



Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

October 30, 2014

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

Re: K142443
Trade/Device Name: Site~Rite® 6 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
Dated: August 29, 2014
Received: September 2, 2014

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.

This determination of substantial equivalence applies to the following transducers intended for use with the Site~Rite® 6 Ultrasound System with Pinpoint™ GT Technology, as described in your premarket notification:

Transducer Model Number

Pinpoint™ GT 20 mm 64 Element Linear Probe

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 Small Manufacturers, International and Consumer Assistance 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" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,



for

Janine M. Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K142443

Device Name

Site~Rite® 6 Ultrasound System with Pinpoint™ GT Technology

Indications for Use (Describe)

The Site~Rite® 6 Ultrasound System with associated probe and accessories provide ultrasound guidance for placement of needles and catheters in vascular structures. Ultrasound guidance may occur intraoperatively or percutaneously. Ultrasound imaging of vascular structures, various organs and structures of the body may also be performed.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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“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.”

Diagnostic Ultrasound Indication for Use

Ultrasound System: Site~Rite® 6 Ultrasound System with Pinpoint™ GT Technology (Ultrasound without 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)
Ophthalmic										
Fetal										
Abdominal		P								
Intraoperative (epiaortic scanning)		P								
Intraoperative Neurological										
Pediatric										
Small Organ (breast, testes, thyroid, etc.)		P								
Neonatal Cephalic		P								N [1]
Adult Cephalic		P								N [1]
Cardiac		P								
Transesophageal										
Transrectal										
Transvaginal										
Transeurethral										
Intravascular										
Peripheral Vascular		P								N [1]
Laparoscopic										
Musculo-skeletal (Conventional)		P								
Musculo-skeletal (Superficial)										
Other (Specify)										

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Notes: [1] Needle Guidance Imaging

(Please do not write below this line – Continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K142443

Prescription Use (per 21 CFR 801.109)

Diagnostic Ultrasound Indication for Use

Ultrasound System: Site~Rite® 6 Ultrasound System with Pinpoint™ GT Technology

Transducer: Pinpoint™ GT 20 mm 64 Element Linear Probe

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)
Ophthalmic										
Fetal										
Abdominal		P								
Intraoperative (epiaortic scanning)		P								
Intraoperative Neurological										
Pediatric										
Small Organ (breast, testes, thyroid, etc.)		P								
Neonatal Cephalic		P								N [1]
Adult Cephalic		P								N [1]
Cardiac		P								
Transesophageal										
Transrectal										
Transvaginal										
Transeurethral										
Intravascular										
Peripheral Vascular		P								N [1]
Laparoscopic										
Musculo-skeletal (Conventional)		P								
Musculo-skeletal (Superficial)										
Other (Specify)										

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Notes: [1] Needle Guidance Imaging

(Please do not write below this line – Continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K142443

Prescription Use (per 21 CFR 801.109)

510(k) Summary
21 CFR 807.92

Site~Rite® 6 Ultrasound System with Pinpoint™ GT Technology

General Provisions:	Submitter Name:	Bard Access Systems, Inc.
	Submitter Address:	605 North 5600 West Salt Lake City, UT 84116
	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:	29 August 2014
Subject Devices:	Trade Names:	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
Primary Predicate Device:	Trade Name:	Site~Rite® 6 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:	K071204, concurrence, 18 May 2007
	Manufacturer:	Bard Access Systems, Inc.
Reference Devices:	Trade Name:	Site~Rite Vision® II Ultrasound System
	Classification Name:	IYN, CFR 892.1550, Ultrasonic Pulsed Doppler Imaging System 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:	IYN, CFR 892.1550, System, Imaging, Pulsed Doppler, Ultrasonic 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
Premarket Notification:	K132942, concurrence, 17 October 2013
Manufacturer:	Bard Access Systems, Inc.
Trade Name:	GE LOGIQ E9
Classification Name:	IYN, CFR 892.1550, Ultrasonic Pulsed Doppler Imaging System IYO, 21 CFR 892.1560, Ultrasonic Pulsed Echo Imaging System ITX, 21 CFR 892.1570, Diagnostic Ultrasonic Transducer
Common Name:	IYN, CFR 892.1550, System, Imaging, Pulsed Doppler, Ultrasonic IYO, 21 CFR 892.1560, System, Imaging, Pulsed Echo, Ultrasonic ITX, 21 CFR 892.1570, Transducer, Ultrasonic, Diagnostic
Premarket Notification:	K092271, concurrence, 17 November 2009
Manufacturer:	GE Healthcare
Trade Name:	Electromagnetic Tracking System (VirtuTRAX)
Classification Name:	IYO, 21 CFR 892.1560, Ultrasonic Pulsed Echo Imaging System JAK, 21 CFR 892.1750, Computed Tomography X-Ray System
Common Name:	IYO, 21 CFR 892.1560, System, Imaging, Pulsed Echo, Ultrasonic JAK, 21 CFR 892.1750, System, X-Ray, Tomography, Computed
Premarket Notification:	K092619, concurrence, 13 November 2009
Manufacturer:	CIVCO Medical
Device	The Site~Rite® 6 Ultrasound System is a lightweight, low-output, real-time B-

