in a medical setting. Typical examinations performed using the BD Prevue™ II Peripheral Vascular Access System include:
[Table]
Imaging Applications:
Vascular [Exam Type (Adult and Pediatric)]: Assessment of vessels in the extremities and neck leading to or coming from the heart, superficial veins in the arms and legs, and vessel mapping. Assessment of superficial thoracic vessels.
Vascular Access [Exam Type (Adult and Pediatric)]: Guidance for PICC, CVC, dialysis catheter, port, PIV, midline, arterial line placement, access to fistula and grafts, and general vein and artery access in adult and pediatric patients, including those patients with difficult intravascular access who may have small, fragile, and/or non-palpable vessels.

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:

Department of Health and Human Services
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."

Bard Access Systems, Inc.
605 North 5600 West
Salt Lake City, UT 84116 USA
Phone: +1-801-522-5000

K240146
510(k) Summary 21 CFR 807.92(a)

General Provisions	Submitter Name:	Bard Access Systems, Inc. (Bard has joined BD)
	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:	January 16 2023
Subject Device:	Trade Name:	BD Prevue II Peripheral Vascular Access System
	Common Name:	Ultrasound System with Needle Tracking
	Regulation Name:	Ultrasonic Pulsed Echo Imaging System Diagnostic Ultrasonic Transducer Picture Archiving and Communication System
	Regulation Number:	21 CFR 892.1560 21 CFR 892.1570 21 CFR 892.2050
	Product Code:	IYO ITX LLZ
	Regulatory Class:	Class II
	Classification Panel:	Radiology
Predicate Device	Trade Name:	BD Prevue II Peripheral Vascular Access System
	Common Name:	Ultrasound System with Needle Tracking
	Regulation Name:	Ultrasonic Pulsed Echo Imaging System Diagnostic Ultrasonic Transducer Picture Archiving and Communication System
	Regulation Number:	21 CFR 892.1560 21 CFR 892.1570 21 CFR 892.2050
	Product Code:	IYO ITX LLZ
	Regulatory Class:	Class II
	Classification Panel:	Radiology
	Premarket Notification Number:	K211193
Device Description	BD Prevue™ II Peripheral Vascular Access System Device Description: The BD Prevue™ II Peripheral Vascular Access System is a portable device that features real-time 2D ultrasound imaging, customized vascular access applications, procedure documentation, vessel measurement tools, and electronic connectivity (if enabled). Cue™ Needle Tracking System Description:	

	The BD Prevue™ II Peripheral Vascular Access System is equipped with Cue™ Needle Tracking System which is designed to track and display the location and trajectory of a needle under ultrasound guidance. The technology consists of software installed on an ultrasound system and sensors incorporated into the ultrasound probes. The sensors detect a passive magnetic field emitted from the needle. The software interprets the data from the sensors and creates a virtual image of the needle on the ultrasound display, providing clinicians with a visual representation of the needle during the insertion process. The Cue™ Needle Tracking System requires the use of either the Cue™ Traditional Probe or Cue™ Vascular Access Probe, the Cue™ Magnetizer and a Cue™ enabled needle. The Cue™ Traditional Probe and Vascular Access Probe contain sensors for tracking Cue™ compatible needles (following magnetization by the Cue™ Magnetizer). The tracked needle's current position, trajectory, and intersection window are displayed over the ultrasound image.
Indications for Use	BD Prevue™ II Peripheral Vascular Access System is indicated for Vascular and Vascular Access Imaging Applications performed by appropriately trained healthcare professionals in a medical setting. Typical examinations performed using the BD Prevue™ II Peripheral Vascular Access System include:

Imaging Applications	Exam Type (Adult and Pediatric)
Vascular	Assessment of vessels in the extremities and neck leading to or coming from the heart, superficial veins in the arms and legs, and vessel mapping. Assessment of superficial thoracic vessels.
Vascular Access	Guidance for PICC, CVC, dialysis catheter, port, PIV, midline, arterial line placement, access to fistula and grafts, and general vein and artery access **in adult and pediatric patients, including those patients with difficult intravascular access who may have small, fragile, and/or non-palpable vessels.**

Technological Characteristics	Technological characteristics of the subject BD Prevue™ II Peripheral Vascular Access System are substantially equivalent with respect to design and function to those of the cited predicate device. The key modification made to the subject device when compared to the predicate device is the specification of difficult intravascular access (DIVA) patients in the indications for use. As a result, the indications for use in the product instructions for use was updated to reflect the modification. There are no other differences between the subject and predicate device.
Performance Tests	As part of Bard Access Systems, Inc.'s design controls, 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 and the performance testing conducted in the predicate device clearance (K211193) covers the proposed specified difficult intravascular access patient population. Therefore, it is not necessary to conduct additional verification and validation testing.

Summary of Substantial Equivalence	The modification to the indications for use and resulting modifications to the product instructions for use 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. Therefore, the subject BD Prevue™ II Peripheral Vascular Access System is substantially equivalent to the predicate BD Prevue™ II Peripheral Vascular Access System.