August 1, 2025

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

Re: K243458

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 5Fr Dual Lumen Marked catheter, 130 cm guidewire - Basic Kit (70002201); HydroPICC 5Fr Dual Lumen Marked catheter, 70 cm guidewire - Basic Kit (70002202); HydroPICC 5Fr Dual Lumen Marked catheter - Maximal Barrier kit (70002204); HydroMID 4Fr Single Lumen Marked catheter - Basic kit (70004302); HydroMID 4Fr Single Lumen Marked catheter - Maximal Barrier Kit (70004304); HydroPICC 4Fr Single Lumen Marked catheter - Mobile Maximal Barrier Kit (90001304); HydroPICC 5Fr Dual Lumen Marked catheter - Mobile Maximal Barrier Kit (90002304); HydroMID 4Fr
Regulation Number: 21 CFR 880.5970
Regulation Name: Percutaneous, implanted, long-term intravascular catheter.
Regulatory Class: Class II
Product Code: LJS, FOZ
Dated: July 3, 2025
Received: July 3, 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,

David Wolloscheck -S

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)*

K243458

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 5Fr Dual Lumen Marked catheter, 130 cm guidewire - Basic Kit (70002201);
HydroPICC 5Fr Dual Lumen Marked catheter, 70 cm guidewire - Basic Kit (70002202);
HydroPICC 5Fr Dual Lumen Marked catheter - Maximal Barrier kit (70002204);
HydroMID 4Fr Single Lumen Marked catheter - Basic kit (70004302);
HydroMID 4Fr Single Lumen Marked catheter - Maximal Barrier Kit (70004304);
HydroPICC 4Fr Single Lumen Marked catheter - Mobile Maximal Barrier Kit (90001304);
HydroPICC 5Fr Dual Lumen Marked catheter - Mobile Maximal Barrier Kit (90002304);
HydroMID 4Fr Single Lumen Marked catheter - Mobile Maximal Barrier Kit (90004304)

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 5.0 mL/s

HydroPICC Dual 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 a maximum power injection flow rate of 5.0 mL/s

HydroMID Single Lumen: 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. Maximum Power Injection Flow Rate: 4Fr Single Lumen, 20cm: 6 mL/sec

The Hydro Catheter lines incorporate MIMIX® Technology, an anti-thrombogenic bulk hydrogel material, designed to minimize the risk of thrombus formation on device surfaces. In vitro studies have demonstrated that both the external surfaces and internal fluid pathways of the catheter effectively reduce thrombus accumulation and thrombotic occlusions. This reduction in thrombus accumulation is achieved due to the catheter's steric barrier. The clinical impact has not been evaluated in human clinical trials. This device is not intended for the treatment of existing vein thrombosis.

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) Summary
K243458

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:	July 31, 2025

Proposed Device(s)

Common/Usual Name:	Intravascular Catheter
Trade/Proprietary 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 5Fr Dual Lumen Marked catheter, 130 cm guidewire - Basic Kit (70002201);
	HydroPICC 5Fr Dual Lumen Marked catheter, 70 cm guidewire - Basic Kit (70002202);
	HydroPICC 5Fr Dual Lumen Marked catheter - Maximal Barrier kit (70002204);
	HydroMID 4Fr Single Lumen Marked catheter - Basic kit (70004302);
	HydroMID 4Fr Single Lumen Marked catheter - Maximal Barrier Kit (70004304);
	HydroPICC 4Fr Single Lumen Marked catheter– Mobile Maximal Barrier Kit (90001304);
	HydroPICC 5Fr Dual Lumen Marked catheter– Mobile Maximal Barrier Kit

	(90002304); HydroMID 4Fr Single Lumen Marked catheter– Mobile Maximal Barrier Kit (90004304)
Classification Name:	Catheter, Intravascular, Therapeutic, Long-Term Greater Than 30 Days
Device Classification:	880.5970, 880.5200
Product Code:	LJS, FOZ
Class:	II
Device Panel:	General Hospital

Predicate Device(s)

The predicate devices are the HydroPICC (K193015), HydroPICC-251 Dual Lumen (K213550), and HydroMID Catheters (K220772).

Device Description

The HydroMID catheters are a family of midline catheters 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. The maximum power injection flow rate for the lumen is indicated on the extension tube clamp. HydroMID has been shown to be effective in reducing thrombus accumulation and thrombotic occlusions. Reduction of thrombus accumulation and thrombotic occlusions were evaluated using an in vitro model. Pre-clinical in vitro evaluations do not necessarily predict clinical performance with respect to thrombus formation.

The HydroPICC catheters are a family of peripherally inserted central catheter (PICC) 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 an in vitro model. Pre-clinical in vitro evaluations do not necessarily predict clinical performance with respect to thrombus formation.

The purpose of this 510(k) is to add an additional statement to the indications for use.

Indications for Use

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 5.0 mL/s

HydroPICC Dual 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 a maximum power injection flow rate of 5.0 mL/s

HydroMID Single Lumen: 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. Maximum Power Injection Flow Rate: 4Fr Single Lumen, 20cm: 6 mL/sec

The Hydro Catheter lines incorporate MIMIX® Technology, an anti-thrombogenic bulk hydrogel material, designed to minimize the risk of thrombus formation on device surfaces. In vitro studies have demonstrated that both the external surfaces and internal fluid pathways of the catheter effectively reduce thrombus accumulation and thrombotic occlusions. This reduction in thrombus accumulation is achieved due to the catheter's steric barrier. The clinical impact has not been evaluated in human clinical trials. This device is not intended for the treatment of existing vein thrombosis.

