DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

C.R. Bard, Inc.
Bard Access Systems, Inc.
% Ms. Kerrie Hamblin
Regulatory Affairs Project Manager
605 North 5600 West
SALT LAKE CITY UT 84116

December 14, 2015

Re: K152554
Trade/Device Name: Site-Rite® 8 Ultrasound System with Pinpoint™ GT Technology
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulatory Class: II
Product Code: IYO, ITX, LLZ
Dated: November 12, 2015
Received: November 13, 2015

Dear Ms. Hamblin:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K152554

Device Name
Site~Rite® 8 Ultrasound System with Pinpoint™ GT Technology

Indications for Use *(Describe)*

The Site~Rite® 8 Ultrasound System is intended for diagnostic ultrasound imaging of the human body. Specific clinical applications include:

- Pediatric
- Peripheral Vessel
- 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:

Imaging Applications	Exam Type (Adult and Pediatric)
Vascular	Assessment of vessels in the extremities and neck (e.g., jugular, carotid) leading to or coming from the heart, superficial veins in the arms and legs (e.g., basilic, cephalic, brachial, femoral, radial, saphenous), and vessel mapping. Assessment of superficial thoracic vessels (e.g., axillary, innominate, subclavian)
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
Interventional	Guidance for biopsy and drainage
Superficial	Assessment of breast, thyroid, parathyroid, testicle, lymph nodes, hernias, musculoskeletal procedures (e.g., joints, ligaments, tendons), soft tissue structures, and surrounding anatomical structures

Pinpoint™ GT Technology is intended to provide clinicians with visual tools for passive magnetic tracking of a needle with respect to ultrasound image data.

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.

Diagnostic Ultrasound Indication for Use

Table 1.3-1
Ultrasound System: Site~Rite® 8 Ultrasound System with 32 mm Linear Probe (Non-detachable Transducer)

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Applications	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Opthalmic										
Fetal										
Abdominal										
Intraoperative (epiaortic scanning)										
Intraoperative Neurological										
Pediatric		N								
Small Organ (breast, thyroid, parathyroid, testicles)		N								
Neonatal Cephalic										
Adult Cephalic										
Cardiac (Adult and Pediatric)		N								
Transesophageal										
Transrectal										
Transvaginal										
Transeurethral										
Intravascular										
Peripheral Vascular		N								
Laparoscopic										
Musculo-skeletal (Conventional)		N								
Musculo-skeletal (Superficial)		N								
Other (Specify)										

N=new indication; P=previously cleared by FDA; E=added under Appendix E
Notes: None

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices

510(k) Number_____

Prescription Use (per 21 CFR 801.109

Diagnostic Ultrasound Indication for Use

Table 1.3-2 - Site~Rite® 8 Ultrasound System with Pinpoint™ GT Technology with 20mm Pinpoint™ GT Technology Linear Probe (Non-detachable transducer)

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Applications	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Opthalmic										
Fetal										
Abdominal										
Intraoperative (epiaortic scanning)										
Intraoperative Neurological										
Pediatric		N								
Small Organ (breast, thyroid, parathyroid, testicles)		N								
Neonatal Cephalic										
Adult Cephalic										
Cardiac (Adult and Pediatric)		N								
Transesophageal										
Transrectal										
Transvaginal										
Transeurethral										
Intravascular										
Peripheral Vascular		N								N [1]
Laparoscopic										
Musculo-skeletal (Conventional)		N								
Musculo-skeletal (Superficial)		N								
Other (Specify)										

N=new indication; P=previously cleared by FDA; E=added under Appendix E
Notes: [1] Needle Guidance Imaging

