September 25, 2018

Piper Access LLC
Jay Muse
CEO
3981 South 700 East Suite 15
Salt Lake City, Utah 84107

Re: K181904
Trade/Device Name: 5 FR Dual Lumen Piper PICC
Regulation Number: 21 CFR 880.5970
Regulation Name: Percutaneous, Implanted, Long-Term Intravascular Catheter
Regulatory Class: Class II
Product Code: LJS
Dated: July 13, 2018
Received: July 16, 2018

Dear Jay Muse:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Geeta K.
Pamidimukkala -S

for 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K181904

Device Name
5 FR DL Piper PICC

Indications for Use *(Describe)*
The 5 FR DL Piper PICC Catheter is indicated for short or long term peripheral access to the central venous system for intravenous therapy, power injection of contrast media, and prolonged exposure to intraluminal solutions containing up to 70% ethanol. The maximum recommended infusion rate is 5mL/sec for power injection of contrast media.

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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510(k) Summary

K181904

Applicant

Name:	Piper Access, LLC
Address:	3981 South 700 East Suite 15 Salt Lake City, UT 84107
Phone:	801-210-2886
Contact:	Shanna Ryan, Regulatory Affairs Project Manager
Email:	shanna.ryan@gmail.com
Date Prepared:	September 13, 2018

Subject Device

Trade Name:	5 FR DL Piper PICC
Manufacturer:	Piper Access
Common Name:	Catheter, Intravascular, Therapeutic, Long-term Greater than 30days
Classification Name:	Percutaneous, Implanted, Long –term Intravascular Catheter
Class:	II
Product Code:	LJS
Regulation:	21 CFR §880.5970
Panel:	General Hospital

Primary Predicate

Premarket Notification:	K151985 (clearance date June 14, 2016)
Trade Name:	PowerPICC® EtOH Catheter
Manufacturer:	Bard Access Systems, Inc.
Common Name:	Catheter, Intravascular, Therapeutic, Long-term Greater than 30days
Classification Name:	Percutaneous, Implanted, Long –term Intravascular Catheter
Class:	II
Product Code:	LJS
Regulation:	21 CFR §880.5970
Panel:	General Hospital

Reference Device

Premarket Notification:	K051672 (clearance date Nov 23, 2005)
Trade Name:	5 Fr DL PowerPICC® Catheter
Manufacturer:	Bard Access Systems, Inc.
Common Name:	Catheter, Intravascular, Therapeutic, Long-term Greater than 30days

Classification Name:	Percutaneous, Implanted, Long –term Intravascular Catheter
Class:	II
Product Code:	LJS
Regulation:	21 CFR §880.5970
Panel:	General Hospital

Device Description

The 5 French (FR) Dual Lumen (DL) Piper PICC is a single use peripherally inserted central catheter made from a specially-formulated medical grade polyurethane material.

The Piper PICC is designed to perform infusion, intravenous therapy, blood sampling and power injection of contrast media, and is compatible with intraluminal solutions containing up to 70% ethanol. The maximum recommended infusion rate is 5 mL/sec.

The Piper PICC is a 5 French catheter with two 18-gauge lumens and will be provided with 55cm of effective length. The catheter has a reverse-tapered design. The catheter is inserted peripherally by the clinician and is trimmable to fit different patient sizes. It is inserted with a Seldinger or modified-Seldinger technique with compatibility to guidewires up to 0.019" in outer diameter. The catheter distal tip is positioned in the lower 1/3 of the Superior Vena Cava (SVC). The effective length of the catheter including the distal end is radiopaque, which allows for catheter tip visualization.

The Piper PICC catheter includes an extruded polyurethane catheter shaft molded to an injection molded polyurethane hub with extruded extension legs molded to luer-lock fittings, which provide attachments for IV administration. The junction has suture wings to allow for securement to the patient. Clamps are attached to both extension legs on the catheter.

The distal end of the catheter shaft is a dual lumen symmetrical D-shape design that does not differ in material from the remainder of the shaft. With the exception of the reverse-tapered section of the shaft, the distal end is also dimensionally identical to the remainder of the shaft.

