K052517

SEP 2 9 2005

Section 5: 510(k) Summary of Safety and Effectiveness (21 CFR 807.92(a))

5.2 Device Name

Device Name:	Site~Rite® 5 Ultrasound System
Trade Name:	Site~Rite® 5 Ultrasound System
Common/Usual Name:	Ultrasonic Pulsed Echo Imaging System and Accessories Diagnostic Ultrasonic Transducers
Classification Name:	90-IYO – Ultrasonic Pulsed Echo Imaging System 21 CFR 892.1560 – Class II Diagnostic Device
	90-ITX – Diagnostic Ultrasonic Transducer 21 CFR 892.1570 – Class II Diagnostic Device
Classification Panel:	Radiology Devices Panel

5.3 Address and Registration

The addresses and registration numbers of the manufacturer for the Site~Rite® 5 Ultrasound System are:

Manufacturer:

Submitter Name:	Bard Access Systems, Inc. (BAS) [Wholly owned Subsidiary of C. R. Bard, Inc.]
Address:	5425 West Amelia Earhart Drive Salt Lake City, Utah 84116
Telephone Number:	(801) 595-0700 ext. 5421
Fax Number:	(801) 595-5425
Contact Person:	Kimberly Geisler
Date of Preparation:	August 9, 2005
Registration Number:	1720496
Additional Registration Numbers:	
C. R. Bard	2212754

Manufacturing Site:

Name:	Dymax Corporation. [Wholly owned Subsidiary of C.R. Bard, Inc.]
Address:	271 Kappa Drive Pittsburgh, Pennsylvania 15238
Registration Number:	2523003

5.4 Device Classification

Classification Name:	90-IYO – Ultrasonic Pulsed Echo Imaging System 21 CFR 892.1560 – Class II Diagnostic Device
	90-ITX – Diagnostic Ultrasonic Transducer 21 CFR 892.1570 – Class II Diagnostic Device

5.5 Predicate Device Information

The predicate devices are:

Device Name:	**Site~Rite® IV Ultrasound System**
Trade Name:	Site~Rite® IV Ultrasound System
Common/Usual Name:	Ultrasonic Pulsed Echo Imaging System and Accessories Diagnostic Ultrasonic Transducers
Classification Name:	90-IYO – Ultrasonic Pulsed Echo Imaging System 21 CFR 892.1560 – Class II Diagnostic Device
	90-ITX – Diagnostic Ultrasonic Transducer 21 CFR 892.1570 – Class II Diagnostic Device
Classification Panel:	Radiology Devices Panel
Premarket Notification:	K032135, concurrence date July 21, 2003

5.6 Device Description

The Site~Rite® 5 Ultrasound System is a lightweight, low-output, real-time B-mode ultrasonic pulsed echo imaging system designed primarily to assist physicians in gaining vascular access to major veins and arteries. It offers high resolution imaging to a depth of 6.0 cm. The Site~Rite® 5 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® 5 Ultrasound System is designed with simple operating controls to facilitate easy operation.

Key features of the Site~Rite® 5 Ultrasound System are:

- Compact, portable, real-time ultrasound scanner with:
  - Intuitive controls allowing for rapid and easy operation
  - Choice of battery or line voltage power
  - Operating parameters of scanner determined by image depth
  - Image freeze frame
  - Image printing and saving
  - Large screen

5.7 Intended Use

The Site~Rite® 5 Ultrasound System with associated probes 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.

The Site~Rite® 5 Ultrasound System is intended to be used for diagnostic ultrasound imaging of fluid flow analysis of the human body in the following clinical applications.

- Abdominal
- Intraoperative (epiaortic scanning)
- Small Organ (breast, testes, thyroid, etc.)
- Neonatal Cephalic

- Adult Cephalic
- Cardiac
- Peripheral Vascular
- Musculo-skeletal Conventional

The Site~Rite® 5 Ultrasound System is not intended for opthalmic applications.

5.8 Substantial Equivalence Summary

New device is compared to marketed device?

Yes.

Does the new device have the same indication statement?

No. The indications for use are the same as the predicate Site~Rite® IV Ultrasound System, except that the indication for intraoperative neurological imaging has been removed. In addition, the Indications for Use statement has been reorganized to emphasize the indication for vascular access guidance:

> *The Site~Rite® 5 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.*

Do the differences alter the intended therapeutic/diagnostic/etc. effect (in deciding, impact on safety and effectiveness may be considered)?

No. The differences do not alter the intended use of the device.

Does the new device have the same technological characteristics, e.g. design, material, etc?

Not in all regards. The Site~Rite® 5 Ultrasound System has an updated design compared to the predicate device. However, both the subject and predicate devices transmit and receive an ultrasound signal that is used to create an image to assist the radiologist or other clinician in placing a needle in the desired location.

Could the new characteristics affect safety or effectiveness?

