Food and Drug Administration
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Silver Spring, MD 20993-0002

June 23, 2017

C. R. Bard, Inc.
Jamie Howell
Associate Regulatory Affairs Specialist
605 North 5600 West
Salt Lake City, Utah 84116

Re: K163437
Trade/Device Name: hypodermic Pinpoint™ GT Needle
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: Class II
Product Code: PVZ
Dated: June 19, 2017
Received: June 20, 2017

Dear Jamie Howell:

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,

Lori A. Wiggins -S6

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)*
K163437

Device Name

hypodermic Pinpoint™ GT Needle

Indications for Use *(Describe)*

The hypodermic Pinpoint™ GT Needle is intended for the injection of medication into or the withdrawal of body fluids from parts of the body below the surface of the skin. The needle is to be used with syringes for general purpose fluid injection/aspiration. The needle tip is echogenic and may be used with ultrasound to provide a visual representation of the needle tip throughout the insertion, medication administration and aspiration process.

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

K163437
510(k) Summary
21 CFR 807.92(a)

General Provisions	Submitter Name: Address:	Bard Access Systems, Inc. 605 North 5600 West Salt Lake City, UT 84116
	Contact Person:	Jamie (Howell) Duke Associate Regulatory Affairs Specialist
	Telephone Number:	(801) 522-5465
	Fax Number:	(801) 522-4969
	Date of Preparation:	23 June 2017
Subject Device	Trade Name:	hypodermic Pinpoint™ GT Needle
	Common Name:	Hypodermic Needle
	Regulation Number:	21 CFR §880.5570
	Regulation Name:	Needle, Hypodermic, Single Lumen
	Regulatory Class:	II
	Product Code:	PVZ
	Manufacturer:	Bard Access Systems, Inc.
	Classification Panel:	General Hospital
Primary Predicate Device	Premarket Notification:	K021475; date of clearance, July 19, 2002
	Trade Name:	BD Single Lumen Needle
	Common Name:	Hypodermic Needle
	Regulation Number:	21 CFR §880.5570
	Regulation Name:	Needle, Hypodermic, Single Lumen
	Regulatory Class:	II
	Product Code:	FMI
	Manufacturer:	Becton Dickinson & Company
	Classification Panel:	General Hospital
Reference Device	Premarket Notification:	K142445, date of clearance, April 13, 2015
	Trade Name:	Pinpoint™ GT Safety Introducer Needle
	Common Name:	Safety Introducer Needle
	Regulation Number:	21 CFR §870.1340
	Regulation Name:	Catheter Introducer
	Regulatory Class:	II
	Product Code:	DYB
	Manufacturer:	Bard Access Systems, Inc.
	Classification Panel:	Cardiovascular

Device Description	Bard Access Systems, Inc's hypodermic Pinpoint™ GT Needles are designed to inject medication or aspirate fluid. The hypodermic Pinpoint™ GT Needles contain a magnet which emits a passive magnetic field that can be detected by ultrasound systems equipped with Pinpoint™ GT Needle Technology. The hypodermic Pinpoint™ GT Needles, 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, medication administration and aspiration process. There are four (4) hypodermic Pinpoint™ GT Needle configurations included in this submission, as shown in the table below.

	Needle configurations
hypodermic 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

Intended Use	The hypodermic Pinpoint™ GT Needles are intended for the injection of medication into or the withdrawal of body fluids from parts of the body below the surface of the skin. The needle is to be used with syringes for general purpose fluid injection/aspiration.
Indications For Use	The hypodermic Pinpoint™ GT Needle is intended for the injection of medication into or the withdrawal of body fluids from parts of the body below the surface of the skin. The needle is to be used with syringes for general purpose fluid injection/aspiration. The needle tip is echogenic and may be used with ultrasound to provide a visual representation of the needle tip throughout the insertion, medication administration and aspiration process.
Technological Characteristics	The technological characteristics of the subject hypodermic 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 any new or different questions regarding equivalence. The subject and predicate devices share equivalent intended use and patient population. The subject device differs from its primary predicate in terms of in types of materials used, dimensions (gauges, lengths), needle tip configurations and the addition of a passive magnet on the subject device. The difference in materials, dimensions (gauges, lengths), and needle tip configurations do not alter the indications for use or intended use of the needles, nor do they raise different questions of equivalence between the subject device and the primary predicate device. A reference device is introduced to support the material and dimensional features of the subject device. Nonclinical testing further demonstrates the equivalence of the subject device to its predicates. The following table provides a comparison between the technological characteristics of the subject and predicate device.