The proximal end of the catheter consists of two power injectable extension legs, which each have a luer lock style connection depicting gage size, thumb clamp, ID tag. The catheter has an average priming volume is 0.61 mL

The Piper PICC is packaged in a catheter only kit and provided sterile to the end user. There are no additional components in the kit.

Intended Use

The Piper PICC Catheter is intended for short- or long-term peripheral access to the central venous system for intravenous therapy and blood sampling.

Technological Characteristics and Comparison to the Predicate Device

Both the subject device and predicate are intended for short- or long-term peripheral access to the central venous system for intravenous therapy and blood sampling. The subject and predicate devices are based on the following same technological elements: Intended use, mechanism of action, placement technique and insertion site, duration of use/dwell time, distal tip placement, design features, dimensions, power injection, sterility, packaging, sterilization, and biocompatibility.

The differences between the subject device and cited predicate include:

- Materials: The Piper PICC is comprised of Quadrasil, a siliconized aromatic polycarbonate polyurethane which differs from the material used in the predicate. The material was evaluated using the same test standards as the predicate devices. Performance testing demonstrated that the material meets the mechanical testing and biocompatibility requirements and demonstrated resistance to intraluminal exposure to 70% ethanol.

The following table shows a comparison of the technological characteristics between the Piper PICC and the cited predicate in sufficient detail to provide an understanding of the basis for determining substantial equivalence.

<table>
<tr><th>Feature</th><th>PREDICATE
BARD ACCESS
PowerPICC® EtOH Catheter</th><th>SUBJECT DEVICE
5 FR Dual Lumen
PIPER PICC</th></tr>
<tr><td>Indication for Use</td><td>The PowerPICC EtOH Catheter is indicated for short- or long-term peripheral access to the central venous system for intravenous therapy including prolonged exposure to intraluminal solutions containing up to 70% ethanol, power injection of contrast media, and allows for central venous pressure monitoring. For blood sampling, infusion, or therapy, use a 4 French or larger catheter. For central venous pressure monitoring, it is recommended that a catheter lumen of 20 gauge or larger be used.
<table>
<tr><th>Catheter Size</th><th>Maximum Flow Rate</th></tr>
<tr><td>4F Single Lumen</td><td>5 ml/sec</td></tr>
<tr><td>5F Dual Lumen</td><td>5 ml/sec</td></tr>
<tr><td>5F Triple Lumen</td><td>4 ml/sec</td></tr>
</table></td><td>The 5 FR DL Piper PICC Catheter is indicated for short or long term peripheral access to the central venous system for intravenous therapy, power injection of contrast media, and prolonged exposure to intraluminal solutions containing up to 70% ethanol. The maximum recommended infusion rate is 5mL/sec for power injection of contrast media.</td></tr>
<tr><td>Placement Technique</td><td>Seldinger, Modified-Seldinger</td><td>Same</td></tr>
</table>

Feature	PREDICATE BARD ACCESS PowerPICC® EtOH Catheter	SUBJECT DEVICE 5 FR Dual Lumen PIPER PICC
Duration of Use	Short (<30 days) or long-term (≥30 days)	Same
Insertion Site	Peripheral	Same
Placement of Distal Tip	Lower 1/3 of the Superior Vena Cava	Same
ID	18 Gauge	Same
OD	5 French	Same
Length	55 cm (Usable)	Same
Number of Lumens	Dual	Same
Catheter configuration	Two power injection lumens	Same
Internal Lumen Configuration	Double D	Same
Catheter Tip Configuration	Trimmable	Same
Maximum Power Injection	300 psi	Same
Max Power Injection Flow Rate	5/mL sec	Same
Ethanol Resistance	Yes	Same
Catheter Design	Reverse Taper	Same
Catheter Materials-Catheter Shaft, Extension Legs, Molded Junction	Aromatic polycarbonate polyurethane	Siliconized aromatic polycarbonate polyurethane (Quadrasil)
Catheter Materials – Luers	Quadraplast polyurethane	Same
Printing	Fr size, depth markings, gauge size	Same
Sterility	Provided sterile (SAL 10^{-6}) / EO	Same
Biocompatibility	To ISO 10993-1	Same
Non-clinical performance testing	To 1SO – 10555-1 and 1SO – 10555-3; ISO 594-1 and 594-2; FDA Guidance, ASTM F640-79	Same

