DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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June 27, 2017

C.R. Bard, Inc.
% Silvia De La Barra
Regulatory Affairs Specialist
C.R. Bard, Inc.
605 North 5600 West
Salt Lake City, Utah 84116

Re: K163216
Trade/Device Name: Pinpoint™ GT Needles
Regulation Number: 21 CFR 868.5150
Regulation Name: Anesthesia Conduction Needle
Regulatory Class: Class II
Product Code: BSP
Dated: May 25, 2017
Received: May 30, 2017

Dear Silvia De La Barra:

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,

James P. Bertram -S

for

CDR Lori A. Wiggins, MPT, CLT
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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)*

K163216

Device Name

Pinpoint™ GT Needles

Indications for Use *(Describe)*

The peripheral nerve block Pinpoint™ GT Needle is intended for use in injecting local anesthetics and/or analgesics into a patient to provide regional anesthesia and/or analgesia and/or to facilitate the placement of a catheter.

The peripheral nerve block Pinpoint™ GT Needle may be used in any appropriate patient population.

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:	Silvia De La Barra
	Telephone Number:	(801) 522-5909
	Fax Number:	(801) 522-4969
	Date of Preparation:	27 June 2017
Subject Device	Subject Trade Name:	Pinpoint™ GT Needles
	Common Name:	Anesthesia Needle
	Regulation Name:	Anesthesia Conduction Needle
	Product Code:	BSP
	Regulation:	21 CFR §868.5150
	Regulatory Class:	II
	Classification Panel:	Anesthesiology
Predicate Device	Predicate Trade Name:	SonoTAP Needle
	Premarket Notification:	K113207 (cleared February 29, 2012)
	Manufacturer:	Pajunk Medical System
	Common Name:	Anesthesia Needle
	Regulation Name:	Anesthesia Conduction Needle
	Product Code:	BSP
	Regulation:	21 CFR §868.5150
	Regulatory Class:	II
	Classification Panel:	Anesthesiology
Reference Device	Reference Trade Name:	Pinpoint™ GT Safety Introducer Needle
	Premarket Notification:	K142445 (cleared April 13, 2015)
	Manufacturer:	Bard Access Systems, Inc.
	Common Name:	Safety Introducer Needle
	Regulation Name:	Catheter Introducer
	Product Code:	DYB
	Regulation:	21 CFR §870.1340
	Regulatory Class:	II
	Classification Panel:	Cardiovascular
Device Description	Bard Access Systems, Inc's Pinpoint™ GT Needle is designed to inject anesthetic for regional anesthesia. The Pinpoint™ GT Needle contains a magnet which emits a passive magnetic field that can be detected by ultrasound systems equipped with Pinpoint™ GT Needle Technology. The Pinpoint™ GT Needle, when used with an ultrasound system equipped with Pinpoint™ GT Needle Technology, creates a virtual image of the needle on the ultrasound display, providing clinicians with a visual representation of the	

	needle throughout the insertion process. The subject device can be used with or without ultrasound assisted procedures and may be used with the Pinpoint™ GT Needle Technology at the discretion of the clinician. The subject peripheral nerve block Pinpoint™ GT Needles included in this submission will be offered in varying configuration types, as summarized in the table below:

	Needle configurations
Pinpoint™ GT Needles	18G x 2.75", 19^0
	21G x 3", 30^0
	22G x 2", 30^0
	24G x 1.5", 30^0
	18G x 3", Tuohy (containing a preloaded stylet)

Intended Use	The peripheral nerve block Pinpoint™ GT Needles are intended to inject anesthetic and/or analgesics to provide regional anesthesia and/or to facilitate the placement of a catheter.
Indications For Use	The peripheral nerve block Pinpoint™ GT Needle is intended for use in injecting local anesthetics and/or analgesics into a patient to provide regional anesthesia and/or analgesia and/or facilitate the placement of a catheter. The peripheral nerve block Pinpoint™ GT Needle may be used in any appropriate patient population.
Technological Characteristics	The technological characteristics of the subject peripheral nerve block Pinpoint™ GT Needles are substantially equivalent with respect to the basic design and function to those of the cited predicate device. The differences between the subject and predicate device (e.g. the addition of the passive magnet) are not critical to the intended use of the device and do not raise new or different questions regarding equivalence. The following table provides a comparison between the technological characteristics of the subject and predicate device. The indications for use of the subject device are different compared to the predicate device. The differences provide additional specificity on the use of the subject device. These differences in the indications for use are not critical to the intended therapeutic, diagnostic, or surgical use of the subject device (i.e., to administer anesthetics and/or analgesics to provide regional anesthesia). Additionally, the minor differences do not affect the safety and effectiveness of the device when used as labeled. The primary technological differences between the subject and predicate devices include material differences, needle tip design, and the addition of a passive magnet on the subject device. These technological differences do not impact substantial equivalence because they do not alter the general purpose or function of the device, or change the patient population, therapeutic or diagnostic use of the subject device compared to the predicate device. The technological differences were evaluated using appropriate test methods and

