March 12, 2021

C.R. Bard, Inc.
Matthew Lyman
Manager, Regulatory Affairs
605 North 5600 West
Salt Lake City, Utah 84116

Re: K201452
Trade/Device Name: Groshong NXT PICC Catheter
Regulation Number: 21 CFR 880.5970
Regulation Name: Percutaneous, implanted, long-term intravascular catheter
Regulatory Class: Class II
Product Code: LJS
Dated: February 8, 2021
Received: February 12, 2021

Dear Matthew Lyman:

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,

for Payal Patel
Acting Assistant Director
DHT3C: Division of Drug Delivery and
General Hospital Devices,
and Human Factors
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology Devices
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)*
K201452

Device Name
Groshong® NXT PICC Catheter

Indications for Use *(Describe)*
The Groshong® NXT PICC provides short (less than 30 days) or long (greater than 30 days) term peripheral access to the central venous system for intravenous therapy or blood sampling.

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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**Bard Access Systems, Inc.**
605 North 5600 West
Salt Lake City, UT 84116 USA
Phone: +1-801-522-5000
Fax: +1-801-522-4948

# 510(k) Summary- K201452

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| **General Provisions** | Submitter Name: | Bard Access Systems, Inc.<br>(wholly owned subsidiary of BD) |
| | Submitter Address: | 605 North 5600 West<br>Salt Lake City, UT 84116 |
| | Contact Person: | Matthew Lyman<br>Sr. Manager, Regulatory Affairs |
| | Telephone Number: | 801.522.5416 |
| | Fax Number: | 801.522.4907 |
| | Date of Preparation: | 3/12/2021 |
| **Subject Device** | Trade Name: | Groshong™ NXT PICC Catheter |
| | Common Name: | Catheter, Intravascular, Therapeutic, Long-Term Greater than 30 Days |
| | Classification Name: | Percutaneous, Implanted, Long-Term Intravascular Catheter |
| | Device Class: | II |
| | Regulation Number: | 21 CFR 880.5970 |
| | Product Code: | LJS |
| | Review Panel | General Hospital |
| **Predicate Device** | Trade Name: | Groshong™ NXT PICC Catheter |
| | Manufacturer: | Bard Access Systems, Inc.<br>(wholly owned subsidiary of BD) |
| | Premarket Notification: | K034020 |
| | Common Name: | Catheter, Intravascular, Therapeutic, Long-Term Greater than 30 Days |
| | Classification Name: | Percutaneous, Implanted, Long-Term Intravascular Catheter |
| | Device Class: | II |
| | Regulation Number: | 21 CFR 880.5970 |
| | Product Code: | LJS |
| | Review Panel | General Hospital |

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| **Device Description** | Groshong™ NXT Peripherally Inserted Central Catheters are made from specially formulated and processed medical grade materials in a tray with accessories for reliable long- (greater than 30 days) or short- (less than 30 days) term vascular access.<br><br>Groshong™ Valve Function<br><br>The Groshong™ catheter incorporates the patented, 3-position, pressure-sensitive Groshong™ valve. The valve is located near the rounded, closed, radiopaque catheter tip and allows fluid infusion and blood aspiration. When not in use, the valve restricts blood backflow and air embolism by remaining closed.<br><br>The Groshong™ valve is designed to remain closed between -7- and 80-mm Hg. Since the normal central venous pressure range in the superior vena cava is 0 to 5 mm Hg, the valve remains closed at normal central venous pressure. Pressure in the superior vena cava must exceed 80 mm Hg to open the valve inward. Also, negative pressure (vacuum) will cause the valve to open inward, allowing blood aspiration.<br><br>Positive pressure into the catheter (gravity, pump, syringe) will open the valve outward, allowing fluid infusion. The need for the anticoagulant effect of heparin is eliminated because the closed valve prevents blood from entering the catheter and clotting. If the catheter is aspirated, pulling the valve inward, it must be flushed with normal saline to clear blood from the lumen and allow the valve to return to its normal, closed position. |
| **Indications for Use** | The Groshong™ NXT PICC provides short (less than 30 days) or long (greater than 30 days) term peripheral access to the central venous system for intravenous therapy or blood sampling. |

**Technological Characteristics**

The technological characteristics of the subject Groshong™ NXT PICC Catheter are substantially equivalent to those of the cited predicate device with respect to basic design, function, and fundamental scientific technology. Modifications to the subject device, when compared to the predicate device, include:

- A change to the inner lumen geometry.
- A material and formulation change to the catheter silicone and catheter silicone colorant.

The technological differences were evaluated per the device risk assessment using the same test requirements and industry consensus standards, where applicable, as the predicate device. The conclusion of these evaluations is that the changes to the subject device compared to the predicate device do not raise new or different questions of safety or effectiveness, and the devices are substantially equivalent.