Descriptions:	<p>mode ultrasonic pulsed echo imaging system designed primarily to assist physicians in gaining vascular access to major veins and arteries. The Site~Rite® 6 Ultrasound System is portable and therefore easy to use at the bedside and in a variety of clinical scenarios, including intensive care units, emergency rooms, operating rooms, angiography suites, catheterization laboratories, etc. In addition, the Site~Rite® 6 Ultrasound System is designed with simple operating controls to facilitate easy operation.</p> <p>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.</p>				
Intended Use/Indications for Use:	<p>The Site~Rite® 6 Ultrasound System with associated probe and accessories provide ultrasound guidance for placement of needles and catheters in vascular structures. Ultrasound guidance may occur intraoperatively or percutaneously. Ultrasound imaging of vascular structures, various organs and structures of the body may also be performed.</p> <p>Pinpoint™ GT Technology is intended to provide clinicians with visual tools for passive magnetic tracking of a needle with respect to ultrasound image data.</p>				
Technological Characteristics:	<p>The Site~Rite® 6 Ultrasound System with Pinpoint™ GT Technology employs the same fundamental scientific technology as the primary predicate device, Site~Rite® 6 Ultrasound System (K071204), 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 Site~Rite® 6 Ultrasound System with Pinpoint™ GT Technology has also been evaluated with consideration to multiple reference devices where differences in technology between the subject and primary predicate device are present. The subject device is technologically similar to the reference devices, Site~Rite Vision® II Ultrasound System (K132942), GE LOGIQ E9 (K092271), and Electromagnetic Tracking System – VirtuTRAX (K092619).</p>				
Safety and Performance Tests:	<p>Verification and validation activities were designed and performed to demonstrate that the subject Site~Rite® 6 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:</p> <table border="0"> <tr> <td data-bbox="565 1602 805 1690">IEC 60601-1:2005, CORR. 1(2006), CORR 2(2007)</td><td data-bbox="834 1602 1529 1690">Medical Electrical Equipment - Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance – Edition 3.1</td></tr> <tr> <td data-bbox="565 1734 805 1759">IEC 60601-1-2:2007</td><td data-bbox="834 1734 1529 1852">Medical Electrical Equipment – Part 1-2: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Electromagnetic Compatibility – Requirements and Tests</td></tr> </table>	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 3.1	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 60601-1:2005, CORR. 1(2006), CORR 2(2007)	Medical Electrical Equipment - Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance – Edition 3.1				
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

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

Summary of Substantial Equivalence	<p>The subject device, Site~Rite[®] 6 Ultrasound System with Pinpoint[™] GT Technology, has the same intended use as the primary predicate device, Site~Rite[®] 6 Ultrasound System (K071204). The subject device has 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 device and the primary predicate device, consideration to the reference devices, Site~Rite Vision[®] II Ultrasound System (K132942), GE LOGIQ E9 Ultrasound System (K092271), and Electromagnetic Tracking System – VirtuTRAX (K092619) was given. The Site~Rite[®] 6 Ultrasound System with Pinpoint[™] GT Technology met the predetermined performance requirements for its intended use and is as safe, as effective, and performs as well as or better than the primary predicate device, Site~Rite[®] 6 Ultrasound System (K071204). Based on this assessment, the subject Site~Rite[®] 6 Ultrasound System with Pinpoint[™] GT Technology is determined to be substantially equivalent to the primary predicate device, Site~Rite[®] 6 Ultrasound System.</p>
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