March 27, 2025

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

Re: K244059
Trade/Device Name: HydroMID 5F Dual Lumen Midline Catheter - Basic Kit (70006102); HydroMID 5F Dual Lumen Midline Catheter - Max Barrier Kit (70006104); HydroMID 5F Dual Lumen Midline Catheter - Mobile Max Barrier Kit (90006104)
Regulation Number: 21 CFR 880.5200
Regulation Name: Intravascular Catheter
Regulatory Class: Class II
Product Code: FOZ
Dated: February 27, 2025
Received: February 27, 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 Bennett

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)*
K244059

Device Name
HydroMID 5F Dual Lumen Midline Catheter - Basic Kit (70006102);
HydroMID 5F Dual Lumen Midline Catheter - Max Barrier Kit (70006104);
HydroMID 5F Dual Lumen Midline Catheter - Mobile Max Barrier Kit (90006104)

Indications for Use *(Describe)*
The HydroMID 5F Dual Lumen Midline Catheter is indicated for short term access (< 30 days) to the peripheral venous access system for intravenous therapy, including but not limited to, the administration of fluids, medications, and the sampling of blood and blood products.

Rated for maximum power injection flow rate of 6ml/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.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

# K244059 510(k) Summary

This 510(k) Summary of Safety and Effectiveness information is prepared in accordance with the requirements of 21 CFR Part 807.92.

**Submitter Information**


| | |
|---|---|
| 510(k) Sponsor | Access Vascular Inc. |
| Address | 749 Middlesex Turnpike Billerica MA 01821 |
| Contact Person(s) | Mr. Scott Blood; Vice President, Quality & Regulatory |
| Phone: | 978.729.5978 |
| Email: | sblood@accessvascularinc.com |
| Date Prepared: | February 28, 2025 |


**Proposed Device(s)**

| | |
|---|---|
| Common/Usual Name: | Intravascular Catheter |
| Trade/Proprietary Name: | HydroMID 5F Dual Lumen Midline Catheter - Basic Kit (70006102);<br>HydroMID 5F Dual Lumen Midline Catheter - Max Barrier Kit (70006104);<br>HydroMID 5F Dual Lumen Midline Catheter - Mobile Max Barrier Kit (90006104) |
| Classification Name: | Catheter, Intravascular, Therapeutic, Short-Term Less Than 30 Days |
| Device Classification: | 880.5200 |
| Product Code: | FOZ |
| Class: | II |
| Device Panel: | General Hospital |

**Predicate Device(s)**

The predicate device is the HydroMID Product Family of Midline Catheters, which was previously cleared under premarket application K220772.

**Reference Device(s)**

The reference device is the HydroPICC-251 5F Dual Lumen, which was previously cleared under premarket application K213550.

**Device Description**

The HydroMID catheter is a 5 French, dual lumen, midline catheter comprised of a radiopaque, hydrophilic catheter 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.

HydroMID 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.

Catheter and accessories are supplied sterile. Product is sterilized by ethylene oxide (EO) except where labeled otherwise. Product should be stored in a cool, dry, dark place. The HydroMID Catheter is supplied in a dry state and must be hydrated before use.

**Indications for Use**

The HydroMID 5F Dual Lumen Midline Catheter is indicated for short term access (< 30 days) to the peripheral venous access system for intravenous therapy, including but not limited to, the administration of fluids, medications, and the sampling of blood and blood products.

Rated for maximum power injection flow rate of 6ml/s.

**Substantial Equivalence Discussion**

The following table is a matrix of the intended use and technological characteristics between the subject device and the predicate device. The table also discusses why these differences do not introduce new or different questions of safety and effectiveness.

| **Specification** | **HydroMID 5F Dual Lumen Midline Catheter Proposed Device (K244059)** | **HydroMID 4F Single Lumen Medline Catheter (K220772) Predicate Device** | **Same / Different between Proposed and Predicate?** |
|---|---|---|---|
| Intended Use | Intended for short- or long-term peripheral access to the central venous system for intravenous therapy | Same | Same |
| Indications for Use | The HydroMID 5F Dual Lumen Midline Catheter is indicated | Same | Same |

| Specification | HydroMID 5F Dual Lumen Midline Catheter Proposed Device (K244059) | HydroMID Product Family of Midline Catheters (K220772) Primary Predicate Device | Same / Different between Proposed and Predicate? |
|---|---|---|---|
| | for short term access (< 30 days) to the peripheral venous access system for intravenous therapy, including but not limited to, the administration of fluids, medications, and the sampling of blood and blood products.<br><br>Rated for maximum power injection flow rate of 6ml/s. | | |
| Device Classification | II | Same | Same |
| Product Code | FOZ | Same | Same |
| Regulation | 21 CFR 880.5200 | Same | Same |
| Prescription Device | Yes | Same | Same |
| Intended population | Adult and pediatric | Same | Same |
| Catheter Type | Midline Catheter (MID) | Same | Same |
| Catheter Outer Diameter French Size | 5 French (1.67mm Post Hydrated) | 4 French (1.40mm Post Hydrated) | Different |
| Catheter Outer Diameter as supplied | 5 French (1.60mm Supplied Dry) | 4 French (1.30 mm Supplied Dry) | Different |
| Catheter Inner Diameter | D-shaped lumens each greater than or equal to 0.48mm2 | 1mm | Different |
| Useable Length | 20cm | Same | Same |
| Priming Volume | < 1.0mL | Same | Same |
| Guidewire Compatibility | Ø.018" | Same | Same |
| Catheter Shaft Design | Taper | Same | Same |
| Number of Lumens | 2 | 1 | Different |
| Clamp ID Tag | 2 | 1 | Different |
| Key Device Components | Catheter shaft, suture wing, extension tube, Luer hub | Same | Same |
| Access | Short Term | Same | Same |
| Use with Power Injection and Specified Flow Rate | Yes<br>6ml/s | Same | Same |

