Bard Access Systems, Inc, (C.R. Bard, Inc.)
% Fabio De Pasquale
Regulatory Affairs
605 North 5600 West
SALT LAKE CITY UT 84116

June 25, 2021

Re: K211193
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, ITX, LLZ
Dated: April 21, 2021
Received: April 21, 2021

Dear Fabio De Pasquale:

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

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and 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)*

K211193

Device Name

BD Prevue™ II Peripheral Vascular Access System

Indications for Use *(Describe)*

The BD Prevue™ II Peripheral Vascular Access System is intended for diagnostic ultrasound imaging of the human body performed by appropriately trained healthcare professionals in a medical setting. Specific clinical applications include:

- *Pediatric*
- *Peripheral Vessel and Vascular Access*

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.
VascularAccess	Guidance for PICC, CVC, dialysis catheter, port, PIV, midline, arterial line placement, accessto fistula and grafts, and general vein and artery access.

The Cue™ Needle Tracking System is intended to provide visual needle tracking to assist with ultrasound guided vascular access.

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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Section 8 – 510(k) Summary

(in accordance with 21 CFR 807.92)

510(k) Number: K211193

I. Applicant Information

Applicant:

Bard Access Systems, Inc. (C.R. Bard, Inc.)
(Bard has now joined Becton Dickinson)
605 North 5600 West
Salt Lake City, UT 84116
USA

Contact Person: **Fabio De Pasquale**
Regulatory Affairs
Tel: 1-250-920-6501
e-mail: fabio.de.pasquale@bd.com

Application Correspondent: **Same as Applicant.**

Date Prepared: April 21, 2021

II. Subject Device Identification

Proprietary Name:	**BD Prevue™ II Peripheral Vascular Access System**
Common/Usual Name:	Ultrasound System with Needle Tracking
Regulation Name:	Ultrasonic Pulsed Echo Imaging System
Regulation Number:	21 CFR 892.1560
Product Code:	IYO
Regulation Name:	Diagnostic Ultrasonic Transducer
Regulation Number:	21 CFR 892.1570
Product Code:	ITX
Regulation Name:	Medical Image Management and Processing System
Regulation Number:	21 CFR 892.2050
Product Code:	LLZ
Regulatory Class:	Class II
Classification Panel:	Radiology

III. Predicate Device

The subject device, the **BD Prevue™ II Peripheral Vascular Access System**, is substantially equivalent to the following cleared predicate device. The subject and predicate devices have the same fundamental scientific technology and intended use:

510(k) Number:	**K182281**
Proprietary Name:	**Site~Rite® 8 Ultrasound System with Cue™ Needle Tracking System and Pinpoint™ GT Needle Technology**
Common/Usual Name:	Ultrasound System with Needle Tracking
Regulation Name:	Ultrasonic Pulsed Echo Imaging System
Regulation Number:	21 CFR 892.1560
Product Code:	IYO
Regulation Name:	Diagnostic Ultrasonic Transducer
Regulation Number:	21 CFR 892.1570
Product Code:	ITX
Regulation Name:	Picture Archiving and Communication System
Regulation Number:	21 CFR 892.2050
Product Code:	LLZ
Regulatory Class:	Class II
Classification Panel:	Radiology

IV. Subject Device Description

The subject device, the **BD Prevue™ II Peripheral Vascular Access System** ("**Prevue II 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).

The subject **Prevue II System** is intended to aid in the placement of peripheral vascular access devices and ultimately increase first stick success. The system is intended to be a relatively low cost, easy to use and adaptable system, targeted specifically for use in the Intensive Care Unit (ICU) and Emergency Department (ED).

The subject **Prevue II System** can be viewed as the next generation Prevue ultrasound system (i.e., K120882 and K150529) and is essentially a pared-down version of its predicate device, the Site~Rite® 8 Ultrasound System with Cue™ Needle Tracking System and Pinpoint™ GT Needle Technology (K182281).

The subject **Prevue II System** includes the optional **Cue™ Needle Tracking System**, which is the same identical needle guidance technology already

cleared with the predicate device, the Site~Rite® 8 Ultrasound System, under K182281.

