February 20, 2018

Access Vascular, Inc
Elizabeth Kinnal
Senior Regulatory Affairs Specialist and Quality Engineer
175 Middlesex Turnpike
Bedford, Massachusetts 01730

Re: K172885
Trade/Device Name: HydroPICC
Regulation Number: 21 CFR 880.5970
Regulation Name: Percutaneous, Implanted, Long-Term Intravascular Catheter
Regulatory Class: Class II
Product Code: LJS
Dated: January 10, 2018
Received: January 11, 2018

Dear Elizabeth Kinnal:

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.

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.

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,

Tina Kiang -S

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)*
K172885

Device Name
HydroPICC

Indications for Use *(Describe)*
HydroPICC is indicated for short- or long-term peripheral access to the central venous system for intravenous therapy, including but not limited to; the administration of fluids, medications, and nutrients; the sampling of blood; central venous pressure monitoring; and power injection of contrast.

HydroPICC is rated for a Maximum Power Injection Flow Rate of 3.5ml/sec.

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 for the HydroPICC PICC

Date prepared: 16 February, 2018

Submitter:

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Tel. 781-538-6594

Contact:

Elizabeth Kinnal
Access Vascular, Inc.
Tel. 978-618-7945

Subject Device

Trade Name:	HydroPICC
Common Name:	Intravascular Catheter
Regulation Number:	21CFR§880.5970
Regulation Name:	Intravascular Catheter
Regulatory Class:	Class II
Product Code:	LJS
Classification Panel:	General Hospital

Predicate Devices

Trade Name:	NMI PICC III, currently marketed as the BioFlo PICC
Manufacturer:	Navilyst Medical, Inc.
510(k) Reference:	K121089
Common Name:	Intravascular Catheter
Regulation Number:	21CFR§880.5970
Regulation Name:	Intravascular Catheter
Regulatory Class:	Class II
Product Code:	LJS
Classification Panel:	General Hospital

The predicate has not been subject to a design-related recall.

Trade Name:	Spectrum Silicone Peripherally Inserted Central Venous Catheter (PICC)
Manufacturer:	Cook Medical
510(k) Reference:	K021557
Common Name:	Intravascular Catheter
Regulation Number:	21CFR§880.5200
Regulation Name:	Intravascular Catheter
Regulatory Class:	Class II
Product Code:	LJS
Classification Panel:	General Hospital

The predicate has not been subject to a design-related recall.

Device Description

The HydroPICC is a peripherally inserted central catheter (PICC) intended for short or long-term use. The HydroPICC is a 4Fr, 55cm long catheter suitable for periodic access to the superior vena cava (SVC). HydroPICC has been shown to be effective in reducing thrombosis accumulation. Reduction of thrombosis accumulation was evaluated using *in vitro* and *in vivo* models. Preclinical *in vitro* and *in vivo* evaluations do not necessarily predict clinical performance with respect to thrombosis formation.. HydroPICC is supplied in a kit with the necessary accessories to insert and maintain the catheter. The following accessories are provided with the HydroPICC:

- Tear-away Introducer
- Introducer needle
- Guidewire
- Male Cap Plug
- 60cm. Paper Tape Measure
- Needle-Free Valve
- Luer Lock Syringe
- Adhesive Fixation Device - Bard StatLock (Venetec, K943147)
- Scalpel
- Transparent Film Dressing

Indications for Use

HydroPICC is indicated for short- or long-term peripheral access to the central venous system for intravenous therapy, including but not limited to; the administration of fluids, medications, and nutrients; the sampling of blood; central venous pressure monitoring; and power injection of contrast media.

HydroPICC is rated for a Maximum Power Injection Flow Rate of 3.5ml/sec.

The Indications for Use statement for the HydroPICC is identical to the predicate device (K121089).

Comparison of Technological Characteristics with the Predicate Device

The technological characteristics of the HydroPICC are substantially equivalent to the predicate, the Navilyst BioFlo (K121089) in terms of intended use, application, user population, basic design, performance, and labeling.

