May 4, 2022

Access Vascular Inc
Brian Hanley
VP, R&D and Operation
749 Middlesex Turnpike
Billerica, Massachusetts 01820

Re: K213550
Trade/Device Name: HydroPICC 5F Dual Lumen Catheter
Regulation Number: 21 CFR 880.5970
Regulation Name: Percutaneous, Implanted, Long-Term Intravascular Catheter
Regulatory Class: Class II
Product Code: LJS
Dated: April 29, 2022
Received: May 2, 2022

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,

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)*
K213550

Device Name
HydroPICC 5F Dual Lumen Catheter

Indications for Use *(Describe)*
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.

Rated for maximum power injection flow rate of 3.5ml/s

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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K213550 510(k) Summary

Preparation Date: May 5, 2022

Submitter:
Access Vascular Inc.
749 Middlesex Turnpike
Billerica, MA 01820

Contact:
Brian M. Hanley
VP, R&D and Operations
Tel: 781.538.6594 x101

Subject Device

Trade Name:	HydroPICC 5F Dual Lumen Catheter
Manufacturer:	Access Vascular Inc.
Common Name:	Intravascular Catheter
Regulation:	21 CFR 880.5970
Regulation Name:	Percutaneous, Implanted, Long Term Intravascular Catheter
Regulatory Class:	II
Product Code:	LJS
Classification Panel:	General Hospital

Predicate Device:

510(k) Reference:	K193015
Trade Name:	HydroPICC-142 Catheter

Device Description

The HydroPICC peripherally inserted central catheter (PICC) is a 5 French, dual lumen catheter comprised of a radiopaque hydrophilic catheter material with a suture wing, Luer lock hubs, and extension tubes made from materials commonly used in the manufacture of catheters. Catheters are provided packaged in kit configurations with the appropriate accessories for placement in the appropriate clinical environments. The maximum power injection flow rate for each lumen is indicated on each extension tube clamp.

HydroPICC has been shown to be effective in reducing thrombus accumulation. Reduction of thrombus accumulation was evaluated using in vitro and in vivo models. Pre-clinical in vitro and in vivo evaluations do not necessarily predict clinical performance with respect to thrombus formation.

Indication for Use

Characteristics	**Predicate Device** **HydroPICC-142** **K193015**	**Subject Device** **HydroPICC-251** **K213550**
Indications for Use	Indicated for short- or long-term peripheral access to the central venous system for	Same

	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. Rated for a maximum power injection flow rate of 3.5ml/s	
Prescription Only or Over the counter	Prescription Only	Same

Discussions of differences in Indications for Use statement:
The indications for use statement for the subject device is identical to the predicate device. The HydroPICC 5F Dual Lumen Catheter is used for the same intended use in the same anatomical location using the same principles of operation as the predicate device. Therefore, the HydroPICC 5F Dual Lumen Catheter can be considered substantially equivalent to the predicate device.

Technological Characteristics

The following table shows a comparison of the technological characteristics between the HydroPICC 5F Dual Lumen Catheter and the cited predicate is sufficient detail to provide an understanding of the basis for determining substantial equivalence.

Technological Characteristics	Predicate Device HydroPICC-142 4F K193015	Subject Device HydroPICC-251 5F DL Catheter K213550	Comment
Device Classification	II	II	Same
Product Code	LJS	LJS	Same
Regulation	21 CFR 880.5970	21 CFR 880.5970	Same
Prescription Device	Yes	Yes	Same
Intended population	Adult	Adult	Same
Catheter Type	Peripherally Inserted Central Catheter (PICC)	Peripherally Inserted Central Catheter (PICC)	Same
Catheter Outer Diameter French Size	4 French (1.40mm) (Post Hydrated)	5 French (1.67 mm) (Post Hydrated)	Difference: see comment # 1
Catheter Outer Diameter as supplied	1.30 mm (Supplied dehydrated)	1.60 mm (Supplied dehydrated)	Difference - see comment # 1
Catheter Inner Diameter	1mm	D-shaped lumens each greater than or equal to 0.48mm^2	Difference – see comment # 2
Useable Length	55cm	Same	Same
Priming Volume	< 1.0mL	Same	Same
Guidewire Compatibility	Ø.018”	Ø.018”	Same
Catheter Shaft Design	Taper	Taper	Same
Number of Lumens	1	2	Difference – see comment # 2