The **Cue™ Needle Tracking System** technology is designed to track and display the location and trajectory of a needle under ultrasound guidance. The technology consists of software installed on the **Prevue II System** and a sensor incorporated into the ultrasound probes. The ultrasound probe sensor detects a passive magnetic field emitted from a needle that has been previously magnetized using the **Cue™ Needle Tracking System Magnetizer**, which is a system also included in the predicate device. The probe interprets the data received from the sensor 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 tracked needle's current position, trajectory and intersection window are displayed over the ultrasound image. The **Cue™ Needle Tracking System** is currently included with the predicate device and is not a subject of this 510(k) submission.

The subject **Prevue II System** differs from its predicate device, the Site~Rite® 8 Ultrasound System (K182281), in that it provides a more portable and simpler to use device that can be operated by less experienced ultrasound users, primarily in an ICU and/or ED medical setting. Aside from this simplification of features, most of the other previously cleared features of the predicate device are being brought forward.

The subject **Prevue II System** includes the following main components:

- Ultrasound System Console
- Ultrasound Beamformer
- System Software (including Cue™ Needle Tracking System Software)
- Ultrasound Probes (Cue™ compatible)
- Cue™ Needle Tracking System Hardware (i.e., Magnetizer and RFID Reader)

Additionally, the subject **Prevue II System** is compatible with the following accessories:

- Site~Rite® Probe Cover Kits
- Cue™ Magnetizer
- Cue™ Compatible Needles
- Probe Holder Accessory
- Cable Wrap Accessory
- Prevue II Magnetizer Cover
- Prevue II Roll Stand
- USB Storage Device (off-the-shelf flash-drive used to save files or perform software updates)

As discussed in the following sections, the intended use, technological characteristics, principles of operation and materials of the subject device are substantially equivalent to the respective ones of the predicate device.

V. Indications for Use

The **BD Prevue™ II Peripheral Vascular Access System** is intended for diagnostic ultrasound imaging of the human body performed by appropriately trained healthcare professionals in a medical setting. Specific clinical applications include:

- Pediatric
- Peripheral Vessel and Vascular Access

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.

The **Cue™ Needle Tracking System** is intended to provide visual needle tracking to assist with ultrasound guided vascular access.

VI. Substantial Equivalence

Intended Use

The **BD Prevue™ II Peripheral Vascular Access System** and its predicate device have the same intended use: diagnostic ultrasound imaging of the human body.

Indications for Use

The **BD Prevue™ II Peripheral Vascular Access System** adopts the same Indications for Use of its predicate device, with some minor differences that do not change the intended use of the **BD Prevue™ II Peripheral Vascular Access System** when compared with the intended use of its predicate device.

The Indications for use for the subject **BD Prevue™ II Peripheral Vascular Access System** include a reduced number of clinical applications with respect to those of the predicate device, the Site~Rite® 8 Ultrasound System with Cue™ Needle Tracking System and Pinpoint™ GT Needle Technology (K182281).

More specifically, the following imaging applications, which are included with the predicate Site~Rite® 8 Ultrasound System with Cue™ Needle Tracking System and Pinpoint™ GT Needle Technology, are not included with the subject **BD Prevue™ II Peripheral Vascular Access System**:

1. Small organs (i.e., breast, thyroid, parathyroid, testicles);
2. Musculo-skeletal (i.e., conventional and superficial);
3. Cardiac (i.e., adult and pediatric);
4. Interventional (i.e., guidance for biopsy and drainage); or
5. Superficial (i.e., assessment of breast, thyroid, parathyroid, testicle, lymph nodes, musculoskeletal procedures, soft tissue structures and surrounding anatomical structures).

For a more detailed comparison of the clinical applications of use between the subject and predicate device, please see the Substantial Equivalence Table below.

Technological Characteristics

The subject **BD Prevue™ II Peripheral Vascular Access System** employs the same identical fundamental scientific technology as the predicate device, the Site~Rite® 8 Ultrasound System with Cue™ Needle Tracking System and Pinpoint™ GT Needle Technology (K182281), in that piezoelectric material in the transducer is used as an ultrasound source to transmit sound waves into the body. Sound waves are reflected back to the transducer and converted to electrical signals that are processed and displayed as 2D images. The subject device is technologically identical to the predicate device and incorporates the same needle guidance technology as the predicate device (i.e., the Cue™ Needle Tracking System). Both subject and predicate devices share substantially equivalent patient contacting materials.