The following table provides a comparison between the subject and predicate devices.

| Attribute | Subject Device – Groshong™ NXT PICC Catheter | Predicate Device – Groshong™ NXT PICC Catheter | Discussion of Characteristics |
|---|---|---|---|
| **Owner** | Same as predicate | Bard Access Systems, Inc. (wholly owned subsidiary of BD) | Same as predicate. |
| **Classification** | Same as predicate | LJS – 21 CFR 880.5970 Percutaneous, implanted, long-term intravascular catheter | The classification of the subject device is the same as the predicate device. |
| **510(k) Status** | Subject of this Premarket Notification | K034020 – Concurrence date: January 21, 2004 | N/A. |
| **Trade Name** | Groshong™ NXT PICC Catheter | Groshong™ NXT PICC Catheter | Same as predicate. |
| **Indications for Use** | Same as predicate | The Groshong™ NXT PICC provides short (less than 30 days) or long (greater than 30 days) term peripheral access to the central venous system for intravenous therapy or blood sampling. | The indications for use of the subject device are the same as the predicate device. |
| **Catheter Dimensions** | Same as predicate | 4 Fr single lumen, 60 cm trimmable length | The dimensions of the subject device are the same as the predicate device. |
| **Catheter Configuration** | 18-gauge, striped blue colored shaft | 18-gauge, solid blue colored shaft | The catheter configuration of the subject device is substantially equivalent to the predicate device, and a risk assessment |

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| | | | did not identify any new or significantly modified risks. These differences do not raise new or different questions of safety or effectiveness. |
| **Inner Lumen** | Round | Rectangular | The inner lumen of the subject device is substantially equivalent to the predicate device, and a risk assessment did not identify any new or significantly modified risks. These differences do not raise new or different questions of safety or effectiveness. |
| **Duration of Use** | Same as predicate | Short (less than 30 days) or long (greater than 30 days) term | The duration of use of the subject device is the same as the predicate device. |
| **Means of insertion** | Same as predicate | Percutaneous introducer, microintroducer | The means of insertion of the subject device is the same as the predicate device. |
| **Insertion Site** | Same as predicate | Peripheral | The insertion site of the subject device is the same as the predicate device. |
| **Intended Patient Population** | Same as predicate | General population | The intended patient population of the subject device is the same as the predicate device. |
| **Catheter Materials (by Device Component)** | *Base Materials*<br>Shaft Tubing:<br>65-durometer radiopaque silicone (33% barium sulfate [$BaSO_4$] in colored stripe), blue silicone colorant, 40-durometer silicone tip<br>Luer Connector:<br>Same<br>Extension Leg:<br>Same<br>Proximal Connector:<br>Same | *Base Materials*<br>Shaft Tubing:<br>80-durometer radiopaque silicone (17% $BaSO_4$ evenly distributed), blue silicone colorant, 40-duromter silicone tip<br>Luer Connector:<br>Polybutylene terephthalate (PBT), stainless steel<br>Extension Leg:<br>Silicone<br>Proximal Connector:<br>Stainless steel, PBT, radiopaque silicone, silicone | The base materials of the catheter for the subject device are the same as the predicate device. All material formulation differences of the subject device were evaluated and are substantially equivalent to the predicate device, and a risk assessment did not identify any new or significantly modified risks. These differences do not raise new or different questions of safety or effectiveness. |

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| | | Distal Connector:<br>Same | Distal Connector:<br>PBT, silicone | |
| | **Catheter Distal Configuration** | Same as predicate | Closed-ended with 3-position, pressure-sensitive Groshong™ valve | The distal configuration of the subject device is the same as the predicate device. |
| | **Catheter Connector** | Same as predicate | 2-piece connection with extension leg and luer lock connector | The catheter connector of the subject device is the same as the predicate device. |
| | **Priming Volume** | 0.24mL | 0.51mL | Differences in priming volume do not raise new or different questions of safety or effectiveness. |
| | **Sterility** | Same as predicate | Provided sterile (ethylene oxide) | The subject and predicate device are both provided sterile. |

**Performance Tests**

Verification and validation tests were performed in accordance with Design Controls per 21 CFR 820.30. The performance tests completed on the subject device were limited to those tests required to support a determination of substantial equivalence to the predicate device. In addition, where technological characteristics between the subject and predicate device were found to be identical, results of performance testing conducted on the predicate device were adopted and applied to the subject device. The following performance tests were conducted per guidance documents, industry standards, and in-house protocols to establish the performance of the device, thereby leading to a conclusion of substantial equivalence of the subject Groshong™ NXT PICC Catheter to the predicate device, the Groshong™ NXT PICC Catheter.

| **Performance Tests for Subject Device** | |
|---|---|
| **Verification / Validation Method** | **Reference Standard** |
| **Performance** | • ISO 10555-1:2013/Amd 1:2017 *Intravascular Catheters - Sterile and Single-Use Intravascular Catheters - Part 1: General Requirements*<br>• *ISO 10555-3:2013 – Intravascular catheters – Sterile and single-use catheters – Part 3: Central venous catheters*<br>• *ASMT F640-12 Standard Test Methods for Determining Radiopacity for Medical Use*<br>• *ASTM F2119-07 Standard Test Method for Evaluation of MR Image Artifacts from Passive Implants*<br>• *ASTM F2182 Standard Test Method for Measurement of Radio Frequency Induced Heating on or Near Passive Implants During Magnetic Resonance Imaging*<br>• *ASTM F2052-15 Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment* |

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| | | • *ASTM F2213-17 Standard Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Resonance Environment* |
| | **Biocompatibility Evaluations** | • ISO 10993-1:2018 – *Biological Evaluation of Medical Devices – Part 1: Evaluation and testing within a risk management process*<br>• *USP<788> Particulate Matters in Injections (method 1 Light Obscuration Particle Count Test)* |
| | **Sterilization** | • *ANSI AAMI ISO 11135:2014C Sterilization of Health Care Products - Ethylene Oxide – Requirements for Development, Validation and Routine Control of a Sterilization Process for Medical Devices.* |
| **Summary of Substantial Equivalence** | Based on the risk management activities and testing, the subject Groshong™ NXT PICC Catheter has demonstrated to be substantially equivalent to the cited predicate device. | |