November 4, 2016

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

Re: K162769
Trade/Device Name: Pinpoint™ GT Introducer Needle
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: II
Product Code: DYB
Dated: September 29, 2016
Received: October 3, 2016

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,

Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure
Indications for Use

510(k) Number *(if known)*
K162769

Device Name
Pinpoint™ GT Introducer Needle

Indications for Use *(Describe)*

The Pinpoint™ GT 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 Introducer 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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PRAS Staff@fda.hhs.gov

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

<table>
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<th>General Provisions</th>
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<tr>
<td><strong>Submitter Name:</strong></td>
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</table>
| **Address:** | 605 North 5600 West  
Salt Lake City, UT  84116 |
| **Contact Person:** | Ms. Jamie Howell  
Regulatory Affairs Specialist |
| **Telephone Number:** | 801-522-5465 |
| **Fax Number:** | 801-522-5425 |
| **Date of Preparation:** | 29 September 2016 |

<table>
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<tr>
<th>Subject Device</th>
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<th>Predicate Devices</th>
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<td><strong>Premarket Notification:</strong></td>
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**Device Description**

Bard Access Systems, Inc.’s, Pinpoint™ GT Introducer Needle is an 18G x 2.75 inch needle designed for percutaneous access to introduce a guidewire. The Pinpoint™ GT Introducer Needle contains a magnet which emits a passive magnetic field that can be detected by ultrasound systems equipped with Pinpoint™ GT Technology. The Pinpoint™ GT Introducer Needle, when used with the Pinpoint™ GT System creates a virtual image of the needle on the ultrasound display, providing clinicians with a visual representation of the needle throughout the insertion process.

**Intended Use**

The Pinpoint™ GT Introducer Needle is designed for percutaneous vascular access or procedures requiring the placement of a guidewire.

**Indications For Use**

The Pinpoint™ GT 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 Introducer Needle may be used in any appropriate patient population.
Technological characteristics of the subject 18G Pinpoint™ GT Introducer Needle is substantially equivalent with respect to the basic design and function to those of the cited predicate device.

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

- Dimensional specification modification from a 21G needle to an 18G needle;
- Tip geometry, primary grind angle modification to the needle from 12° to 19° (required to accommodate the larger diameter of 18G needle shaft);
- Removal of the active safety mechanism on the subject 18G Pinpoint™ GT Introducer Needle;
- Modification to the hub design owing to the removal of the safety mechanism;
- Use of a different, non-patient contacting, adhesive that is used to bond the needle to the magnet, in the subject 18G Pinpoint™ GT Introducer Needle; and
- Change to protective cover (packaging retainer)
  - Change in the type of polyethylene used in the needle protective cover; and
  - Protective cover changed from clam shell to tube over cannula.

The following table provides a comparison between the technological characteristics of the subject and predicate device.

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<thead>
<tr>
<th>Attribute</th>
<th>Subject: Pinpoint™ GT Introducer Needle</th>
<th>Predicate: Pinpoint™ GT Safety Introducer Needle</th>
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<tr>
<td>Classification</td>
<td>Same as predicate device.</td>
<td>DYB – 21 CFR §870.1340 Catheter Introducer</td>
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<tr>
<td>510k Status</td>
<td>Subject of this Premarket Notification</td>
<td>K142445 - date of clearance April 13, 2015</td>
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<tr>
<td>Commercial Name</td>
<td>Pinpoint™ GT Introducer Needle</td>
<td>Pinpoint™ GT Safety Introducer Needle</td>
</tr>
<tr>
<td>Indications for Use</td>
<td>The Pinpoint™ GT Introducer Needle is intended for patients requiring percutaneous access to place a guidewire for subsequent placement of catheters or other medical procedures</td>
<td>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</td>
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<tr>
<td>Technological Characteristics (cont.)</td>
<td>Scientific Technology Description</td>
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<td><strong>Technological Characteristics</strong></td>
<td><strong>Scientific Technology Description</strong></td>
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<tr>
<td><strong>Technological Characteristics</strong></td>
<td>The primary intent of the subject device, Pinpoint™ GT Introducer Needle, is to assist with percutaneous vasculature access or procedures requiring the placement of a guidewire. Additionally, the Pinpoint™ GT Introducer Needle contains, 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 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.</td>
<td></td>
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<tr>
<td><strong>Technological Characteristics</strong></td>
<td>The primary intent of the predicate device, Pinpoint™ GT Safety Introducer Needle, is to assist with percutaneous vasculature access or procedures requiring the placement of a guidewire. 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.</td>
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requiring introducer needle access. The Pinpoint™ GT Introducer Needle may be used in any appropriate patient population.