Briefly, both the subject and predicate device are,

- intended for short- or long-term peripheral access to the central venous system for intravenous therapy, including but not limited to, the administration of fluids, medications, nutrients; the sampling of blood; for central venous pressure monitoring and for power injection of contrast media.
- available in 4 French size
- rated for maximum power injection flow rate up to 3.5ml
- available kitted with a range of procedural accessories for user convenient; and
- demonstrates reduction of thrombosis accumulation using *in vitro* and *in vivo* models.

The only difference between the subject device and the K121089 predicate is the composition of the catheter body, however the results of biocompatibility and mechanical testing and evaluation of compatibility with sterilization, demonstrate the subject device raises no additional questions related to safety or effectiveness. In addition, the subject device and predicate device were tested concurrently in the Catheter Thrombus Accumulation Evaluation Using *in vitro* Blood Loop and Catheter Compatibility with Medications testing, and the results demonstrate that the proposed device is substantially equivalent to the predicate device with regard to catheter body performance.

Specification	**BioFlo PICC with ENDEXO Technology Angiodynamics K121089**	**Spectrum Silicone Catheter COOK K021557**	**HydroPICC Access Vascular PICC-141**	
Intended Use	Intended for short- or long-term peripheral access to the central venous system for intravenous therapy.	The COOK Spectrum@ Silicone Catheter is used for the intravenous administration of nutrient fluids, chemotherapeutic agents and other drugs for therapy, blood sampling,	Intended for short- or long-term peripheral access to the central venous system for intravenous therapy.	Same as K121089, Substantially equivalent to K01557. Difference does not raise additional safety or effectiveness questions.

Specification	BioFlo PICC with ENDEXO Technology Angiodynamics K121089	Spectrum Silicone Catheter COOK K021557	HydroPICC Access Vascular PICC-141	
		blood delivery, and venous pressure monitoring. The catheter is impregnated with the antimicrobials minocycline and rifampin to help provide protection against catheter related bloodstream infections (CRBSI). It is not intended to be used as a treatment for existing infections. Catheters are available in single and double lumen PICC; and single, double and triple lumen CVC. The device is supplied sterile and intended for one-time use.		
Indication for Use	BioFlo is indicated for short- or long-term peripheral access to the central venous system for intravenous therapy, including but not limited to; the administration of fluids, medications, and nutrients; the sampling of blood;	The COOK Spectrum@ Silicone Catheter is used for the intravenous administration of nutrient fluids, chemotherapeutic agents and other drugs for therapy, blood sampling, blood delivery, and venous pressure monitoring. The catheter is impregnated with the	HydroPICC is indicated for short- or long-term peripheral access to the central venous system for intravenous therapy, including but not limited to; the administration of fluids, medications, and nutrients; the sampling of blood; central venous pressure	Same as K121089, Substantially equivalent to K01557. Difference does not raise additional safety or effectiveness questions.

Specification	BioFlo PICC with ENDEXO Technology Angiodynamics K121089	Spectrum Silicone Catheter COOK K021557	HydroPICC Access Vascular PICC-141	
	central venous pressure monitoring; and power injection of contrast media.	antimicrobials minocycline and rifampin to help provide protection against catheter-related bloodstream infections (CRBSI). It is not intended to be used as a treatment for existing infections. Catheters are available in single and double lumen PICC; and single, double and triple lumen CVC.	monitoring; and power injection of contrast media.	
Device Class	Class II	Class II	Class II	Same
Product Code	LJS	LJS	LJS	Same
Regulation Number	880.5970	880.5970	880.5970	Same
Prescription Device	Yes	Yes	Yes	Same
Catheter Type	Peripherally Inserted Central Catheter (PICC)	Peripherally Inserted Central Catheter (PICC)	Peripherally Inserted Central Catheter (PICC)	Same
Catheter Outer Diameter	4 French	4 French	4 French	Same
Catheter Inner Diameter	0.90mm	0.66mm	0.90mm	Same as K121089 Substantially equivalent to K021557. Difference does not raise additional safety or effectiveness questions.
Usable Catheter Length	55cm	60cm	55cm	Same as K121089, Substantially equivalent to K021557. Difference does