Additionally, all the features presented by the **BD Prevue™ II Peripheral Vascular Access System** are included and are similar and substantially equivalent to the corresponding features of the predicate device.

The following table summarizes the substantial equivalence comparison between the subject and the predicate device.

Substantial Equivalence Comparison Table

Device Name	**Subject Device:** **BD Prevue™ II Peripheral Vascular Access System**	**Predicate Device: (K182281)** **Site~Rite® 8 Ultrasound System with Cue™ Needle Tracking System and Pinpoint™ GT Needle Technology**
Product Codes	IYO – ITX – LLZ	IYO – ITX – LLZ
Regulation #s	892.1560 – 892.1570 – 892.2050	892.1560, 892.1570, 892.2050
Device Class	II	II
Intended Use / Indications for Use	The BD Prevue™ II Peripheral Vascular Access System is intended for diagnostic ultrasound imaging of the human body performed by appropriately trained healthcare professionals in a medical setting. Specific clinical applications include: • Pediatric • Peripheral Vessel and Vascular Access Typical examinations performed using the BD Prevue™ II System include:	The Site~Rite® 8 Ultrasound System with Cue™ Needle Tracking System and Pinpoint™ GT Needle Technology is intended for diagnostic ultrasound imaging of the human body. Specific clinical applications include: • Pediatric • Peripheral Vessel and Vascular Access • Small Organ (breast, thyroid, parathyroid, testicles) • Musculo-skeletal (conventional and superficial) • Cardiac (adult and pediatric) Typical examinations performed using the Site~Rite® 8 Ultrasound System include:

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<tr><th>Imaging Applications</th><th>Exam Type (Adult and Pediatric)</th></tr>
<tr><td>Vascular</td><td>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.</td></tr>
<tr><td>Vascular Access</td><td>Guidance for PICC, CVC, dialysis catheter, port, PIV, midline, arterial line placement, access to fistula and grafts, and general vein and artery access</td></tr>
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The Cue™ Needle Tracking System is intended to provide visual needle tracking to assist with ultrasound guided vascular access.
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<tr><td>Vascular Access</td><td>Guidance for PICC, CVC, dialysis catheter, port, PIV, midline, arterial line placement, access to fistula and grafts, and general vein and artery access</td></tr>
<tr><td>Interventional</td><td>Guidance for biopsy and drainage</td></tr>
<tr><td>Superficial</td><td>Assessment of breast, thyroid, parathyroid, testicle, lymph nodes, hernias, musculoskeletal procedures (e.g., joints, ligaments, tendons), soft tissue structures, and surrounding anatomical structures</td></tr>
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Cue™ Needle Tracking System and Pinpoint™ GT Needle Technology are each intended to provide visual needle tracking to assist with ultrasound guided vascular access.
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<td>Environment of Use</td>
<td>Hospital/clinic medical setting.</td>
<td>Hospital/clinic medical setting.</td>
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Track 1 or Track 3	Track 1	Track 1
Power Source	AC Adapter with Internal Lithium-Ion Battery Pack. Power Consumption: 65 W	AC Adapter with Internal Lithium-Ion Battery Pack. Power Consumption: 60 W
System Components	The BD Prevue™ II Ultrasound System includes the following components: • Prevue II Console • Ultrasound Beamformer • Software • Ultrasound Probes • Cue™ Needle Tracking System Hardware	The Site~Rite® 8 Ultrasound System includes the following components: • Site~Rite 8 Console • Beamformer • Software • Ultrasound Probes • Cue™ Needle Tracking System Hardware
System Console	The BD Prevue™ II Ultrasound System includes: • 7” Touch Screen Monitor • Portable • Weight 3.5 lbs Graphic User Interface (GUI): Touchscreen user interface with icons to access all available functionality, including the Cue™ Needle Tracking System.	The Site~Rite® 8 Ultrasound System includes: • 10” Touch Screen Monitor • Portable • Weight 5 lbs Graphic User Interface (GUI): Touchscreen user interface with icons to access all available functionality, including the Cue™ Needle Tracking System.
Ultrasound Beamformer	The BD Prevue™ II Ultrasound System uses B mode for all compatible probes.	The Site~Rite® 8 Ultrasound System uses B mode for all compatible probes.
Ultrasound Features	The BD Prevue™ II Ultrasound System includes the following features: • Intuitive controls allowing for rapid and easy operation; • Choice of battery or line voltage power;	The Site~Rite® 8 Ultrasound System includes the following features: • Intuitive controls allowing for rapid and easy operation; • Choice of battery or line voltage power;

