September 11, 2023

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

Re: K231283
Trade/Device Name: SiteRite™ 9 Ultrasound System
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulatory Class: Class II
Product Code: IYO, ITX, LLZ
Dated: August 10, 2023
Received: August 11, 2023

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,

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

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)*

K231283

Device Name

SiteRite™ 9 Ultrasound System

Indications for Use *(Describe)*

The SiteRite™ 9 Ultrasound 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*
- *Small Organ (breast, thyroid, parathyroid, testicles)*
- *Musculo-skeletal (conventional and superficial)*
- *Cardiac (adult and pediatric)*

The SiteRite™ 9 Ultrasound System is indicated for Vascular, Vascular Access, Interventional, and Superficial Imaging Applications. Typical examinations performed using the SiteRite™ 9 Ultrasound 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.*
Interventional	*Guidance for biopsy and drainage.*
Superficial	*Assessment of breast, thyroid, parathyroid, testicle, lymph nodes, musculoskeletal procedures, soft tissue structures, and surrounding anatomical structures.*

The SiteRite™ 9 Ultrasound System transducer operates using B mode imaging.

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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Section 8 – 510(k) Summary

(in accordance with 21 CFR 807.92)

510(k) Number: K231283

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 28, 2023

II. Subject Device Identification

Proprietary Name:	**SiteRite™ 9 Ultrasound 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 **SiteRite™ 9 Ultrasound 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:	Medical Image Management and Processing 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 **SiteRite™ 9 Ultrasound System** ("**SiteRite 9 System**") is a portable device that features real-time 2D ultrasound imaging for vascular access device placement, which includes vessel measurement tools, vascular access device selection, procedure documentation and electronic connectivity.

The subject **SiteRite 9 System** is intended to aid in the placement of peripheral and central line vascular access devices and ultimately increase first stick success. The system is the replacement platform for the Site~Rite® 8 Ultrasound System with Cue™ Needle Tracking System and Pinpoint™ GT Needle Technology (i.e., the predicate device) and includes more up-to-date and reliable components aimed at providing improved image quality, while maintaining ease of operation.

The subject **SiteRite 9 System** can be viewed as the next generation SiteRite™ ultrasound system and is equivalent from a functionality standpoint to its predicate device, to the Site~Rite® 8 Ultrasound System with Cue™ Needle Tracking System and Pinpoint™ GT Needle Technology (K182281). The **SiteRite 9 System** is essentially replacing its predicate device, the Site~Rite® 8 Ultrasound System with Cue™ Needle Tracking System and

Pinpoint™ GT Needle Technology ("Site~Rite 8 System"), due to the end-of-life obsolescence of its components.

The subject **SiteRite 9 System** differs from its predicate device, the Site~Rite 8 System (K182281), in that it includes newer, more "state of the art" hardware components resulting in a more efficient and reliable use of the device. Aside from these technical upgrades, most of the previously cleared features of the predicate device are being brought forward.

The subject **SiteRite 9 System** includes the following main components:

- Ultrasound System Console
- Ultrasound Beamformer
- System Software
- Ultrasound Probe

Additionally, the subject **SiteRite 9 System** is compatible with the following accessories:

- SiteRite™ Probe Cover Kits
- Site~Rite® Needle Guide Kits
- Pinpoint™ GT Needle Guide Kits
- MER Roll Stand with Mounting Accessory (optional accessory)
- Kickstand with Mounting Accessory (optional accessory)
- Sony Printer UP-X898MD (off-the-shelf, optional accessory)
- USB Storage Device (off-the-shelf, optional accessory)

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 **SiteRite™ 9 Ultrasound 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
- Small Organ (breast, thyroid, parathyroid, testicles)
- Musculo-skeletal (conventional and superficial)
- Cardiac (adult and pediatric)

Typical examinations performed using the **SiteRite™ 9 Ultrasound 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.
Interventional	Guidance for biopsy and drainage.
Superficial	Assessment of breast, thyroid, parathyroid, testicle, lymph nodes, musculoskeletal procedures, soft tissue structures, and surrounding anatomical structures.

The SiteRite™ 9 Ultrasound System transducer operates using B mode imaging.

VI. Substantial Equivalence

Intended Use

The **SiteRite™ 9 Ultrasound System** and its predicate device have the same intended use: diagnostic ultrasound imaging of the human body.

Indications for Use

The **SiteRite™ 9 Ultrasound System** includes substantially equivalent Indications for Use with respect to its predicate device.

Technological Characteristics

The subject **SiteRite™ 9 Ultrasound 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.