Specification	BioFlo PICC with ENDEXO Technology Angiodynamics K121089	Spectrum Silicone Catheter COOK K021557	HydroPICC Access Vascular PICC-141	
				not raise additional safety or effectiveness questions.
Guidewire compatibility	0.018”	0.018”	0.018”	Same
Catheter Shaft Design	With taper	No taper	No taper	Same as K021557, Substantially equivalent to K121089. Blood loop testing with K121089 demonstrated no impact on safety or effectiveness.
Number of Catheter Lumens	Single	Single	Single	Same
Key Device Components	Catheter Shaft, Suture Wing, Extension Tube, Luer Hub	Catheter Shaft, Suture Wing, Extension Tube, Luer Hub	Catheter Shaft, Suture Wing, Extension Tube, Luer Hub	Same
Short or Long Term Access	Yes	Yes	Yes	Same
Use with Power Injection Power Settings Flow Rate	Yes Flow rate: 3.5mL/sec	No	Yes Flow rate: 3.5mL/sec	Same as K121089.
X-Ray Confirmation Required	Yes	Yes	Yes	Same
Sterilization Method	Ethylene Oxide	Ethylene Oxide	Ethylene Oxide	Same
Single Use	Yes	Yes	Yes	Same
Length Marking	Yes	No	No	Same as K021557, Substantially equivalent to K121089. Labeling for HydroPICC

Specification	BioFlo PICC with ENDEXO Technology Angiodynamics K121089	Spectrum Silicone Catheter COOK K021557	HydroPICC Access Vascular PICC-141	
				includes sizing information similar to K021557. Therefore, no impact on safety or effectiveness.
Catheter Materials	Radiopaque, polyurethane catheter with luer lock hub, polyurethane extension tube, and suture wing	Radiopaque silicone catheter with luer lock hub, with extension tube and suture wing	Radiopaque, hydrophilic polyol catheter with luer lock hub, polyurethane extension tube, and suture wing	Substantially equivalent. Testing described above demonstrated no impact on safety or effectiveness.
Ink	MD-1001 No-Tox Medical Device Ink, NT 16 Black w/ MD01210 Reducer	Not present	Not present	Same as K021557. Biocompatibility testing of the proposed device demonstrated no impact on safety or effectiveness.
How supplied	Convenience kit	Convenience kit	Convenience kit	Same

Performance Data

The following performance data were provided in support of the substantial equivalence determination:

Biocompatibility Testing

The biocompatibility evaluation of the HydroPICC was conducted in accordance with ISO 10993-1 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 battery of testing included the following tests:

- Cytotoxicity
- Intracutaneous reactivity
- Sensitization
- Intramuscular Implant
- Pyrogenicity
- Chemical Extractables
- *In vivo* thrombogenicity

Mechanical Testing

- Power Injection Flow Rate
- Static Burst Strength
- Lifecycle Power Injections
- Gravity Flow Rate
- Catheter Length
- Priming Volume
- Dimensional Verification (including ID, OD, Length)
- Catheter Kink/Flex Resistance (including Elongation, Stiffness, Flex Life Strength)
- Alcohol Compatibility
- Catheter Marking & Identification/Radio Detectability Testing
- Tensile Testing (of Catheter and Assembly)
- Catheter Compatibility with Medications
- Catheter Thrombus Accumulation Evaluation Using *in Vitro* Blood Loop
- Catheter Collapse Resistance
- Central Venous Pressure Monitoring
- Pyrogens testing (Limulus Amoebocyte Lysate and Material Mediated)

Sterilization

The HydroPICC Catheter is sterilized to a Sterility Assurance Level (SAL) of 10^{-6} via a validated overkill Ethylene Oxide (EO) method. This validated cycle meets the requirements of ISO 11135-1.

Conclusion

Based on the intended use, technological characteristics, and performance testing, the HydroPICC device meets the requirements that are considered sufficient for its intended use as compared to the predicate devices cited. Therefore, the subject device is substantially equivalent to the predicates.