Performance Testing Summary

Verification and validation tests have been performed in accordance with Design Controls as per 21 CFR §820.30. The following guidance and standards used to determine test methods and acceptance criteria:

- Guidance on Premarket Notification [510(k)] Submission for Short- Term and Long-Term Intravascular Catheters, March 16, 1995
- Design Control Guidance for Medical Device Manufacturers, March 11, 1997
- ISO 10555-1: 2013, Sterile, single-use intravascular catheters, Part 1: General requirements
- ISO 10555-3: 2013, Intravascular catheters--Sterile and single-use catheters, Part 3: Central venous catheters
- 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
- ASTM F640-79 (reapproved 2000): 2012, Standard Test Methods for Radiopacity of Plastics for Medical Use

Sterilization and Packaging Guidance and standards:

- ISO 11135:2014, Medical Devices – Validation and Routine Control of Ethylene Oxide Sterilization
- ISO 11607-1: 2006, Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems
- ISO 11607-1 AMD 1: 2014, Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems
- ISO 10993-7: 2008, Biological Evaluation of Medical Devices Part 7: Ethylene Oxide Sterilization Residuals
- ANSI/AAMI ST72:2011, Bacterial endotoxins – Test methods, routine monitoring, and alternatives to batch testing
- FDA Guidance for Industry Pyrogen and Endotoxins Testing: Questions and Answers, 2010

The following tests were performed:

- Dimensional Analysis
- Ink Permanence
- Radiopacity
- Leak Testing
- Extension Leg Leak w/ Clamp
- Pump Flow
- Priming Volume
- Gravity Flow
- Kink Diameter
- Catheter Collapse
- Tip Stability
- Suture Wing Integrity
- Assembly Tensile
- Shaft Tensile
- Catheter Elongation
- Catheter Modulus
- Catheter Fatigue
- Power Injection
- Assembly Burst
- Extension Leg Burst

- ISO Luer Gauging
- ISO Luer Testing
- Sterilization
- Packaging Validation
- Residuals, EO and ECH
- Pyrogenicity - Bacterial Endotoxin Test (LAL)

Biocompatibility evaluations were completed per ISO 10993 Biological Evaluation of Medical Devices Part 1: Evaluation and Testing for externally communicating, blood contacting, permanent devices and FDA Guidance Use of International Standard ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process. The following were evaluated:

- Cytotoxicity
- Sensitization
- Irritation/Intracutaneous Reactivity
- Acute Systemic Toxicity
- Material Mediated Pyrogenicity
- Hemolysis (indirect/direct)
- Complement Activation
- Partial Thromboplastin Time
- Sheep Thrombogenicity
- Implantation 13 weeks
- Chemical Characterization
- Subacute/ Sub-chronic Toxicity
- Genotoxicity
- Chronic Toxicity
- Carcinogenicity

To meet the requirements in ISO10993-4, a reference device, the Bard 5F Dual Lumen PowerPICC was used for in vivo thrombogenicity evaluations as the legally marketed comparative device (LMCD). The Bard 5F Dual Lumen PowerPICC was selected as the Bard PowerPICC EtOH Catheter was not available on the market and could not be obtained for use as the LMCD. The Bard 5F Dual Lumen PowerPICC provides a point of comparison and is one of the most commonly used PICC products throughout the world, and has proven acceptable clinical performance with over a decade of use. Further justifying the acceptability of the 5F Dual Lumen is the fact that it is the device to which the cited predicate device claimed substantial equivalence. During evaluations reported within this 510k submission, it has been shown that the subject device performs equivalent to, or better than, the reference device with respect to thrombogenic potential.

The 5 FR DL Piper PICC met all of the predetermined acceptance criteria derived from the standards and guidance listed above. Risk management of the subject device was conducted in accordance with ISO 14971:2007, Medical Devices – Risk Management for Medical Devices.

Conclusions

The subject device, 5 FR DL Piper PICC, has the same intended use as the cited predicate device. Testing performed on the subject device demonstrates the device meets the requirements and is substantially equivalent to the predicate.