August 27, 2021

Piper Access, LLC
Jay Muse
President and CEO
6030 W. Harold Gatty Dr.
Salt Lake City, Utah 84116

Re: K210047
Trade/Device Name: Stiletto Extended Dwell Catheter
Regulation Number: 21 CFR 880.5200
Regulation Name: Intravascular Catheter
Regulatory Class: Class II
Product Code: PND
Dated: January 7, 2021
Received: January 8, 2021

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/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,

Payal Patel
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)*
K210047

Device Name

Stiletto Extended Dwell Catheter

Indications for Use *(Describe)*

The Stiletto Extended Dwell Catheter is inserted into a patient's vascular system for short-term use (<28 days) to sample blood or administer fluids intravenously. These catheters may be used for any patient population with consideration given to adequacy of vascular anatomy and appropriateness of the procedure. The Stiletto Extended Dwell Catheter is suitable for use with power injectors.

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 (21 CFR 807.92(c))

I. SUBMITTER

Submitter Name:	Piper Access, LLC
Address:	6030 West Harold Gatty Dr. Salt Lake City, UT 84116
Telephone:	801-210-2886
Contact Person:	Jay Muse
Email of Contact:	jay.muse@piperaccess.com
Date Prepared:	**26 August 2021**

II. DEVICE

Trade Name:	Stiletto Extended Dwell Catheter
Common/Usual Name:	Midline Catheter
Regulation Name:	Intravascular catheter
Regulation Number:	21 CFR 880.5200
Product Code:	PND
Device Class:	Class II
Review Panel:	General Hospital

III. PREDICATE DEVICE

Predicate Name:	PowerGlide Pro™ Midline Catheter
Common/Usual Name:	Intravascular Catheter, Therapeutic, Short-Term Less Than 30 Days
Classification Name:	Intravascular catheter
Premarket Notification:	K162377
Product Code:	FOZ
Manufacturer:	Bard Access Systems, Inc.

IV. DEVICE DESCRIPTION

The Stiletto Extended Dwell Catheter (EDC) is a sterile, single use device designed to allow users to sample blood and/or administer fluids over a short duration (<28 days) through a peripherally inserted catheter. The Stiletto EDC utilizes an introducer needle and sheathing cannula to support advancement of a single lumen, power-injectable, catheter into peripheral vasculature. Unique catheter tip geometry is employed that works in conjunction with a sheathing cannula to provide support as the catheter advances into the vessel, providing a reliable method of insertion without need of a guidewire. The

catheter, hub and insertion components are integrated into a single housing to enhance ease of use.
The Stiletto EDC will be available in 8 cm and 10 cm lengths with a 20 gauge catheter, and 10 cm and 12 cm lengths with an 18 gauge catheter.

V. INDICATIONS FOR USE

The Stiletto Extended Dwell Catheter is inserted into a patient's vascular system for short-term use (<28 days) to sample blood or administer fluids intravenously. These catheters may be used for any patient population with consideration given to adequacy of vascular anatomy and appropriateness of the procedure. The Stiletto Extended Dwell Catheter is suitable for use with power injectors.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The following table provides a comparison of technological characteristics basis for a substantial equivalence determination utilizing the PowerGlide Pro™ Midline Catheter as the predicate device.

Attribute	Predicate Device	Subject Device	
Device Name	PowerGlide Pro™ Midline Catheter	Stiletto Extended Dwell Catheter	Substantially Equivalent or Identical to Predicate
Variants	• 18 Gauge Catheter • 20 Gauge Catheter • 22 Gauge Catheter	• 18 Gauge Catheter • 20 Gauge Catheter	Different

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Attribute	Predicate Device	Subject Device	
Device Name	PowerGlide Pro™ Midline Catheter	Stiletto Extended Dwell Catheter	Substantially Equivalent or Identical to Predicate
Indications for Use	The PowerGlide Pro™ Midline Catheter is intended to be inserted in the patient's vascular system for short term use (less than 30 days) to sample blood or administer fluids intravenously. These catheters may be used for any patient population with consideration given to adequacy of vascular anatomy and appropriateness of the procedure. The PowerGlide Pro™ Midline Catheter is suitable for use with power injectors.	The Stiletto Extended Dwell Catheter is inserted into a patient's vascular system for short-term use (<28 days) to sample blood or administer fluids intravenously. These catheters may be used for any patient population with consideration given to adequacy of vascular anatomy and appropriateness of the procedure. The Stiletto Extended Dwell Catheter is suitable for use with power injectors.	Different
Duration of Use	Short Term (less than 30 days)	Short Term (less than 28 days)	Different
Insertion Site	Peripheral	Peripheral	Identical
Insertion Method	Percutaneous, over a guidewire	Percutaneous, over a needle (utilizing a sheathing cannula)	Different
Specific Drug Use	None	None	Identical
Lumens	Single Lumen	Single Lumen	Identical