In addition, the subject and predicate devices share substantially equivalent patient contacting materials and software features, allowing the **SiteRite™ 9 Ultrasound System** to perform in a substantially equivalent fashion with respect to 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:** **SiteRite™ 9 Ultrasound 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 SiteRite™ 9 Ultrasound System 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 SiteRite™ 9 Ultrasound 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:

<table>
<tr><th>Device Name</th><th>Subject Device:

SiteRite™ 9 Ultrasound System</th><th>Predicate Device:
(K182281)

Site~Rite® 8 Ultrasound System with Cue™ Needle Tracking System and Pinpoint™ GT Needle Technology</th></tr>
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Device Name	**Subject Device:** **SiteRite™ 9 Ultrasound System**	**Predicate Device:** **(K182281)** **Site~Rite® 8 Ultrasound System with Cue™ Needle Tracking System and Pinpoint™ GT Needle Technology**
	(The Cue™ Needle Tracking System is not included in the current version of the SiteRite™ 9 Ultrasound System.)	Cue™ Needle Tracking System and Pinpoint™ GT Needle Technology are each intended to provide visual needle tracking to assist with ultrasound guided vascular access.
Environment of Use	Hospital/clinic medical setting.	Hospital/clinic medical setting.
Track 1 or Track 3	Track 1	Track 1
Power Source	AC Adapter with Internal Lithium-Ion Battery Pack. Power Consumption: 150 W	AC Adapter with Internal Lithium-Ion Battery Pack. Power Consumption: 60 W
Main System Components	The SiteRite™ 9 Ultrasound System includes the following main components: • SiteRite™ 9 Console • Ultrasound Beamformer • System Software • Ultrasound Probe • *(no Cue™ Needle Tracking System functionality is currently included in the subject device)*	The Site~Rite® 8 Ultrasound System includes the following main components: • Site~Rite® 8 Console • Ultrasound Beamformer • System Software • Ultrasound Probes • Cue™ Needle Tracking System Hardware
System Console	The SiteRite™ 9 Ultrasound System includes: • *15.6" Touch Screen Monitor* • *Portable*	The Site~Rite® 8 Ultrasound System includes: • *10.4" Touch Screen Monitor* • *Portable*

Device Name	Subject Device: SiteRite™ 9 Ultrasound System	Predicate Device: (K182281) Site~Rite® 8 Ultrasound System with Cue™ Needle Tracking System and Pinpoint™ GT Needle Technology
	• *Weight 6.8 lbs* Graphic User Interface (GUI): Touchscreen user interface to access all available functionality *(no Cue™ Needle Tracking System functionality is currently included in the subject device)*.	• *Weight 5 lbs* Graphic User Interface (GUI): Touchscreen user interface to access all available functionality, including the Cue™ Needle Tracking System.
Ultrasound Beamformer	The SiteRite™ 9 Ultrasound System uses B mode for the compatible probe.	The Site~Rite® 8 Ultrasound System uses B mode for all compatible probes.
Ultrasound Features	The SiteRite™ 9 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;*	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;*

Device Name	**Subject Device:** **SiteRite™ 9 Ultrasound System**	**Predicate Device:** **(K182281)** **Site~Rite® 8 Ultrasound System with Cue™ Needle Tracking System and Pinpoint™ GT Needle Technology**
	• *Patient information and file management; and* • *On-screen keyboard.*	• *Patient information and file management; and* • *On-screen keyboard.*
Software	Operating System (OS): • *MS Windows 10 Embedded* Needle Guidance Technology: • *(no Cue™ Needle Tracking System functionality is currently included in the subject device)* Image Depths: • *1 cm* • *1.5 cm* • *3 cm* • *4.5 cm* • *6 cm* Ultrasound Settings: • *Gain/Brightness* • *Image filter*	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* Image Depths: • *1 cm* • *1.5 cm* • *3 cm* • *4.5 cm* • *6 cm* Ultrasound Settings: • *Gain/Brightness* • *Image filter* • *Contrast (low/high)*

Device Name	**Subject Device:** **SiteRite™ 9 Ultrasound System**	**Predicate Device:** **(K182281)** **Site~Rite® 8 Ultrasound System with Cue™ Needle Tracking System and Pinpoint™ GT Needle Technology**
Magnetic Field Detection Technology	*(The Cue™ Needle Tracking System is not included in the current version of the SiteRite™ 9 Ultrasound System.*	The 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.*
Visualization Features	The SiteRite™ 9 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 virtual catheter size during vascular access placement.* • *Measure of remaining catheter length based on vessel depth and assumed insertion angle.*	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 virtual catheter size during vascular access placement.* • *Measure of remaining catheter length based on vessel depth and assumed insertion angle.* • *Visualization of a needle trajectory.*

Device Name	**Subject Device:** **SiteRite™ 9 Ultrasound System**	**Predicate Device:** **(K182281)** **Site~Rite® 8 Ultrasound System with Cue™ Needle Tracking System and Pinpoint™ GT Needle Technology**
	• *(no Cue™ Needle Tracking System functionality is currently included in the subject device)*	• *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 Transducers	The SiteRite™ 9 Ultrasound System includes the following probe: • *Detachable Linear 25 mm Probe* SiteRite™ 9 Probe Characteristics: • Cue™ compatible → **No** *(no Cue™ Needle Tracking System functionality is currently included in the subject device)*	The Site~Rite® 8 Ultrasound System includes the following 3 probes: • *Detachable Cue™ 20mm Linear Probe* • *Detachable 20mm Pinpoint™ GT Linear probe* • *Detachable 32mm Linear Probe* Site~Rite® 8 Probes Characteristics: • Cue™ compatible → **Yes**

