July 1, 2025

Access Vascular, Inc.
Scott Blood
Vice President, Quality & Regulatory
749 Middlesex Turnpike
Billerica, Massachusetts 01821

Re: K251212
Trade/Device Name: Dual Lumen 5Fr HydroPICC Catheter (PICC-251CM) (PICC-251CM); Dual Lumen 5Fr HydroPICC Catheter (PICC-252CM) (PICC-252CM)
Regulation Number: 21 CFR 880.5970
Regulation Name: Percutaneous, Implanted, Long-Term Intravascular Catheter
Regulatory Class: Class II
Product Code: LJS
Dated: June 2, 2025
Received: June 2, 2025

Dear Scott Blood:

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,

PORSCHE P. BENNETT -S

Porsche Bennett
For 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.

510(k) Number *(if known)*
K251212

Device Name
Dual Lumen 5Fr HydroPICC Catheter (PICC-251CM) (PICC-251CM);
Dual Lumen 5Fr HydroPICC Catheter (PICC-252CM) (PICC-252CM)

Indications for Use *(Describe)*
Dual Lumen 5Fr HydroPICC Catheter (PICC-251CM): 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 4.0ml/s.

Dual Lumen 5Fr HydroPICC Catheter (PICC-252CM): 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.

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510(k) #: K251212

510(k) Summary

Prepared on: 2025-05-20

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	(978) 729.5978
Applicant Contact	Mr. Scott Blood
Applicant Contact Email	sblood@accessvascularinc.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Dual Lumen 5Fr HydroPICC Catheter (PICC-251CM) (PICC-251CM); Dual Lumen 5Fr HydroPICC Catheter (PICC-252CM) (PICC-252CM)
Common Name	Catheter, intravascular, therapeutic, long-term greater than 30 days
Classification Name	Percutaneous, implanted, long-term intravascular catheter.
Regulation Number	880.5970
Product Code(s)	LJS, N/A

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K213550	Dual Lumen 5Fr HydroPICC Catheter	LJS

Device Description Summary

21 CFR 807.92(a)(4)

The HydroPICC catheters are a family of peripherally inserted central catheters (PICC) made of radiopaque hydrophilic material with a suture wing, Luer lock hub, and extension tubing made from materials commonly used in catheter manufacturing. The catheters are provided in kit configurations with the necessary accessories for placement in 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. These reductions were evaluated using in vitro and in vivo models. Pre-clinical evaluations do not necessarily predict clinical performance with respect to thrombus formation. HydroPICC 5F Dual Lumen Catheter Components include: HydroPICC 5Fr Dual Lumen Catheter Assembly, Dispensing Tube, 2 Channel Clip, and Guidewire Introducer and Straightener.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

Dual Lumen 5Fr HydroPICC Catheter (PICC-251CM): 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 4.0ml/s.

Dual Lumen 5Fr HydroPICC Catheter (PICC-252CM): 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)

The indications for use for the proposed and predicate devices is primarily the same. The only difference in indications for use is the

power injection rating, specifically:
• Dual Lumen 5Fr HydroPICC Catheter (PICC-251CM): modify the indicated power injection flow rate from 3.5 mL/s to 4.0 mL/s.
• Dual Lumen 5Fr HydroPICC Catheter (PICC-252CM): modify the indicated power injection flow rate from 3.5 mL/s to 5.0 mL/s, modify the length from 55cm to 45cm
The change of the power injection rating does not introduce no new or different questions of safety and effectiveness, and testing has demonstrated that the proposed device will perform as intended.

Technological Comparison

21 CFR 807.92(a)(6)

This 510(k) is being submitted for a change to the indications for use for the Access Vascular Dual Lumen 5Fr HydroPICC Catheter (PICC-251CM) to modify the power injection rating and to add an additional model of the 5F HydroPICC Catheter (PICC-252CM) to decrease the length to 45cm and modify the power injection rating. The submission includes in vitro data demonstrating acceptable performance of the devices with the modified power injection rating and device length. The specific modifications are:
• Dual Lumen 5Fr HydroPICC Catheter (PICC-251CM): modify the indicated power injection flow rate from 3.5 mL/s to 4.0 mL/s.
• Dual Lumen 5Fr HydroPICC Catheter (PICC-252CM): modify the indicated power injection flow rate from 3.5 mL/s to 5.0 mL/s, modify the length from 55cm to 45cm
The Dual Lumen 5Fr HydroPICC Catheter (PICC-251CM), shares the same technological characteristics as the predicate devices identified. These characteristics include design, material, chemical composition, and principle of operation. We confirm that there have been no changes in the design, materials, form, fit, or function of the devices compared to the predicate devices identified in the submission. The devices maintain the same specifications, performance characteristics, and intended use as the predicate device.
The Dual Lumen 5F HydroPICC Catheter (PICC-252CM) shares the same general technological characteristics as the predicate device identified. The only change is the length of the catheter, from 55cm of the predicate to 45cm for the proposed HydroPICC PICC-252CM. There are no changes to the material, chemical composition, principle of operation, and intended use.

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

Power injection Cyclical and Static Burst testing as well as dimensional verification testing were performed to demonstrate that the modifications to the power injection rating and the length do not adversely impact product performance.