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Attribute	Predicate Device	Subject Device	
Device Name	PowerGlide Pro™ Midline Catheter	Stiletto Extended Dwell Catheter	Substantially Equivalent or Identical to Predicate
Catheter Dimensions	18 Gauge Catheter Length: 8 and 10 cm 20 Gauge Catheter Length: 8 and 10 cm 22 Gauge Catheter Length: 8 cm	18 Gauge Catheter Length: 10 and 12 cm 20 Gauge Catheter Length: 8 and 10 cm	Different
Needle Dimensions	18 Gauge Device Needle OD: 21 gauge 20 Gauge Device Needle OD: 22 gauge 22 Gauge Device Needle OD: 24 gauge	18 Gauge Device Needle OD: 22 gauge 20 Gauge Device Needle OD: 24 gauge	Different
Catheter Base / Needle Base Materials	Shaft tubing: Polyurethane Luer hub: Polyurethane Needle: Stainless Steel	Shaft tubing: Polyurethane Luer hub: Polyurethane Needle: Stainless Steel	Identical
Power Injection Maximum Flow Rate	18 Gauge Catheter: 7mL/sec 20 Gauge Catheter: 5mL/sec 22 Gauge Catheter: 2mL/sec	18 Gauge Catheter: 7mL/sec 20 Gauge Catheter: 5mL/sec	Different
Needle Bevel	B Bevel	B Bevel	Identical
Single-Use	Yes	Yes	Identical
Target Population	Any patient population with consideration given to adequacy of vascular anatomy and appropriateness of the procedure.	Any patient population with consideration given to adequacy of vascular anatomy and appropriateness of the procedure.	Identical

Attribute	Predicate Device	Subject Device	
Device Name	PowerGlide Pro™ Midline Catheter	Stiletto Extended Dwell Catheter	Substantially Equivalent or Identical to Predicate
Shelf Life	24 Months	60 Days: 20G -10cm 6 Months: 18G – 10cm 18G – 12cm 20G – 8cm	Different
Packaging	Device provided in a sterile pouch. Entire pouch is EO sterilized	Device provided in a sterile pouch. Entire pouch is EO sterilized	Identical
Sterilization	Provided Sterile (EO)	Provided Sterile (EO)	Identical
Biocompatibility	ISO 10993 Compliant	ISO 10993 Compliant	Identical

Discussion

- **Trade Name:** Both trade names are appropriate for identifying the subject and predicate devices. The trade names are therefore substantially equivalent.
- **Product Code, Duration of Use:** The PND Product Code is specific to midline catheters, which was determined by the Agency to be more appropriate for the subject device than the more general FOZ Product Code. The PND Product Code specifies short term use as <28 days, rather than <30 days for FOZ. Therefore, the duration of use for the subject device was adjusted accordingly. The slightly shorter patient contact time does not introduce any new risks to safety or efficacy for the subject device, as verified through biocompatibility testing per ISO 10993 series of applicable standards, and is therefore substantially equivalent to the predicate device.
- **Variants:** The subject device size variants are bracketed by the predicate device size variants. All device variants were thoroughly tested in their worst case configurations via benchtop, simulated use/human factors, and biocompatibility testing (See Section VII), and no new risks of safety or efficacy were identified. The subject device variants are therefore substantially equivalent to the predicate device variants.
- **Indications for Use:** The indications for use are identical with the exception of the duration of use. The slightly shorter patient contact time does not introduce

any new risks to safety or efficacy for the subject device, as discussed above. The subject device is therefore substantially equivalent to the predicate device.

- **Insertion Method:** The use of a sheathing cannula to insert the subject devices has been evaluated through both validation and verification testing. No new concerns of safety or efficacy were identified in either validation or verification testing. The subject device is therefore substantially equivalent to the predicate device.
- **Catheter Dimensions:** Outer diameters of 18G and 20G catheters were verified to be compliant with ISO 10555-5 and applicable color coding. With respect to other catheter dimensions, the subject device catheters underwent benchtop verification testing in their worst-case dimensional configurations (See Section VII for a comprehensive list) and were shown to comply with applicable performance criteria specified in ISO 10555-1 and ISO 10555-5. All pre-determined acceptance criteria were met, and the slight variations in dimensions introduced no new concerns of safety or efficacy. The subject device is therefore substantially equivalent to the predicate device.
- **Needle Dimensions:** The needle dimensions for the two subject device offerings are bracketed by the predicate device offerings. Furthermore, engineering evaluations, including FMEA, dimensional, benchtop, and simulated use/human factors testing, established that the needle dimensions of the subject device are adequate for the intended use of the device. Needles were inspected and verified to be compliant with needle requirements per ISO 10555-5 and applicable portions of ISO 9626 and ISO 7864, including criteria for needle point. The subject device needle dimensions are therefore substantially equivalent to the predicate device needle dimensions.
- **Power Injection Maximum Flow Rate:** The maximum flow rate for the two comparable device sizes between the subject device and predicate devices are identical. The subject device catheters were evaluated in compliance with ISO 10555-1 for power injection and maximum flow rates and comply with all associated criteria. The predicate device offers a smaller device outside of the subject device offerings which is not applicable for comparison. The subject device power injection maximum flow rates are therefore substantially equivalent to the comparable size offerings of the predicate device.
- **Shelf Life:** The subject device and predicate device are both verified through their respective labeled shelf lives without performance degradation by benchtop evaluations following shelf life conditioning. Testing following shelf life conditioning was performed on appropriate characteristics that have the potential to be affected by time and adequately assess the potential for performance degradation. Shelf life testing raised no new concerns of safety or efficacy for the subject device, and applicable acceptance criteria were met following conditioning. The subject device and predicate device are therefore substantially equivalent for their respective labeled shelf lives.