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices

510(k) Number_____

Prescription Use (per 21 CFR 801.109

510(k) Summary
21 CFR 807.92

Site~Rite® 8 Ultrasound System and Site~Rite® 8 Ultrasound System with Pinpoint™ GT Technology		
General Provisions:	Submitter Name:	Bard Access Systems, Inc.
	Submitter Address:	605 North 5600 West Salt Lake City, UT84116
	Contact Person:	Kerrie Hamblin Regulatory Affairs Project Manager Bard Access Systems, Inc. Kerrie.Hamblin@crbard.com 801-522-5000 ext. 4909 801-522-5425 fax
	Date of Preparation:	13 November 2015
Subject Devices:	Trade Names:	Site~Rite® 8 Ultrasound System Site~Rite® 8 Ultrasound System with Pinpoint™ GT Technology
	Classification Name:	IYO, 21 CFR 892.1560, Ultrasonic Pulsed Echo Imaging System ITX, 21 CFR 892.1570, Diagnostic Ultrasonic Transducer LLZ, 21 CFR 892.2050, Picture Archiving and Communications System
	Common Name:	IYO, 21 CFR 892.1560, System, Imaging, Pulsed Echo, Ultrasonic ITX, 21 CFR 892.1570, Transducer, Ultrasonic, Diagnostic LLZ, 21 CFR 892.2050, System, Image Processing, Radiological
Primary Predicate Device:	Trade Name:	Site~Rite Vision® II Ultrasound System
	Classification Name:	IYO, 21 CFR 892.1560, Ultrasonic Pulsed Echo Imaging System ITX, 21 CFR 892.1570, Diagnostic Ultrasonic Transducer

		LLZ, 21 CFR 892.2050, Picture Archiving and Communications System IYN, CFR 892.1550, Ultrasonic Pulsed Doppler Imaging System
	Common Name:	IYO, 21 CFR 892.1560, System, Imaging, Pulsed Echo, Ultrasonic ITX, 21 CFR 892.1570, Transducer, Ultrasonic, Diagnostic LLZ, 21 CFR 892.2050, System, Image Processing, Radiological IYN, CFR 892.1550, System, Imaging, Pulsed Doppler, Ultrasonic
	Premarket Notification:	K132942, concurrence, 17 October 2013
	Manufacturer:	Bard Access Systems, Inc.
Predicate Device:	Trade Name:	Site~Rite® 6 Ultrasound System with Pinpoint™ GT Technology
	Classification Name:	IYO, 21 CFR 892.1560, Ultrasonic Pulsed Echo Imaging System ITX, 21 CFR 892.1570, Diagnostic Ultrasonic Transducer
	Common Name:	IYO, 21 CFR 892.1560, System, Imaging, Pulsed Echo, Ultrasonic ITX, 21 CFR 892.1570, Transducer, Ultrasonic, Diagnostic
	Premarket Notification:	K142443, concurrence, 30, October, 2014
	Manufacturer:	Bard Access Systems, Inc.
Predicate Device:	Trade Name:	Site~Rite Prevue® Ultrasound System
	Classification Name:	IYO, 21 CFR 892.1560, Ultrasonic Pulsed Echo Imaging System ITX, 21 CFR 892.1570, Diagnostic Ultrasonic Transducer
	Common Name:	IYO, 21 CFR 892.1560, System, Imaging, Pulsed Echo, Ultrasonic ITX, 21 CFR 892.1570, Transducer, Ultrasonic, Diagnostic

Premarket Notification:	K120882, concurrence, 30, May, 2012
Manufacturer:	Bard Access Systems, Inc.

Device Descriptions:

The Site~Rite® 8 Ultrasound 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 Pinpoint™ GT Technology 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 probe. The sensors detect a passive magnetic field emitted from a 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 throughout the insertion process.

Intended Use/Indications for Use for Site~Rite® Ultrasound System and Site~Rite® 8 Ultrasound System with Pinpoint™ GT Technology:

The **Site~Rite® 8 Ultrasound System** is intended for diagnostic ultrasound imaging of the human body. Specific clinical applications include:

- Pediatric
- Peripheral Vessel
- 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:

Imaging Applications	Exam Type (Adult and Pediatric)
Vascular	Assessment of vessels in the extremities and neck (e.g., jugular, carotid) leading to or coming from the heart, superficial veins in the arms and legs (e.g., basilic, cephalic, brachial, femoral, radial, saphenous), and vessel mapping. Assessment of superficial thoracic vessels (e.g., axillary, innominate, subclavian)
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
Interventional	Guidance for biopsy and drainage
Superficial	Assessment of breast, thyroid, parathyroid, testicle, lymph nodes, hernias, musculoskeletal procedures (e.g., joints, ligaments, tendons), soft tissue structures, and surrounding anatomical structures

Pinpoint™ GT Technology is intended to provide clinicians with visual tools for passive magnetic tracking of a needle with respect to ultrasound image data.