Device Name	**Subject Device:** **SiteRite™ 9 Ultrasound System**	**Predicate Device:** **(K182281)** **Site~Rite® 8 Ultrasound System with Cue™ Needle Tracking System and Pinpoint™ GT Needle Technology**
	• SiteRite™ Needle Guides compatible → **Yes** • Probe Buttons → **Yes** • Acoustics → **B-mode imaging**	• SiteRite™ Needle Guides compatible → **Yes** • Probe Buttons → **Yes** • Acoustics → **B-mode imaging**
Accessories	The SiteRite™ 9 Ultrasound System is compatible with the following accessories: • *SiteRite™ Probe Cover Kits* • *Site~Rite® Needle Guide Kits* • *Pinpoint™ GT Needle Guide Kits* • *MER Roll Stand with Mounting Accessory (optional)* • *Kickstand with Mounting Accessory (optional)* *(no Cue™ Needle Tracking System functionality is currently included in the subject device)* • *Keyboard (touchscreen only)* • *Sony Printer UP-X898MD with mounting hardware (optional)(*)* • *USB storage device (optional)(*)*	The Site~Rite® 8 Ultrasound System is compatible with the following accessories: • *SiteRite™ Probe Cover Kits* • *Site~Rite® Needle Guide Kits* • *Pinpoint™ GT Needle Guide Kits* • *MER Roll Stand with Mounting Accessory (optional)* • *Kickstand with Mounting Accessory (optional)* • *Cue™ Compatible Needles* • *Cue™ Activator Mounting Arm* • *Site~Rite® 8 Ultrasound System Roller Bag* • *Keyboard (optional)* • *Optional printers with mounting hardware (optional)(*)* • *USB storage device (optional)(*)*

Device Name	Subject Device: SiteRite™ 9 Ultrasound System	Predicate Device: (K182281) Site~Rite® 8 Ultrasound System with Cue™ Needle Tracking System and Pinpoint™ GT Needle Technology
	• *Wireless connectivity provided by an internal component equivalent to the Silex® Wireless Bridge(*)*	• *Silex® Wireless Bridge (optional)(*)*
Compatible Needles and Catheters	All needles available in the market are compatible with the SiteRite™ 9 Ultrasound System. *(no Cue™ Needle Tracking System functionality is currently included in the subject device).*	All needles available in the market are compatible with the Site~Rite 8 system. Additionally, the system is also compatible with all Cue™ needles/catheters currently cleared for sale.

(*) The optional printer(s) and the USB storage device are standard off-the-shelf (non-medical) accessories qualified to be used with both products.

VII. Non-Clinical Performance Data

C.R. Bard, Inc. has conducted extensive verification and validation testing of the **SiteRite™ 9 Ultrasound 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 **SiteRite™ 9 Ultrasound System** for a determination of substantial equivalence.

SiteRite™ 9 System – Nonclinical Tests Performed
Acoustic Safety Testing
Electrical Safety Testing
Electromagnetic Compatibility Testing
FCC Compliance Testing
Biocompatibility Testing
Mechanical Testing
Vibration Reliability Testing
Fluid Ingress Testing
Functional Testing
Operating Temperature and Humidity Testing
Electrical Reliability and Power Cycling Testing
Software Verification Testing
Cybersecurity Assessment
Human Factors Assessment
Ultrasound Image Testing
Ultrasound Response Time Testing
Cleaning/Reprocessing Testing
Ship Testing
Battery Testing

The **SiteRite™ 9 Ultrasound 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 the SiteRite 9 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	Content of Human Factors Information in Medical Device Marketing Submissions (DRAFT)
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 Device Software Functions (DRAFT)
FDA Guidance	Content of Premarket Submissions for Management of Cybersecurity in Medical Devices
FDA Guidance	Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions (DRAFT)
FDA Guidance	Post Market Management of Cybersecurity in Medical Devices
FDA Guidance	Cybersecurity in Medical Devices: Refuse to Accept Policy for Cyber Devices and Related Systems Under Section 524B of the FD&C Act
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 60601-1:2020	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
IEC 60601-1-2:2020	Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic disturbances – Requirements and tests
IEC TR 60601-4-2:2016	Medical electrical equipment – Part 4-2: Guidance and interpretation – Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems
IEC 60601-1-6:2020	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

Standards and Guidance Documents Applicable to the SiteRite 9 System	
Standard/Guidance	**Title**
IEC 62359:2017	Ultrasonics – Field characterization - Test methods for the determination of thermal and mechanical indices related to medical diagnostic ultrasonic field
IEC 62133-2:2017	Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications - Part 2: Lithium systems
IEC 62304:2015	Medical device software – Software life cycle processes
IEC 62366-1:2020	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 15223-1:2021	Medical devices – Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements
ISO 14971:2019	Medical devices – Application of risk management to medical devices
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 **SiteRite™ 9 Ultrasound 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 **SiteRite™ 9 Ultrasound 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 **SiteRite™ 9 Ultrasound 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.