Technological Characteristics Continued

Subject and Primary Predicate Device Comparison Table			
Attribute	**Subject: hypodermic Pinpoint™ GT Needles**	**Primary Predicate: BD Single Lumen Needle**	**Reference: Pinpoint™ GT Safety Introducer Needle**
Owner	Bard Access Systems, Inc.	Becton Dickinson & Company	Bard Access Systems, Inc.
Classification	21 CFR §880.5570 Hypodermic Needle	FMI 21 CFR §880.5570 Hypodermic Needle	DYB 21 CFR §870.1340 Catheter Introducer
510k Status	Subject of this Premarket Notification	K021475 - date of clearance July 19, 2002	K142445 – date of clearance April 13, 2015
Commercial Name	hypodermic Pinpoint™ GT Needles	BD Single Lumen Needle	Pinpoint™ GT Safety Introducer Needle
Indications for Use	The hypodermic Pinpoint™ GT Needle is intended for the injection of medication into or the withdrawal of body fluids from parts of the body below the surface of the skin. The needle is to be used with syringes for general purpose fluid injection/aspiration. The needle tip is echogenic and may be used with ultrasound to provide a visual representation of the needle tip throughout the insertion, medication administration and aspiration process.	These needles are intended for general purpose fluid injection/aspiration, infusion, venipuncture to obtain blood collection and insulin injection.	The Pinpoint™ GT Safety Introducer Needle is intended for patients requiring percutaneous access to place a guidewire for subsequent placement of catheters or other medical procedures requiring introducer needle access. The Pinpoint™ GT Safety Introducer Needle may be used in any appropriate patient population.
Intended Use	The hypodermic Pinpoint™ GT Needles are intended for the injection of medication into or the withdrawal of body fluids from parts of the body below the surface of the skin. The needle is to be used with syringes for general purpose fluid injection/aspiration.	These needles are intended for general purpose fluid injection/aspiration, infusion, venipuncture to obtain blood collection and insulin injection.	The Pinpoint™ GT Safety Introducer Needle is designed for percutaneous vascular access or procedures requiring the placement of a guidewire.
Scientific Technology Description	The primary intent of the subject device, hypodermic Pinpoint™ GT Needles, are to inject medication or aspirate fluid from parts of the body below the surface of the skin.	Not publically available.	The primary intent of the reference device, Pinpoint™ GT Safety Introducer Needle, is to assist with percutaneous vasculature access or procedures requiring the placement of a guidewire.

Technological Characteristics Continued

Subject and Primary Predicate Device Comparison Table			
Attribute	**Subject: hypodermic Pinpoint™ GT Needles**	**Primary Predicate: BD Single Lumen Needle**	**Reference: Pinpoint™ GT Safety Introducer Needle**
Scientific Technology Description Continued	Additionally, the hypodermic 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 (**not the subject of this submission**). The Pinpoint™ GT Needle Technology 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. The presence of the passive magnet does not impact the ability of the device to perform as a hypodermic needle.	Not publically available.	Additionally, the Pinpoint™ GT Safety Introducer Needle contains, integral, within the needle hub an active safety mechanism and a passive magnet. The needle's incorporated passive magnet can be detected by an ultrasound system equipped with Pinpoint™ GT Technology. The Pinpoint™ GT 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 technology is an optional feature and tool/device offered to clinicians for visual representation of a needle throughout the insertion process; the presence of the passive magnet does not impact the ability of the device to perform as an introducer needle.

