DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

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

May 22, 2017

C.R. Bard, Inc.
Bard Access Systems, Inc
% Mr. Christopher Phillips
Regulatory Affairs Associate Manager
650 North 5600 West
SALT LAKE CITY UT 84116

Re: K171348
Trade/Device Name: Pinpoint™ GT Needle Guide Kits
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic ultrasonic transducer
Regulatory Class: II
Product Code: ITX
Dated: May 5, 2017
Received: May 8, 2017

Dear Mr. Phillips:

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,

For

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)*

K171348

Device Name
Pinpoint™ GT Needle Guide Kits

Indications for Use *(Describe)*
Pinpoint™ GT Needle Guide Kits are intended to be used with Site~Rite® Ultrasound Systems.

Pinpoint™ GT Needle Guides provide guidance for a needle to intersect an ultrasound beam at a fixed distance below the skin to assist the medical practitioner in placing the tip of a needle in a specific structure.

Site~Rite® Probe Covers sheathe the transducer and isolate a site of surgical penetration from microbial and other contamination.

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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BARD
ACCESS SYSTEMS

510(k) Summary
21 CFR 807.92(a)

General Provisions	Submitter Name:	Bard Access Systems, Inc.
	Address:	605 North 5600 West Salt Lake City, UT 84116
	Contact Person:	Christopher M. Phillips
	Telephone Number:	801.522.5000 ext 5965
	Fax Number:	801.522.5091
	Date of Preparation:	05 May 2017
Subject Device Kits	Trade Name:	Pinpoint™ GT Needle Guide Kits
	Common Name:	Transducer, Ultrasonic, Diagnostic
	Regulation Name:	Diagnostic Ultrasonic Transducer
	Product Code:	ITX
	Regulation Number:	21 CFR 892.1570
	Regulatory Class:	Class II
	Classification Panel:	Radiology
Predicate Device Kits	Predicate Trade Name:	Site~Rite® Needle Guide Kits and Probe Cover Kit
	Common Name:	Transducer, Ultrasonic, Diagnostic
	Regulation Name:	Diagnostic Ultrasound Transducer
	Premarket Notification:	K042445 (cleared Oct. 19, 2004)
	Product Code:	ITX
	Regulation Number:	21 CFR 892.1570
	Regulatory Class:	Class II
	Manufacturer:	Bard Access Systems, Inc.
	Classification Panel:	Radiology

Device Description

Pinpoint™ GT Needle Guide Kits consist of the following single use sterile disposables: a set of Pinpoint™ GT Needle Guides, conductive gel, a Site~Rite® Probe Cover, and elastic bands to secure the probe cover to the ultrasound probe.

A summary of the sterile, single-use ultrasound accessories included in subject device kits is included in the Table below.

Summary of Sterile, Single-Use Ultrasound Accessories included in Subject Device Kits (Pinpoint™ GT Needle Guide Kits)	
Shallow Pinpoint™ GT Needle Guide Kit with a 96" Site~Rite® Probe Cover	• A set of shallow Pinpoint™ GT Needle Guides (0.5cm, 1.0cm, 1.5cm, and 2.0cm depths)*, • Conductive gel, • A 96" 1 mil Site~Rite® Probe Cover*, and • Elastic bands
Deep Pinpoint™ GT Needle Guide Kit with a 96" Site~Rite® Probe Cover	• A set of deep Pinpoint™ GT Needle Guides (2.5cm, 3.0cm, and 3.5cm depths)*, • Conductive gel, • A 96" 1 mil Site~Rite® Probe Cover*, and • Elastic bands
Shallow Pinpoint™ GT Needle Guide Kit with a 48" Site~Rite® Probe Cover	• A set of shallow Pinpoint™ GT Needle Guides (0.5cm, 1.0cm, 1.5cm, and 2.0cm depths)*, • Conductive gel, • A 48" 1 mil Site~Rite® Probe Cover, and • Elastic bands
Deep Pinpoint™ GT Needle Guide Kit with a 48" Site~Rite® Probe Cover	• A set of deep Pinpoint™ GT Needle Guides (2.5cm, 3.0cm, and 3.5cm depths)*, • Conductive gel, • A 48" 1 mil Site~Rite® Probe Cover, and • Elastic bands

*Indicates a change from the predicate device kits.

Intended Use

Pinpoint™ GT Needle Guide Kits are intended to be used with Site~Rite® Ultrasound Systems.

Indications For Use

Pinpoint™ GT Needle Guide Kits are intended to be used with Site~Rite® Ultrasound Systems.

Pinpoint™ GT Needle Guides provide guidance for a needle to intersect an ultrasound beam at a fixed distance below the skin to assist the medical practitioner in placing the tip of a needle in a specific structure.

Site~Rite® Probe Covers sheathe the transducer and isolate a site of surgical penetration from microbial and other contamination.

Technological Characteristics

Technological Characteristics of the subject device kits, Pinpoint™ GT Needle Guide Kits, are substantially equivalent to the basic design and function to those of the cited predicate device kits. The differences do not alter the intended use of the subject device kits and do not raise new questions of equivalence.

Modifications made to the subject device kits when compared to the predicate device kits are as follows:

(1) New packaging configuration:
- New packaging configuration for the subject device kits (Pinpoint™ GT Needle Guide Kits).