Key Device Components	Catheter shaft, suture wing, extension tube, Luer hub	Catheter shaft, suture wing, extension tube, Luer hub	Same
Short- or Long-Term Access	Yes	Yes	Same
Use with Power Injection and Specified Flow Rate	Yes 3.5 ml/s	Yes 3.5 ml/s	Same
Static Burst Pressure	Average max pressure exceeds power injection pressure	Average max pressure exceeds power injection pressure	Same
Catheter Materials	Radiopaque hydrophilic polyol catheter with Luer lock hub, polyurethane extension tubing, and suture wing	Radiopaque hydrophilic polyol catheter with Luer lock hub, polyurethane extension tubing, and suture wing	Same
X-Ray Confirmation Required	Yes	Yes	Same
Sterilization Method	Ethylene Oxide	Ethylene Oxide	Same
Single Use	Yes	Yes	Same
MRI Safety	MRI Conditional	MRI Conditional	Same
How Supplied	Convenience Kit: Basic IR Kit Full Nursing Kit Maximal Barrier Kit	Convenience Kit: Basic IR Kit Full Nursing Kit Maximal Barrier Kit	Same

Discussions of differences in technological characteristics:

Comment #1 - French Size:

The subject device is 1 French size larger in diameter than the single lumen predicate device because a larger diameter was needed to accommodate the introduction of a second lumen. The subject device provides clinicians with the option of a second lumen for the same intended use as predicate device. The difference in French size between the subject device and predicate device are minor and do not raise any different questions of safety and effectiveness as determined through performance testing.

Comment #2 - Lumen Configuration:

The subject device is provided with two d-shaped lumens as compared to the single, round lumen of the predicate device because the subject device is a dual lumen catheter which requires a different lumen configuration and inner diameter to accommodate the second lumen. The difference in lumen configuration between the subject device and predicate device are minor and do not raise any different questions of safety and effectiveness as determined through performance testing.

Performance Testing

The sterile single lumen HydroPICC 5 F Dual lumen Catheter (PICC 251) described in this summary was tested and demonstrated to be in conformance with the following FDA recognized standards.

- 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 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"

Biocompatibility

The biocompatibility of the HydroPICC is both direct and indirect blood path. The catheter body (radiopaque hydrophilic polyol) is direct body contact for greater than 30days and Luer lock hub, polyurethane extension tubing, and suture wing are external body contacting for greater than 30 days. evaluation of the HydroPICC 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."

Sterility, Shipping, and Shelf-life

- 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 as determined through AAMI TIR28:2016 Product Adoption and Process Equivalence for Ethylene Oxide Sterilization
- Package integrity testing, after environmental conditioning and simulated transportation complies to ISTA 3A:2016 (Packaged Products for Parcel Delivery System Shipment 70kg (150 lb.) or Less) and ASTM D4169 to demonstrate protection of product and sterility maintenance.
- All labeling was evaluated according to ISO 15223-1:2016 (Symbols to be used with medical device labels, labelling, and information to be supplied - Part 1: General Requirements) and the subject device was determined to have the appropriate labeling.
- Sterile Barrier Packaging Testing complies to Seal strength ASTM F88/F88-15 and Detecting Gross Leaks ASTM F20965
- Shelf life 13 months is validated using the FDA recognized standard ASTM F1980-16 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices

Conclusion:

Upon reviewing the information provided in this submission and comparing the intended use, principle of operation and overall technological characteristics, the HydroPICC 5F Dual Lumen Catheter is substantially equivalent to the predicate device, the HydroPICC-142 4F Catheter cleared by K193015.