Technological Characteristics Continued

Subject and Primary Predicate Device Comparison Table			
Attribute	**Subject: hypodermic Pinpoint™ GT Needles**	**Primary Predicate: BD Single Lumen Needle**	**Reference: Pinpoint™ GT Safety Introducer Needle**
Needle Components	Needle Shaft: Silicone coated Needle tip: Echogenic A-Bevel 19° or Short 30° Hub: Open ended luer locking hub Bevel Indicator Passive Magnet	Needle Shaft: Silicone coated Needle tip: Regular, Short, Intradermal Bevel Hub: Open ended luer locking hub	Needle Shaft: Silicone coated Needle tip: Echogenic A-Bevel 12° Hub Open ended luer locking hub Bevel Indicator Passive Magnet
	Safety Mechanism: None	Safety Mechanism: None	Safety Mechanism Incorporated active safety mechanism
Needle Materials	Luer Hub: Makrolon®2458 Polycarbonate Clear Needle Shaft: Silicone Coated alloy Magnet; Neodymium Iron Boron (NdFeB) Nickel (Ni) Coated Needle Protective Cover (packaging retainer): High Density Polyethylene (HDPE) No colorant	Luer Hub: Polypropylene Needle shaft: Stainless Steel Silicone Coated Magnet: None Needle Protective Cover (packaging retainer): Protective Plastic sheath Details not publically available	Luer Hub: Makrolon®2458 Polycarbonate Clear Needle Shaft: Silicone Coated alloy Magnet; Neodymium Iron Boron (NdFeB) Nickel (Ni) Coated Needle Protective Cover (packaging retainer): Clear Amorphous Polyethylene Terephtalate (APET)
	Safety Mechanism: None	Safety Mechanism: None	Safety Mechanism: Translucent Green Polycarbonate Silicone O-ring 301 Stainless Steel Cap polycarbonate
Needle Dimensions	There are four (4) total subject device configurations consisting of the following gauge sizes and lengths: Diameter: 18, 21, 22, 24 gauge Length: 1.50”, 2.00”, 2.75”, 3.00”	Diameter: 16 to 30 gauge Length: 3/8” to 2”	Diameter: 21 gauge Length: 2.75”

Technological Characteristics Continued

Subject and Primary Predicate Device Comparison Table			
Attribute	**Subject: hypodermic Pinpoint™ GT Needles**	**Primary Predicate: BD Single Lumen Needle**	**Reference: Pinpoint™ GT Safety Introducer Needle**
Needle Labeling	Gauge Size: No gauge size coloring* **Note: Needle hubs for the different needle gauge sizes are not colored to ensure visualization of blood flashback. Colors used in the subject device labeling are based on needle length and are consistent with the needle color coding used with the Pinpoint™ GT Needle Technology.* Bevel-Up Indicator: V in ribs of the hub (extra ribs on the hub form a V-shape on the hub that indicates bevel-up).	Gauge Size: Translucent, color-coded hubs: Gray (27-gauge), Tan (26), Blue (25), Turquoise (23), Black (22), Green (21), Yellow (20), Brown (19), Pink (18), and Purple (16) Bevel-Up Indicator: None	Gauge Size: Safety mechanism is a translucent green color Bevel-Up Indicator: Raised embossed arrow on the hub
Sterility	Provided Sterile SAL 10^{-6} Ethylene Oxide	Provided Sterile SAL 10^{-6} Gamma irradiation or Ethylene Oxide	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 Force	
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	
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	
Magnetic Axis Orientation	
System Compatibility	
Needle Tip to Magnet Length	
Needle Chemical Properties	
Needle Bevel Dimensions (Primary Grind)	
Needle Insertion Force	

Performance Tests Continued	**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*

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 hypodermic Pinpoint™ GT Needles met the requirements that are considered sufficient for its intended use and demonstrate that the subject devices are substantial equivalent to the cited predicate device.