January 17, 2025

Access Vascular, Inc.
Brian Hanley
Chief Operating Officer
749 Middlesex Turnpike
Billerica, Massachusetts 01821

Re: K243941
Trade/Device Name: HydroPICC 4Fr Single Lumen Marked catheter, 130 cm guidewire - Basic Kit (70001201); HydroPICC 4Fr Single Lumen Marked catheter, 70 cm guidewire - Basic Kit (70001202); HydroPICC 4Fr Single Lumen Marked catheter, Maximal Barrier kit (70001204); HydroPICC 4Fr Single Lumen Marked catheter, Mobile Maximal Barrier Kit (90001204)
Regulation Number: 21 CFR 880.5970
Regulation Name: Percutaneous, Implanted, Long-Term Intravascular Catheter
Regulatory Class: Class II
Product Code: LJS
Dated: December 20, 2024
Received: December 20, 2024

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

David Wolloscheck, Ph.D.
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K243941

Device Name

HydroPICC 4Fr Single Lumen Marked catheter, 130 cm guidewire - Basic Kit (70001201);
HydroPICC 4Fr Single Lumen Marked catheter, 70 cm guidewire - Basic Kit (70001202);
HydroPICC 4Fr Single Lumen Marked catheter, Maximal Barrier kit (70001204);
HydroPICC 4Fr Single Lumen Marked catheter, Mobile Maximal Barrier Kit (90001204)

Indications for Use *(Describe)*

HydroPICC Single Lumen: 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 5.0ml/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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510(k) #:

510(k) Summary

Prepared on: 2025-01-14

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Access Vascular, Inc.
Applicant Address	749 Middlesex Turnpike Billerica MA 01821 United States
Applicant Contact Telephone	781.538.6594
Applicant Contact	Mr. Brian Hanley
Applicant Contact Email	bhanley@accessvascularinc.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	HydroPICC 4Fr Single Lumen Marked catheter, 130 cm guidewire - Basic Kit (70001201); HydroPICC 4Fr Single Lumen Marked catheter, 70 cm guidewire - Basic Kit (70001202); HydroPICC 4Fr Single Lumen Marked catheter - Maximal Barrier kit (70001204); HydroPICC 4Fr Single Lumen Marked catheter – Mobile Maximal Barrier Kit (90001204)
Common Name	Percutaneous, implanted, long-term intravascular catheter
Classification Name	Catheter, Intravascular, Therapeutic, Long-Term Greater Than 30 Days
Regulation Number	880.5970
Product Code(s)	LJS

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K193015	HydroPICC	LJS

Device Description Summary

21 CFR 807.92(a)(4)

The HydroPICC 4F Single Lumen Catheter is comprised of a radiopaque hydrophilic catheter material with a suture wing, Luer lock hub, and extension tubing 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 respective clinical environments. The maximum power injection flow rate for the lumen is indicated on the extension tube clamp. HydroPICC has been shown to be effective in reducing thrombus accumulation and thrombotic occlusions. Reduction of thrombus accumulation and thrombotic occlusions were 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.

The purpose of this 510(k) is to modify the power injection ratings in the indications for use.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

HydroPICC Single Lumen: 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 5.0ml/s

Indications for Use Comparison

21 CFR 807.92(a)(5)

Rationale Supporting 21 CFR 807.92(a)(5) for a Change in Indications for Use
1. Technological Characteristics and Performance Data: The proposed device has the same technological characteristics as the predicate devices. In vitro data demonstrates that the devices will perform as intended with the modified power injection rating.
2. Safety and Effectiveness The proposed device has been shown to be safe and effective for its intended use.
3. Comparison with Predicate Devices The predicate device, HydroPICC (K193015) is indicated for similar uses, including short-term and long-term peripheral access to the venous system for intravenous therapy, administration of fluids, medications, and nutrients, and the sampling of blood.
4. Intended Use and Indications The intended use of the proposed devices aligns with that of the predicate device. The proposed indications for use are consistent with the current clinical practices and address the same patient population and clinical needs as the predicate devices. The only modification is to the power injection rating.
5. Regulatory Compliance The proposed changes comply with the requirements of 21 CFR 807.92(a)(5), which necessitates a comparison of the new device with a legally marketed predicate device to demonstrate that the new device is as safe and effective as the predicate device. The data provided support that the proposed devices meet these criteria.
Conclusion The proposed HydroPICC 4Fr Single Lumen Catheter provide for an increase to the power injection ratings, supported by data, justify the change in indications for use and demonstrate that the proposed devices are as safe and effective as the predicate devices.

Technological Comparison

21 CFR 807.92(a)(6)

The proposed device, HydroPICC 4F Single Lumen Catheter subject to this submission, has the same technological characteristics as the predicate device identified above. These characteristics include design, material, chemical composition, and principle of operation.

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

This 510(k) submission provides comprehensive data demonstrating the safety and efficacy of the HydroPICC 4F Single Lumen Catheter. Rigorous testing protocols were employed to evaluate these devices' performance under various conditions, ensuring they meet all applicable regulatory standards. The submission includes a summary of in vitro which substantiate the devices' intended use and their ability to perform as claimed. Additionally, the form, fit, and function of these devices have not changed from their previous clearances. The data presented herein supports the conclusion that the HydroPICC 4F Single Lumen Catheter is substantially equivalent to the predicate device(s) in terms of safety and effectiveness.

Upon reviewing the information provided in this submission and comparing the intended use, principle of operation and overall technological characteristics, the HydroPICC 4F Single Lumen Catheter with the modified power injection rating is substantially equivalent to existing legally marketed devices.