VII. PERFORMANCE DATA

Bench Testing

Bench tests are listed below in Table 2.

Standard	Test Name	Result
ISO 7864 ISO 9626 ISO 10555-1	Needle Surface and Sharpness	Passed
Internal Requirement	Dimensions – Needle Effective Length	Passed
ISO 10555-5	Catheter to Needle Bevel Heel Lie Distance	Passed
ISO 10555-1 ASTM F640	Radiopacity	Passed
Internal Requirement	Needle Cap Removal Force	Passed
ISO 10555-5	Flashback Detection	Passed

Standard	Test Name	Result
ANSI/AAMI HE75 ISO 23908	Assembly Force/Safety Activation Force	Passed
Internal Requirement	Insertion Tool Withdrawal Force	Passed
Internal Requirement	Catheter Kink Diameter	Passed
FDA Guidance Document	Dimensions – Catheter Effective Length	Passed
ISO 10555-5	Dimensions – Catheter OD	Passed
ISO 10555-1	Ink Permanence	Passed
ISO 10555-1	Leak	Passed
Internal Requirement	Pump Flow	Passed
Internal Requirement	Assembly Tensile – Cannula – PEEK to Stainless Steel	Passed
ISO 23908 ANSI/AAMI HE75	Needle Safety Override Force	Passed
ISO 7864	Assembly Tensile – Needle to Top Case	Passed
ISO 9626	Needle Tubing Stiffness	Passed
Internal Requirement	Assembly Tensile – Cannula – Stainless Steel to Thumb Slide	Passed
ISO 9626	Cannula Resistance to Breakage	Passed
ISO 9626	Needle Resistance to Breakage	Passed
ISO 10555-5	Needle Loosening	Passed
FDA Guidance Document	Priming Volume	Passed
Internal Requirement	Gravity Flow	Passed
Internal Requirement	Catheter Collapse	Passed
Internal Requirement	Dimensions – Catheter Outer Diameter (Optical Micrometer)	Passed
ISO 10555-1	Assembly Tensile – Catheter Shaft to Core Hub	Passed
ISO 10555-1	Catheter Shaft Tensile	Passed
ISO 10555-1	Catheter Burst	Passed
ISO 80369	Luer/Hub Evaluations Per ISO 80369	Passed

Clinical Testing

No Clinical Testing was performed.

Biocompatibility

Biological Effect	Mitigation Step	Result
Cytotoxicity	MEM Elution	Non-cytotoxic
Sensitization	Magnusson-Kligman Maximization	Non-sensitizer
Irritation	Intracutaneous Reactivity	Non-irritant
Systemic Toxicity (Acute)	Systemic Injection	Non-toxic

Biological Effect	Mitigation Step	Result
	Material Mediated Pyrogen	Non-pyrogenic
Hemocompatibility	Hemolysis (indirect)	Non-hemolytic
	Hemolysis (direct)	Non-hemolytic
	Partial Thromboplastin Time	Minimal Activator
	Complement Activation	Similar to Comparison Device
	Dog Thrombogenicity	Equivocal
Implantation	Rationalization for evaluation with previous testing on representative test sample (See M114-006)	Non-irritant
Acute/Subacute/Subchronic Toxicity	Assessed through chemical evaluation of leachates and a Toxicological Risk Assessment	MOS > 1 for all compounds and populations
Genotoxicity		
Chronic Toxicity		
Carcinogenicity		
Particulate Matter	Sizing and Counting Particulate Matter: Light Obscuration Method	Acceptable per USP <788> and Legally Marketed Comparative Device

VIII. CONCLUSION

Through performance bench testing results, it has been demonstrated that the subject device is substantially equivalent to the predicate device, PowerGlide Pro™ Midline Catheter (K162377)with respect to the intended use, target populations, treatment method, and technological characteristics. The identified differences between the devices do not raise any new questions of safety or effectiveness.