introducer needle access. The Pinpoint™ GT Safety Introducer Needle may be used in any appropriate patient population.
<table>
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<tr>
<th><strong>Technological Characteristics (cont.)</strong></th>
<th><strong>Needle Components</strong></th>
<th><strong>Needle Materials</strong></th>
<th><strong>Needle Dimensions</strong></th>
<th><strong>Needle Labeling</strong></th>
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</table>
| **Needle Components** | **Needle Shaft:** Same as predicate device.  
**Needle tip:** Same as predicate device. A Bevel 19°  
**Hub:** Same as predicate device. | **Needle Shaft:** Silicone coated  
**Needle tip:** Echogenic A Bevel 12°  
**Hub:** Open ended luer locking hub Bevel Indicator Passive Magnet | **Diameter:** 18 gauge  
**Length:** Same as predicate | **Gauge Size:** No gauge size coloring due to removal of the safety mechanism  
**Bevel up Indicator:** V in ribs of the hub |
| **Needle Materials** | **Luer Hub:** Same as predicate device  
**Needle Shaft:** Same as predicate device.  
**Magnet:** Same as predicate device.  
**Needle Protective Cover (packaging retainer):** High Density Polyethylene (HDPE) No colorant  
**Safety Mechanism:** None | **Luer Hub:** Clear Polycarbonate  
**Needle shaft:** Silicone Coated Alloy  
**Magnet:** Neodymium Iron Boron (NdFeB) Nickel (Ni) Coated  
**Needle Protective Cover (packaging retainer):** Clear Amorphous Polyethylene Terephthalate (APET)  
**Safety Mechanism:** Translucent Green Polycarbonate Silicone O-ring 301 Stainless Steel Cap polycarbonate | **Diameter:** 21 gauge  
**Length:** 2.75” or 7cm | **Gauge Size:** Safety mechanism a translucent green color  
**Bevel up Indicator:** Raised embossed arrow on the hub |
Sterility | Same as predicate device. | Provided Sterile
| | SAL 10^{-6} | Ethylene Oxide |

The differences between the subject and predicate device are not critical to the intended use of the device and do not raise any new or different questions regarding safety or effectiveness.

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 in-house protocols to determine appropriate methods for evaluating the performance of the device:

**Performance Testing – Bench:**
- Needle Tip
- Needle Dimensions
- Cannula Surface Finish
- Needle-Hub Tensile Force
- Needle Stiffness
- Effective Needle Length
- Needle Echogenicity
- Needle Bevel Up Indicator
- Needle Hub
- Needle Fluid Path
- Introducer Needle Interface with Guidewire
- Needle Protective Cover
- Magnetic Axis Orientation
- Needle Tip to Magnet Length

The following guidance documents and standards in conjunction with in-house protocols were used to determine the appropriate methods for evaluating the performance of the device:

- 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
- ISO 9626: 2001, Stainless steel needle tubing for the manufacturer of medical devices
- ISO 7864: 1993, Sterile hypodermic needles for single use
- Guidance Document; Medical Devices with Sharps Injury Prevention Features, August 9, 2005
- Guidance on the Content of Premarket Notification [510(k)] Submissions for Hypodermic Single Lumen Needles, April 1993
- Guidance Document; Applying Human Factors and Usability Engineering to Optimize Medical Device Design, June 22, 2011
ISO 10993-7:2008, Biological Evaluation of Medical Devices Part 7: Ethylene Oxide Sterilization Residuals
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 met all predetermined acceptance criteria derived from the above listed references 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 18G Pinpoint™ GT Introducer Needle meets the requirements that are considered sufficient for its intended use and demonstrates substantial equivalence to the cited predicate device.