February 20, 2020

Access Vascular, Inc
Brian Hanley
Sr. Director, Operations
175 Middlesex Turnpike
Suite 1A
Bedford, Massachusetts 01730

Re: K193015
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 17, 2020
Received: January 21, 2020

Dear Brian Hanley:

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 Geeta Pamidimukkala
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K193015

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 media.

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.

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

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K193015
510(k) Summary for the HydroPICC PICC

Date prepared: 18 February, 2020

Submitter:
Access Vascular, Inc.
175 Middlesex Turnpike
Suite 1A
Bedford, MA 01730
Tel. 781-538-6594

Contact:
Brian Hanley
Access Vascular, Inc.
Tel. 781-538-6594

Subject Device

Trade Name:	HydroPICC
Common Name:	Intravascular Catheter
Regulation Number:	21CFR§880.5970
Regulation Name:	Percutaneous, Implanted, Long-Term Intravascular Catheter
Regulatory Class:	Class II
Product Code:	LJS
Classification Panel:	General Hospital

Primary Predicate Device

Trade Name:	HydroPICC
Manufacturer:	Access Vascular
510(k) Reference:	K172885
Common Name:	Intravascular Catheter
Regulation Number:	21 CFR§880.5970
Regulation Name:	Percutaneous, Implanted, Long-Term Intravascular Catheter
Regulatory Class:	Class II
Product Code:	LJS
Classification Panel:	General Hospital

Device Description

The device description of HydroPICC-142 is the same as the predicate device, HydroPICC-141 (K172885).

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) while maintaining a reduced level of thrombus accumulation. HydroPICC is supplied in a kit with the necessary accessories to insert and maintain the catheter. The patient population for the proposed and predicate devices are identical, namely patients who require short- and long-term vascular access.

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
- 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-142 is identical to the predicate device, HydroPICC-141 (K172885).

Comparison of Technological Characteristics with the Predicate Device

The technological characteristics of the HydroPICC-142 are substantially equivalent to the predicate, the HydroPICC-141 (K172885), in terms of intended use, application, user population, basic design, performance, and labeling. The hydration aid, nominal catheter dimensions, and product packaging were modified in order to reduce the time it takes for the catheter to hydrate during procedural setup. A radiopaque additive was removed from the suture wing overmold. The labeling of the HydroPICC-142 was revised to indicate MRI Safety Information following the evaluation of the device.

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/sec
- available kitted with a range of procedural accessories for user convenient; and
- demonstrative of enhanced resistance to blood component (platelet and thrombus) accumulation

Table 1 Summary of Technological Characteristics of Proposed and Predicate Devices

Specification	HydroPICC-142 Access Vascular Proposed Device	HydroPICC-141 Access Vascular K172885
Intended Use	intended for short- or long-term peripheral access to the central venous system for intravenous therapy.	Same
Indication 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.	Same
Device Class	Class II	Same
Product Code	LJS	Same
Regulation Number	880.5970	Same
Prescription Device	Yes	Same
Catheter Type	Peripherally Inserted Central Catheter (PICC)	Same
Catheter Outer Diameter	4 French	Same
Catheter Inner Diameter	1mm	Substantially equivalent
Usable Catheter Length	55cm	Same
Guidewire compatibility	0.018”	Same
Catheter Shaft Design	No Taper	Same
Number of Catheter Lumens	Single	Same

Specification	HydroPICC-142 Access Vascular Proposed Device	HydroPICC-141 Access Vascular K172885
Key Device Components	Catheter Shaft, Suture Wing, Extension Tube, Luer Hub	Same
Short or Long Term Access	Yes	Same
Use with Power Injection Power Settings Flow Rate	Yes Flow rate: 3.5mL/sec	Same
Catheter Materials	Radiopaque hydrophilic polyol catheter with luer lock hub, polyurethane extension tub, and suture wing without radiopaque additive	Same - suture wing contained radiopaque additive
X-Ray Confirmation Required	Yes	Same
Sterilization Method	Ethylene Oxide	Same
Single Use	Yes	Same
How supplied	Convenience kit	Same
MRI Safety	Evaluated – labeled with MRI Safety Information	Not evaluated – labeled with contraindication to use in a MR environment

Performance Data

Verification and validation tests have been performed in accordance with Design Controls per 21 CFR §820.30. The subject devices met all predetermined acceptance criteria derived from the applicable guidance documents, standards and in-house protocols, which were used to determine appropriate methods for evaluating the performance of the device.

The following performance tests were performed in support of the substantial equivalence determination:

Mechanical and Performance Testing

The testing and test methods that were performed for HydroPICC-142 are substantially equivalent to testing and tests methods that were performed for the predicate, the HydroPICC-141 (K172885). Testing was conducted in accordance with the following FDA Guidance Document and international standards:

- FDA's "Guidance on Premarket Notification [510(k)] Submissions for Short-Term and Long-Term Intravenous Catheter"
- EN ISO 10555-1:2013 – "Intravascular Catheters – Sterile and Single-Use Catheters – Part 1: General Requirements"
- EN ISO 10555-3:2013 – "Intravascular Catheters – Sterile and Single-Use Catheters – Part 3 Central Venous Catheters:

- EN ISO 11135:2014 “Sterilization of Health-Care Products - Ethylene Oxide - Requirements for The Development, Validation and Routine Control Of A Sterilization Process For Medical Device”
- EN ISO 13868:2014 “Catheters – Test method for kinking of single lumen catheters and medical tubing”
- ASTM F2052:2015 “Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment”
- ASTM F2182: 2011 “Standard Test Method for Measurement of Radio Frequency Induced Heating on or Near Passive Implants During Magnetic Resonance Imaging”
- ASTM F2213: 2017 “Standard Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Resonance Environment”
- ASTM F2119: 2013 “Standard Test Method for Evaluation of MR Image Artifacts from Passive Implants”
- USP <788> Particulate Matter in Injections (Method 1)
- Evaluation of Humectant change on Thrombus accumulation compared to predicate (internal specifications)

The following tests were conducted in accordance with the standards identified above as applicable:

- Power Injection Flow Rate
- Static Burst Strength
- Multiple Power Injections
- Catheter Length
- Dimensional Verification (including ID, OD, Length)
- Catheter Kink/Flex Resistance
- Tensile Testing (of Catheter and Assembly)
- Particulate testing
- Shelf life testing
- Sterility testing
- Packaging distribution testing
- MR Compatibility testing

Biocompatibility Testing
Risk assessment evaluation that the proposed modifications did not impact biocompatibility

Conclusion
Based on the performance testing, intended use, materials, design, and components the HydroPICC-142 is determined to be substantially equivalent to the predicate HydroPICC-141 (K172885).