	• Portable system; • Operating parameters of scanner determined by image depth; • Image freeze frame; • Simplified, touch screen user interface; • Image saving; • Vessel assessment tools; • Clinician preference presets; • Patient information and file management; and • On-screen keyboard.	• Portable system; • Operating parameters of scanner determined by image depth; • Image freeze frame; • Simplified, touch screen user interface; • Image saving; • Vessel assessment tools; • Clinician preference presets; • Patient information and file management; and • On-screen keyboard.
Software	Operating System (OS): • MS Windows 10 Embedded Needle Guidance Technology: • Passive magnetic tracking using the Cue™ Needle Tracking System Needle Measurement Depths: • 1.5 cm • 2.5 cm Ultrasound Settings: • Gain/Brightness	Operating System (OS): • MS Windows 7 Embedded Needle Guidance Technology: • Passive magnetic tracking using the Cue™ Needle Tracking System • Passive magnetic tracking using the Pinpoint GT Needle Technology Needle Measurement Depths: • 1 cm • 1.5 cm • 3 cm • 4.5 cm • 6 cm Ultrasound Settings: • Gain/Brightness

		• Image filter • Contrast (low/high)
Magnetic Field Detection Technology	Cue™ Needle Tracking System Requires the use of: • Prevue™ II Ultrasound System Console. • Detachable Cue™ compatible Probe. • Cue™ RFID Reader (embedded into the console handle) and a Cue™ Magnetizer (mounted to the side of the console). • Qualified disposable needle that is present in the system's needle library and packaged in Cue™ compatible packaging. The Cue™ Needle Tracking System software module is included with the Prevue™ II Ultrasound System. The Cue™ compatible needle is magnetized ("activated") using the Cue™ Needle Tracking System Magnetizer. The Cue™ Needle Tracking System software module receives the information transmitted by the Cue™ compatible Probe sensor board. The software receives information from the sensor board regarding the relative position and movement	Cue™ Needle Tracking System Requires the use of: • Site~Rite® 8 Ultrasound System Console. • Detachable Cue™ compatible Probe. • Cue™ RFID-Reader/Magnetizer unit (i.e., the "Activator", a component of the Cue™ Needle Tracking System) externally connected to the console via USB cable. • Qualified disposable needle that is present in the system's needle library and packaged in Cue™ compatible packaging. The Cue™ Needle Tracking System software module is included with the Site~Rite® 8 Ultrasound System. The Cue™ compatible needle is magnetized ("activated") using the Cue™ Needle Tracking System Activator. The Cue™ Needle Tracking System software module receives the information transmitted by the Cue™ compatible Probe sensor board. The software receives information from the sensor board regarding the relative position and