Technological Characteristics:	The subject Site~Rite® 8 Ultrasound System and subject Site~Rite® 8 Ultrasound System with Pinpoint™ GT Technology employ the same fundamental scientific technology as the primary predicate device, Site~Rite Vision® II Ultrasound System (K132942), 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 devices have also been evaluated with consideration to the predicate devices, Site~Rite® 6 Ultrasound System with Pinpoint™ GT Technology and Site~Rite Prevue® Ultrasound System where differences in technology between the subject devices and the primary predicate device are present. The subject devices are technologically similar to the predicate devices in that both the subject and predicate devices incorporate a similar passive magnetic tracking technology and/or they share similar patient contacting materials.
Safety and Performance Tests:	Verification and validation activities were designed and performed to demonstrate that the subject Site~Rite® 8 Ultrasound System and subject Site~Rite® 8 Ultrasound System with Pinpoint™ GT Technology met predetermined performance requirements. The following standards in conjunction with internal protocols were used to determine appropriate methods for evaluating the performance of the subject device.

IEC 60601-1:2005, CORR. 1(2006), CORR 2(2007)	Medical Electrical Equipment - Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance – Edition 3
IEC 60601-1-2:2007	Medical Electrical Equipment – Part 1-2: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Electromagnetic Compatibility – Requirements and Tests
IEC 60601-2-37:2007	Medical Electrical Equipment – Part 2-37: Particular Requirements for the Basic Safety and Essential Performance of Ultrasonic Medical Diagnostic and Monitoring Equipment
IEC 60601-1-6:2010	Medical Electrical Equipment-Part 1-6: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Usability
IEC 62304:2006	Medical Device Software – Software Life Cycle Processes – Edition 1.0
IEC 62366:2007	Medical Devices – Application of Usability Engineering to Medical Devices – Edition 1.0
ISO 10993-1:2009	Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within a Risk Management Process
NEMA UD-2:2004	Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment

	Title 47 CFR FCC, Part 15 B, 15 C, and Part 18	Title 47 – Telecommunication; Part 15 – Radio Frequency Devices; Subpart B – Unintentional Radiators; Subpart C – Intentional Radiators; and subpart 18, Industrial, Scientific, and Medical Equipment

The subject devices met all pre-determined acceptance criteria and demonstrated substantial equivalence as compared to the primary predicate device. Where differences between the subject devices and the primary predicate device exist with respect to technological characteristics, consideration to the predicate devices was given to support substantial equivalence for those technological characteristics.

Accessories	The following accessories are covered under this premarket notification and have been qualified for use with the subject devices described herein. The following accessories are intended for use with the subject devices, Site~Rite® 8 Ultrasound System and Site~Rite® 8 Ultrasound System with Pinpoint™ GT Technology: • MER Roll Stand • Brother™ Printer MW-260 with mounting hardware • Kickstand mounting accessory • Probe holder accessory • Site~Rite® Keyboard • USB storage device (flash/pen drive) with no external power connection • Site~Rite® 8 Ultrasound System Roller Bag
Summary of Substantial Equivalence	The subject devices, Site~Rite® 8 Ultrasound System and Site~Rite® 8 Ultrasound System with Pinpoint™ GT Technology, have the same intended use as the primary predicate device, Site~Rite Vision® II Ultrasound System (K132942) and the predicate devices, Site~Rite® 6 Ultrasound System with Pinpoint™ GT Technology (K142443) and Site~Rite Prevue® Ultrasound System (K120882). The subject devices have similar indications for use, technological characteristics, and safety and performance testing as the primary predicate device. Where there are differences in indications for use and technological characteristics between the subject devices and the primary predicate device, consideration to the predicate devices, Site~Rite® 6 Ultrasound System with Pinpoint™ GT Technology (K142443) and Site~Rite Prevue® Ultrasound System (K120882) was given. The subject Site~Rite® 8 Ultrasound System and subject Site~Rite® 8 Ultrasound System with Pinpoint™ GT Technology met the predetermined performance requirements for their intended use and are as safe, as effective, and perform as well as or better than the primary predicate device, Site~Rite Vision® II Ultrasound System (K132942) and the predicate devices, Site~Rite® 6 Ultrasound System with Pinpoint™ GT Technology (K142443) and Site~Rite Prevue® Ultrasound System (K120882). Based on this assessment, the subject Site~Rite® 8 Ultrasound System and subject Site~Rite® 8 Ultrasound System with Pinpoint™ GT Technology are determined to be substantially equivalent to the primary predicate device, Site~Rite Vision® II Ultrasound System (K132942) and the predicate devices, Site~Rite® 6 Ultrasound System with Pinpoint™ GT Technology (K142443) and Site~Rite Prevue® Ultrasound System (K120882).