Yes. The updated design could affect the safety or effectiveness of the device. The technological characteristics are similar to the predicate devices except that the electronics design has been updated from the Site~Rite® IV Ultrasound System. The Site~Rite® 5 Ultrasound System has been designed for manufacturability and improved reliability. The Site~Rite® 5 Ultrasound System was designed to utilize a single linear array probe with a maximum imaging depth of 6.0cm in place of mechanical sector fluid filled probes of the predicate device.

Do the new characteristics raise new types of safety or effectiveness questions?

No. Safety and effectiveness questions are the same for the predicate and subject devices. Refer to the Risk Analysis Document in **Attachment 7.**

Do accepted scientific methods exist for assessing effects of the new characteristics?

Yes. Testing based on the following standards will be completed in order to evaluate the device's performance. Testing will be completed prior to placing the Site~Rite® 5 Ultrasound System on the market.

- *IEC 60601-1:1988, Medical Electrical Equipment – Part 1: General Requirements for Safety*
- *IEC 60601-1-1:2000, Medical Electrical Equipment – Part 1-1: General Requirements for Safety – Collateral Standard: Safety Requirements for Medical Electrical Systems*
- *IEC 60601-1-2:2004, Medical Electrical Equipment – Part 1-2: General Requirements for Safety – Collateral Standard: Electromagnetic Compatibility – Requirements and Tests*
- *IEC 60601-1-4:2000, Medical Electrical Equipment - Part 1-4: General Requirements for Safety – Collateral Standard: Programmable Electrical Medical Systems*
- *IEC 60601-2-37:2005, Medical Electrical Equipment – Part 2-37: Particular Requirements for the Safety of Ultrasonic Medical Diagnostic and Monitoring Equipment*
- *UL 60601-1:2003, Medical Electrical Equipment, Part 1: General Requirements for Safety*
- *NEMA UD-2:2004, Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment*
- *NEMA UD-3:2004, Standard for Real-Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment*

Are performance data available to assess effects of new characteristics?

Performance testing will be completed prior to placing the Site~Rite® 5 Ultrasound System on the market. Performance data must meet predetermined acceptance criteria prior to placing the Site~Rite® 5 Ultrasound System on the market.

Performance data demonstrate equivalence?

Performance data must demonstrate that the Site~Rite® 5 Ultrasound System is substantially equivalent to the Site~Rite® IV Ultrasound System prior to placement of the Site~Rite® 5 Ultrasound System on the market.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 9 2005

Bard Access Systems, Inc.
Division of C.R. Bard, Inc.
c/o Mr. Robert Mosenkis
President
CITECH
5200 Butler Pike
PLYMOUTH MEETING PA 19462-1298

Re: K052517
Trade Name: Site~Rite 5® Ultrasound System
Regulation Number: 21 CFR §892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Product Code: IYO
Regulation Number: 21 CFR §892.1570
Regulation Name: Diagnostic ultrasonic transducer
Product Code: ITX
Regulatory Class: II
Dated: September 13, 2005
Received: September 14, 2005

Dear Mr. Mosenkis:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we 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). 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.

This determination of substantial equivalence applies to the following transducers intended for use with the Site~Rite 5® Ultrasound System as described in your premarket notification:

Transducer Model Number

Site~Rite 5

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997, "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded.

The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

If you have any questions regarding the content of this letter, please contact Mr. Rodrigo C. Perez at (301) 594-1212.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosures

1.2 Statement of Indications for Use

510(k) Number (if known): K052517

Device Name: Site~Rite® 5 Ultrasound System

Indications for Use:

The Site~Rite® 5 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.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C. Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K052517

Site~Rite® 5 Ultrasound System

Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each 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 (specify)		P								
Intraoperative Neurological										
Pediatric										
Small Organ (specify)		P								
Neonatal Cephalic		P								
Adult Cephalic		P								
Cardiac		P								
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular		P								
Laparoscopic										
Musculo-skeletal Conventional		P								
Musculo-skeletal Superficial										
Other (specify										

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

Additional Comments:

Intraoperative (epiaortic scanning)

Small organ (breast, testes, thyroid, etc.)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

(Concurrence of CDRH, Office of Device Evaluation (ODE))

Prescription Use (Per 21 CFR 801.109)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K052517

Site~Rite® 5 Ultrasound Transducer

Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each 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 (specify)		P								
Intraoperative Neurological										
Pediatric										
Small Organ (specify)		P								
Neonatal Cephalic		P								
Adult Cephalic		P								
Cardiac		P								
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular		P								
Laparoscopic										
Musculo-skeletal Conventional		P								
Musculo-skeletal Superficial										
Other (specify										

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

Additional Comments:

Intraoperative (epiaortic scanning)

Small organ (breast, testes, thyroid, etc.)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

(Concurrence of CDRH, Office of Device Evaluation (ODE))

Nancy C Brogdon – Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K052517