	of a passive magnet with a known magnetic signature (associated with a specific Cue™ compatible needle). This information is converted by the software into an overlay that is projected over the ultrasound image representing the relative position, projected needle path, and movement of a needle on the ultrasound image.	movement of a passive magnet with a known magnetic signature (associated with a specific Cue™ compatible needle). This information is converted by the software into an overlay that is projected over the ultrasound image representing the relative position, projected needle path, and movement of a needle on the ultrasound image.
Visualization Features	The BD Prevue™ II Ultrasound System Console includes the following visualization features: • Visualization of a vessel and surrounding anatomy. • Visualization and measure of catheter size relative to a vessel. • Visualization of a needle trajectory. • Visualization of virtual catheter location during vascular access placement. • Measure of remaining catheter length based on vessel depth and assumed insertion angle. • Visualization of the insertion angle while using the Cue™ Needle Tracking System, allowing the user to set a "maximum angle rule" for system notification. Visualization of the remaining catheter length while using the Cue™ Needle Tracking System, allowing the user to set a "minimum remaining catheter length" rule for system notification.	The Site~Rite® 8 Ultrasound System Console includes the following visualization features: • Visualization of a vessel and surrounding anatomy. • Visualization and measure of catheter size relative to a vessel. • Visualization of a needle trajectory. • Visualization of virtual catheter location during vascular access placement. • Measure of remaining catheter length based on vessel depth and assumed insertion angle. • Visualization of the insertion angle while using the Cue™ Needle Tracking System, allowing the user to set a "maximum angle rule" for system notification. Visualization of the remaining catheter length while using the Cue™ Needle Tracking System, allowing the user to set a "minimum remaining catheter length" rule for system notification.
Ultrasound Probes	The BD Prevue™ II Ultrasound System includes the following 2 probes: • Prevue II Traditional Probe	The Site~Rite® 8 Ultrasound System includes the following 3 probes: • Detachable Cue™ 20mm Linear Probe

	• Prevue II Vascular Access Probe Prevue II Probes Characteristics: • Cue™ compatible → Yes • Buttons → No • Acoustics → B-mode imaging	• Detachable 20mm Pinpoint™ GT Linear probe • Detachable 32mm Linear Probe Site~Rite 8 Probes Characteristics: • Cue™ compatible → Yes • Buttons → Yes • Acoustics → B-mode imaging
Accessories	The BD Prevue™ II Ultrasound System is compatible with the following accessories: • Site~Rite® Probe Cover Kits • Probe Holder Accessory • Prevue II Roll Stand • Cue™ Compatible Needles • Cue™ Magnetizer Cover • Cable Wrap Accessory • USB storage device(*) (*) Users are able to save files or perform software updates using a standard off-the-shelf USB storage device.	The Site~Rite® 8 Ultrasound System is compatible with the following accessories: • Site~Rite® Probe Cover Kits • Probe Holder Accessory • MER Roll Stand • Cue™ Compatible Needles • Cue™ Activator Mounting Arm • Site~Rite® Needle Guide Kits • Pinpoint™ GT Needle Guide Kits • Keyboard • Kickstand Mounting Accessory • Site~Rite® 8 Ultrasound System Roller Bag • Optional printers (with mounting hardware)(*) • Silex® Wireless Bridge(*) • USB storage device(*) (*) The optional printer(s) and the Silex® Wireless Bridge are standard off-the-shelf (non-medical) accessories qualified to be used with the Site~Rite® 8 Ultrasound System. Users are also

		able to save files or perform software updates using a standard off-the-shelf USB storage device.
Compatible Needles and Catheters	All needles available in the market are compatible with the Prevue II system. Additionally, the system is also compatible with all Cue™ catheters currently cleared for sale.	All needles available in the market are compatible with the Site~Rite 8 system. Additionally, the system is also compatible with all Cue™ catheters currently cleared for sale.

VII. Non-Clinical Performance Data

C.R. Bard, Inc. has conducted extensive verification and validation testing of the **BD Prevue™ II Peripheral Vascular Access System**, as an ultrasonic pulsed echo imaging system capable of providing diagnostic ultrasound imaging of the human body. The subject device was tested to ensure that it can provide all the capabilities necessary to operate safely and effectively.

Acceptance criteria have been established to ensure that the subject device performs in a manner that is substantially equivalent to the cited predicate device. Testing was conducted to verify the safety and performance requirements of the subject device and the test results support substantial equivalence to the predicate device. The following table lists the nonclinical tests performed on the subject **BD Prevue™ II Peripheral Vascular Access System** for a determination of substantial equivalence.