requirements, as defined in the Risk Assessment, to ensure they perform according to their intended use and do not raise different questions of safety and efficacy. The needle tip designs include common industry configurations, and all materials were determined to be biocompatible in accordance with the intended use of the subject device. Additionally, the risks associated with the use of the subject device with Pinpoint™ GT Needle Technology have been further mitigated, and the benefits have been determined to outweigh the risks of using the subject Pinpoint™ GT Needle with the Pinpoint™ GT Needle Technology (not the subject of this submission).

Therefore, the differences in technological characteristics between the subject and predicate devices do not raise different questions of safety or effectiveness.

Subject and Predicate Device Comparison Table		
Attribute	**Subject: Pinpoint™ GT Needle**	**Primary Predicate: SonoTAP Needle**
Owner	Bard Access Systems, Inc.	PAJUNK MEDICAL SYSTEMS
Classification	Same as predicate	BSP - 21 CFR 868.5150 Anesthesia Conduction Needle
510k Status	Subject of this Premarket Notification	K113207 - Concurrence date February 29, 2012
Commercial Name	Pinpoint™ GT Needle	SonoTAP Neelde
Intended Use	The peripheral nerve block Pinpoint™ GT Needles are intended for use in injecting local anesthetics and/or analgesics into a patient to provide regional anesthesia and/or analgesia and/or to facilitate the placement of a catheter.	The cannulas/needles for anesthesia and analgesia enhanced for ultrasound visibility– Tuohy Sono, Sono TAP, Quincke Sono, Chiba Sono, Sono and Crawford Sono – are intended for the transient delivery of anesthetics to provide regional anesthesia and analgesia or to facilitate placement of a catheter.
Indications for Use	The peripheral nerve block Pinpoint™ GT Needle is intended for use in injecting local anesthetics and/or analgesics into a patient to provide regional anesthesia and/or analgesia and/or to facilitate the placement of a catheter. The peripheral nerve block Pinpoint™ GT Needle may	The cannulas/needles for anesthesia and analgesia enhanced for ultrasound visibility– Tuohy Sono, Sono TAP, Quincke Sono, Chiba Sono, Sono and Crawford Sono – are intended for the transient delivery of anesthetics to provide regional anesthesia and analgesia or to facilitate placement of a catheter.

	be used in any appropriate patient population.	
Scientific Technology Description	The primary intent of the subject device, peripheral nerve block Pinpoint™ GT Needles, are to inject anesthetic for regional anesthesia and/or to facilitate the placement of a catheter. Additionally, the peripheral nerve block Pinpoint™ GT Needles contain, integral within the needle hub, a passive magnet. The needle's incorporated passive magnet can be detected by an ultrasound system equipped with Pinpoint™ GT Needle Technology. The Pinpoint™ GT Needle Technology (not the subject of this submission) consists of a magnet sensing probe and software loaded on ultrasound equipment, creating the Pinpoint™ GT System; this system is capable of displaying a visual representation of the needle on an ultrasound image. The detection of the needle's passive magnet by the Pinpoint™ GT Needle Technology is an optional feature and tool/device offered to clinicians for visual representation of a needle throughout the anesthetic process; the presence of the passive magnet does not impact the ability of the device to perform as an anesthetic needle.	The SonoTAP cannula has been designed especially to meet the requirements for single shot TAP and rectus sheath blocks. Equipped with the patented "Cornerstone" reflectors, it ensures that the ultrasonic waves are maximally reflected at both steep and shallow puncture angles. This is an essential prerequisite for the precise placement of the cannula in the appropriate neurovascular plane.