(2) Modified needle guide offering:
- New subject Pinpoint™ GT Needle Guides will be offered in the subject device kits (Pinpoint™ GT Needle Guide Kits). The subject Pinpoint™ GT Needle Guides are modified from the predicate Site~Rite® Needle Guides (which were included in predicate device kits), and include a needle insertion funnel and stabilizing notches. The subject Pinpoint™ GT Needle Guides also utilize different colorant formulations than the predicate Site~Rite® Needle Guides, though they are comprised of the same base materials (Low-Density Polyethylene) and the same colorant additive base materials (Linear Low-Density Polyethylene) in the same blend.

(3) Additional probe cover offering:
- In addition to the predicate 48” 1 mil Site~Rite® probe cover (which were included in predicate device kits), new subject 96” 1 mil Site~Rite® Probe Cover will be offered in the subject device kits (Pinpoint™ GT Needle Guide Kits). The subject 96” 1 mil Site~Rite® Probe Cover is modified from the predicate 48” long, 1 mil Site~Rite® Probe Cover, and includes dimensional changes along with a different material formulation.

(4) Labeling updates:
- The Indications for Use statement for the subject device kit has been clarified from that of the predicate device kits to reflect Pinpoint™ GT and Site~Rite® branding, and
- An IFU and labels were generated for the subject device kits with content modified from the predicate device kits’ IFU and labels, to provide clarity and to ensure safe and effective use of the subject device kit.

The differences identified above between the subject and predicate device kits do not alter the intended use of the subject device kits and do not raise any new questions of equivalence.

Safety & Performance Tests

Verification and validation tests were designed and performed in accordance with Design Controls as per 21 CFR §820.30. The following tests were conducted per guidance documents and standards in conjunction with internal test protocols to determine appropriate methods for evaluating the performance of the device:

<u>Validation of Pinpoint™ GT Needle Guide Use</u>

- Loading the Needle Guide
- Force to Insert a Needle
- Force to Remove a Needle

<u>Verification Testing of the Pinpoint™ GT Needle Guide Kits and of the Ultrasound Accessories contained therein, including Pinpoint™ GT Needle Guides and 96" 1 mil Site~Rite® Probe Covers</u>

- Needle Guide Depth Accuracy
- Needle Guide Depth Distinction and Material Compatibility
- Needle Guide ID Dimension
- Needle Guide Damage during Needle Insertion
- Needle Guide Removal Force
- Force to Remove a Needle from a Needle Guide
- Needle Retention
- Force to Insert a Needle
- Packaging Integrity
- Kit Component Integrity
- Packaging Minimum Seal Width
- Packaging Sterile Barrier Integrity

The following guidance documents and standards were used to determine appropriate methods for evaluating the performance of the device:

- *AAMI / ANSI / ISO 10993-5:2009/(R)2014*, Biological Evaluation Of Medical Devices - Part 5: Tests For In Vitro Cytotoxicity
- *AAMI / ANSI ST72:2011*, Bacterial Endotoxins - Test Methods, Routine Monitoring, And Alternatives To Batch Testing
- *ASTM D4332-14*, Standard Practice For Conditioning Containers, Packages, Or Packaging Components For Testing
- *ASTM F1980-16*, Standard Guide For Accelerated *Aging Of Sterile Barrier Systems For Medical Devices*
- *ISO 10993-1: 2009*, Biological Evaluation of Medical Devices; Part 1 – Evaluation and Testing
- *ISO 10993-7:2008*, Biological Evaluation of Medical Devices Part 7: Ethylene Oxide Sterilization Residuals
- *ISO 10993-10 Third Edition 2010-08-01*, Biological Evaluation Of Medical Devices - Part 10: Tests For Irritation And Skin Sensitization
- *ISO 10993-11 Second Edition 2006-08-15*, Biological Evaluation Of Medical Devices - Part 11: Tests For Systemic Toxicity
- *ISO 10993-12 Fourth Edition 2012-07-01*, Biological Evaluation Of Medical Devices - Part 12: Sample Preparation And Reference Materials
- *ISO 11135: 2014*, Sterilization of healthcare products - Ethylene Oxide - Requirements For Development, Validation And Routine Control Of A Sterilization

Safety & Performance Tests	• *ISO 11607-1* First Edition 2006-04-15, Packaging For Terminally Sterilized Medical Devices - Part 1: Requirements For Materials, Sterile Barrier Systems And Packaging Systems [Including: Amendment 1 (2014)] • *ISO 11607-2* First Edition 2006-04-15, Packaging For Terminally Sterilized Medical Devices - Part 2: Validation Requirements For Forming, Sealing And Assembly Processes [Including: Amendment 1 (2014)] • *USP 39-NF34:2016 , <85>*, Bacterial Endotoxins Test • *USP 39-NF34:2016 , <161>*, Transfusion And Infusion Assemblies And Similar Medical Devices The subject device kits, Pinpoint™ GT Needle Guide Kits, met all predetermined acceptance criteria derived from the above listed tests and demonstrated substantially equivalent performance as compared to the cited predicate device kits. Risk management, including failure mode and effects analysis (FMEA) of the subject device kits (and the ultrasound accessories included therein) was conducted in accordance with BS EN ISO 14971:2012, *Medical Devices – Application of risk management to medical devices*.
Summary of Substantial Equivalence	Based on the intended use, technological characteristics, and performance testing, the subject device kits, Pinpoint™ GT Needle Guide Kits, meet the requirements that are considered sufficient for their intended use and demonstrate substantial equivalence to the cited predicate device kits.