Prevue™ II System – Nonclinical Tests Performed
Acoustic Safety Testing
System Electrical Safety Testing
Electromagnetic Compatibility Testing
FCC Compliance Testing
Biocompatibility Testing
System Mechanical Testing
Fluid Ingress Testing
Operating Temperature and Humidity Testing
Electrical Reliability Testing
Software Verification Testing
Cybersecurity Assessment
Human Factors and Validation
Ultrasound Image Testing
Ultrasound Response Time Testing
Cue Needle Tracking Accuracy Testing
Cue Tools Accuracy Testing
Cleaning/Reprocessing Testing
Ship Testing
Roll Stand Testing

The **BD Prevue™ II Peripheral Vascular Access System**, complies with all the applicable voluntary standards related to its Regulations and Product Codes and successfully passed all respective testing.

The following guidance documents and standards were followed to determine appropriate methods for evaluating the performance of the subject device.

Standards and Guidance Documents Applicable to Prevue™ II System	
Standard/Guidance	**Title**
FDA Guidance	Marketing Clearance of Diagnostic Ultrasound Systems and Transducers
FDA Guidance	Applying Human Factors and Usability Engineering to Medical Devices
FDA Guidance	Format for Traditional and Abbreviated 510(k)s
FDA Guidance	Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices
FDA Guidance	Content of Premarket Submissions for Management of Cybersecurity in Medical Devices
FDA Guidance	Post Market Management of Cybersecurity in Medical Devices
FDA Guidance	Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process"
FDA Guidance	Recommended Content and Format of Non-Clinical Bench Performance Testing Information in Premarket Submissions
FDA Guidance	The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]
FDA Guidance	Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices
FDA Guidance	Refuse to Accept Policy for 510(k)s
FDA Guidance	eCopy Program for Medical Device Submissions
IEC 60601-1:2012	Medical Electrical Equipment - Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance
IEC 60601-1-2:2014	Medical Electrical Equipment – Part 1-2: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Electromagnetic Disturbances – Requirements and Tests
IEC 60601-1-6:2013	Medical Electrical Equipment-Part 1-6: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Usability
IEC 60601-2-37:2015	Medical Electrical Equipment – Part 2-37: Particular Requirements for the Basic Safety and Essential Performance of Ultrasonic Medical Diagnostic and Monitoring Equipment
IEC 62359:2017	Ultrasonics - Field Characterization - Test Methods For The Determination Of Thermal And Mechanical Indices Related To Medical Diagnostic Ultrasonic Fields
IEC 62304:2015	Medical device software – Software Life Cycle Processes
IEC 62366-1:2015	Medical Devices – Part 1: Application of Usability Engineering to Medical Devices
ISO 10993-1:2018	Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing within a Risk Management Process
ISO 15223-1:2016	Medical Devices - Symbols To Be Used With Medical Device Labels, Labelling, And Information To Be Supplied - Part 1: General Requirements
ISO 14971:2007	Medical Devices – Application of Risk Management To Medical Devices

Standards and Guidance Documents Applicable to Prevue™ II System	
Standard/Guidance	**Title**
FCC Title 47 CFR part 18	Telecommunication, Part 18 – Industrial, Scientific and Medical Equipment
FCC Title 47 CFT Part 15 B	Telecommunication, Part 15 – Radiofrequency devices, Part B (Clan A) – Unintentional Radiators
FCC Title 47 CFR part 15 C	Telecommunication, Part 15 – Radio Frequency Devices; Part C – Intentional Radiators

VIII. Clinical Performance Data

No clinical testing was conducted in support of the **BD Prevue™ II Peripheral Vascular Access System**, as the intended use, indications and technology are equivalent to those of the predicate device. The non-clinical testing summarized in this submission supports the substantial equivalence of this device to the predicate with respect to safety and effectiveness.

IX. Statement of Substantial Equivalence

Based on substantially equivalent intended use, technological characteristics and safety and performance testing as the predicate device, the **BD Prevue™ II Peripheral Vascular Access System** is deemed to be substantially equivalent to its predicate, the Site~Rite® 8 Ultrasound System with Cue™ Needle Tracking System and Pinpoint™ GT Needle Technology cleared under K182281.

The **BD Prevue™ II Peripheral Vascular Access System**, as designed and manufactured, does not raise new questions regarding safety and effectiveness as compared to its predicate device and is concluded to be substantially equivalent to its predicate device.