| Specification | HydroMID 5F Dual Lumen Midline Catheter Proposed Device (K244059) | HydroMID Product Family of Midline Catheters (K220772) Primary Predicate Device | Same / Different between Proposed and Predicate? |
|---|---|---|---|
| Catheter Materials | Radiopaque hydrophilic polyol catheter with Luer lock hub, polyurethane extension tubing, and suture wing. | Same | Same |
| X-Ray Confirmation Required | Yes | Same | Same |
| Sterilization Method | Ethylene Oxide | Same | Same |
| Single Use | Yes | Same | Same |
| MRI Safety | MRI Conditional | Same | Same |
| How Supplied | Convenience Kit:<br>Basic IR Kit<br>Full Nursing Kit<br>Maximal Barrier Kit | Same | Same |
| Catheter Markings | Markings (every cm) | Same | Same |

**Discussion of Similarities and Differences**

**Similarities**

*Intended Use* – There is no change to the intended use of the proposed and predicate HydroMID Product Family of Midline Catheters (K220772) devices. The intended use remains identical to the previously cleared predicate device.

*Indications for Use* - There is no change to the Indications for Use of the proposed and predicate HydroMID Product Family of Midline Catheters (K220772) devices. The Indications for Use remains identical to the previously cleared predicate device.

*Classification* – There is no change to the classification of the proposed and predicate HydroMID Product Family of Midline Catheters (K220772) devices. The classification remains identical to the previously cleared predicate device.

A*ccessories* – There is no change to the accessories provided with the proposed and predicate HydroMID Product Family of Midline Catheters (K220772) devices. The accessories remain identical to the previously cleared predicate device.

*Design* – While most of the design features of the predicate device are the same with the proposed devices, there are minor changes to the design of the proposed device with respect to the previously-cleared HydroMID Product Family of Midline Catheters (K220772). Any design differences are explained below.

*Materials* – There is no change to the materials of the proposed and predicate HydroMID Product Family of Midline Catheters (K220772) devices. The materials remain identical to the previously cleared predicate device.

*Sterility* – There is no change to the sterilization or sterility of the proposed and predicate HydroMID Product Family of Midline Catheters (K220772) devices. The sterilization and sterility remain identical to the previously cleared predicate device.

*Principles of Operation* – There is no change to the principles of the proposed and predicate HydroMID Product Family of Midline Catheters (K220772) devices. The principles of operation remain identical to the previously cleared predicate device.

**Differences**

*Power Injection Rating* - The reference device indicates a power injection rating of 3.5 mL/s, while the subject device specifies 6.0 mL/s. Performance testing at T=0 and over the shelf life demonstrates the difference does not raise new or different questions of safety or effectiveness by this modification.

*Design* - There are changes to the design of the proposed device with respect to the predicate HydroMID Product Family of Midline Catheters (K220772) devices. Those changes are:

- Change from 4 French outside diameter to 5 French outside diameter
- Add second lumen, requiring a second Clamp ID Tag and luer fitting.
- Change lumen cross-section from circular 1mm diameter to "D"-shaped of similar cross-sectional area

The design changes from a 4Fr to a 5Fr catheter OD, an additional lumen and a different cross-sectional shape from circular to "D"-shape do not raise new questions of safety and effectiveness. The power injection rating, which was tested as part of the verification of the product design. The French size is equivalent to the reference device. The addition of a second lumen is identical to that of the reference device. The need for a second Clamp ID Tag and luer fitting is identical to the reference device, which also includes a second lumen. No luer connection testing was required with the addition of this second luer fitting, as the second luer fitting is identical to the one used on the reference device, which was cleared per K213550. Both luminal area values are close in dimension and are therefore substantially equivalent. The lumen cross-section is identical to that on the reference device.
The reference device was used to leverage the specification and methods to demonstrate the differences in technological characteristics between the subject and predicate devices do not raise new or different questions of safety and effectiveness..

**Bench Data**

The following tests were conducted to show substantial equivalence to the predicate device:

- Power injection flow rate
- Static burst strength
- Catheter length
- Dimensional verification
- Catheter kink/ resistance

- Tensile (tubing and joint)
- Particulate
- Packaging distribution
- Sterility
- MR compatibility
- Shelf-life

Testing was identical to the predicate in standard conformance, sample size, methods, and acceptance criteria.

All testing was completed with final, finished devices that represent commercial product. All tests passed the acceptance criteria specified for both the subject and predicate devices. The results of the testing show that the subject device is substantially equivalent to the predicate device.

**Conclusion**

The differences in technological characteristics do not raise new or different questions of safety and effectiveness. There is no change to the intended use of the subject device compared to the predicate device. This 510(k) proposes a modification to the power injection rating specification similar to that of the reference device (HydroPICC- 251 5Fr Dual Lumen  K213550). Performance data provided in this submission demonstrates that the modification of the power injection rating is supported, and the subject and predicate devices can be considered substantially equivalent.