Needle Components	Needle Shaft Needle tip: Echogenic Curve Tip (Tuohy) A Bevel 19° Short Bevel 30° Hub: Same as Predicate Device	Needle Shaft Needle tip: Echogenic Curve Tip (Tuohy) Quincke tip Crawford tip Chiba tip Hub: Open ended Luer locking hub Bevel Indicator
Needle Materials	Luer Hub: Makrolon®2458 Polycarbonate Clear Needle Shaft: Silicone Coated alloy Magnet: Neodymium Iron Boron (NdFeB) Nickel (Ni) Coated Cap: Polypropylene **Available only on the Tuohy Needle; the other needles do not include a cap.* Stylet: Polypropylene **Available only on the Tuohy Needle; the other needles do not include a stylet.*	Luer Hub: Information is not publically available Needle shaft: Information is not publically available Magnet: None Cap: Information is not available Stylet: Information is not available
	Needle Protective Cover (packaging retainer): High Density Polyethylene (HDPE) No colorant	Needle Protective Cover (packaging retainer): Information is not available
Needle Dimensions	Diameter: 18G, 21G, 22G and 24G Length: 38.1mm, 50.8mm, 69.85mm, 76.2mm	Diameter: 16G – 26G Length: 20mm – 180mm

Needle Labeling	Gauge Size: Tuohy needle – 18G indicated by hub color (i.e., pink) Other needles - Gauge size not identified Bevel up Indicator: V in ribs of the hub	Gauge Size: Information is not publically available Bevel up Indicator: Raised feature on the Cap
Catheter Compatibility	20G catheter *Compatible only with the 18G Needles*	Needles are compatible with catheters per Instructions for use, however catheter sizes are not publicly available
Sterility	Same as Predicate Device	Provided Sterile SAL 10^{-6} Ethylene Oxide

Performance Tests

Verification and validation tests were designed and performed in accordance with Design Controls as per 21 CFR §820.30. The following table identifies the performance tests conducted per standards in conjunction with in-house protocols to determine appropriate methods for evaluating the performance of the device.

Performance Tests	Test Description / Standard Utilized
Needle Lumen Patency	ISO 7864:1993, *Sterile hypodermic needles for single use*
Needle-Hub Tensile	
Effective Needle Length	
Needle Tip Inspection	
Cannula Surface Finish	ISO 9626:1991/Amd 1, 2001, *Stainless steel needle tubing for the manufacturer of medical devices* ISO 7864:1993, *Sterile hypodermic needles for single use*
Needle OD and ID Dimensions	ISO 9626:1991/Amd 1, 2001, *Stainless steel needle tubing for the manufacturer of medical devices* ASTM A908-03 (2013): *Standard Specification for Stainless Steel Needle Tubing*
Needle Stiffness	ISO 9626:1991/Amd 1, 2001, *Stainless steel needle tubing for the manufacturer of medical devices*
Corrosion	

Performance Tests Cont.	Needle Hub – Luer Connector Testing	ISO 594-1:1986, *Conical fittings with 6% luer taper for syringes, needles and certain other medical equipment – Part 1: General Requirements* ISO 594-2:1998, *Conical fittings with 6% luer taper for syringes, needles and certain other medical equipment – Part 2: Lock Fittings*
	Fluid Path Leakage	ISO 594-2:1998, *Conical fittings with 6% luer taper for syringes, needles and certain other medical equipment – Part 2: Lock Fittings*
	Needle Particulate	USP<788> (2011): *Particulate Matter in Injections*
	Needle Echogenicity	Bard internal standards and procedures
	Needle Bevel Up Indicator	
	Priming Volume	
	Needle Interface With Catheter	
	Magnetic Axis orientation	
	System Compatibility	
	Needle Tip to Magnet Length	
	Needle Chemical Properties	
	Needle Bevel Dimensions (Primary Grind)	
	Needle Insertion Force	
	Biocompatibility	• ISO 10993-1:2009, *Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within a Risk Management Process* • ISO 10993-5:2009, *Biological Evaluation of Medical Devices – Part 5: Tests for in vitro cytotoxicity* • ISO 10993-10:2010, *Biological Evaluation of Medical Devices – Part 10: Tests for irritation and skin sensitization* • ISO 10993-11:2006, Biological Evaluation of Medical Devices – *Part 11: Tests for systemic toxicity* • ISO 10993-12:2012, *Biological Evaluation of Medical Devices – Part 12: Sample preparation and reference materials*

Performance Tests Cont.

Sterilization	• ISO 10993-7:2008, *Biological Evaluation of Medical Devices – Part 7: Ethylene Oxide Sterilization Residuals.* • ANSI/AAMI/ISO 11135:2014, *Annex B Sterilization of Health Care Products – Ethylene Oxide – Requirements for Development, Validation and Routine Control of A Sterilization Process for Medical Devices*

The subject device configurations met all predetermined acceptance criteria derived from the above listed verification tests and demonstrated substantially equivalent performance as compared to the cited predicate device.

Summary of Substantial Equivalence

Based on the intended use, technological characteristics, and performance testing, the subject peripheral nerve block Pinpoint™ GT Needles met the requirements that are considered sufficient for its intended use and demonstrates that the subject devices are substantially equivalent to the predicate device cited.