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	***HydroPICC Single Lumen Catheter (K243458)*** **Subject device**	**HydroPICC Single Lumen (K193015) Access Vascular Inc. Primary 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	intended for short- or long-term peripheral access to the central venous system for intravenous therapy	Same
Indications for Use	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 The following language is proposed to be added to the current indications for use for the HydroPICC Single-Lumen Catheter. There is no	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 5.0 mL/s	Substantially equivalent.

Specification	*HydroPICC Single Lumen Catheter (K243458)* **Subject device**	**HydroPICC Single Lumen (K193015) Access Vascular Inc. Primary Predicate Device**	**Same / Different between Proposed and Predicate?**
	change to the remainder of the indications for use for the device: The Hydro catheter lines incorporate MIMIX® Technology, an anti-thrombogenic bulk hydrogel material, designed to minimize the risk of thrombus formation on the device surfaces. In vitro studies have demonstrated that both the external surfaces and internal fluid pathways of the catheter effectively reduce thrombus accumulation and thrombotic occlusions. This reduction in thrombus accumulation is achieved due to the catheter's steric barrier. The clinical impact has not been evaluated in human clinical trials. This device is not intended for the treatment of existing vein thrombosis.		
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)	4 French (1.40mm) (Post Hydrated)	Same
Catheter Outer Diameter as supplied	1.30 mm (Supplied dehydrated)	1.30 mm (Supplied dehydrated)	Same
Catheter Inner Diameter	1mm	1mm	Same
Useable Length	55cm	55cm	Same
Priming Volume	< 1.0mL	< 1.0mL	Same
Guidewire Compatibility	Ø.018"	Ø.018"	Same

Specification	*HydroPICC Single Lumen Catheter (K243458)* **Subject device**	**HydroPICC Single Lumen (K193015) Access Vascular Inc. Primary Predicate Device**	**Same / Different between Proposed and Predicate?**
Catheter Shaft Design	Taper	Taper	Same
Number of Lumens	1	1	Same
Key Device Components	Catheter shaft, suture wing, extension tube, Luer hub	Catheter shaft, suture wing, extension tube, Luer hub	Same
Implant Time	Short- or Long-term	Short- or Long-term	Same
Use with Power Injection and Specified Flow Rate	Yes 5.0 mL/s	Yes 5.0 mL/s	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
Catheter Markings	Markings (every cm)	Markings (every cm)	Same

Specification	***Hydro PICC Dual Lumen (K243458)* Subject device**	**HydroPICC-251 5F DL Catheter (K213550) Access Vascular Inc. Primary 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 HydroMID: Intended for short-term access to the peripheral venous system	intended for short- or long-term peripheral access to the central venous system for intravenous therapy HydroMID: Intended for short-term access to the peripheral venous system	Same
Indications for Use	Indicated for short- or long term peripheral access to the central venous system for	Indicated for short- or long term peripheral access to the central venous	Substantially equivalent.

Specification	*Hydro PICC Dual Lumen (K243458)* Subject device	HydroPICC-251 5F DL Catheter (K213550) Access Vascular Inc. Primary Predicate Device	Same / Different between Proposed and Predicate?
	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 6.0mL/s The following language is proposed to be added to the current indications for use for the HydroPICC Single-Lumen Catheter. There is no change to the remainder of the indications for use for the device: The Hydro catheter lines incorporate MIMIX® Technology, an anti-thrombogenic bulk hydrogel material, designed to minimize the risk of thrombus formation on the device surfaces. In vitro studies have demonstrated that both the external surfaces and internal fluid pathways of the catheter effectively reduce thrombus accumulation and thrombotic occlusions. This reduction in thrombus accumulation is achieved due to the catheter's steric barrier. The clinical impact has not been evaluated in human clinical trials. This device is not intended for the treatment of existing vein thrombosis.	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 a maximum power injection flow rate of 6.0mL/s	
Device Classification	Same	II	Same
Product Code	Same	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	5 French (1.67mm) (Post Hydrated)	5 French (1.67mm) (Post Hydrated)	Same
Catheter Outer Diameter as supplied	1.60 mm (Supplied dehydrated)	1.60 mm (Supplied dehydrated)	Same
Catheter Inner Diameter	1mm	1mm	Same
Useable Length	55cm	55cm	Same

Specification	*Hydro PICC Dual Lumen* *(K243458)* **Subject device**	**HydroPICC-251 5F DL Catheter (K213550) Access Vascular Inc. Primary Predicate Device**	**Same / Different between Proposed and Predicate?**
Priming Volume	< 1.0mL per lumen	< 1.0mL per lumen	Same
Guidewire Compatibility	Ø.018"	Ø.018"	Same
Catheter Shaft Design	Taper	Taper	Same
Number of Lumens	2	2	Same
Key Device Components	Catheter shaft, suture wing, extension tube, Luer hub	Catheter shaft, suture wing, extension tube, Luer hub	Same
Implant Time	Short- or Long-term	Short- or Long-term	Same
Use with Power Injection and Specified Flow Rate	Yes 6.0 mL/s	Yes 6.0 mL/s	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
Catheter Markings	Markings (every cm)	Markings (every cm)	Same

Specification	*HydroMID* **Single Lumen** *(K243458)* **Subject device**	**HydroMID (K220772) Access Vascular Inc. Primary Predicate Device**	**Same / Different between Proposed and Predicate?**
Intended Use	Intended for short-term access to the peripheral venous system	Intended for short-term access to the peripheral venous system	Same

Specification	*HydroMID* Single Lumen *(K243458)* Subject device	HydroMID (K220772) Access Vascular Inc. Primary Predicate Device	Same / Different between Proposed and Predicate?
Indications for Use	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. Maximum Power Injection Flow Rate: 4Fr Single Lumen, 20cm: 6 mL/sec The following language is proposed to be added to the current indications for use for the HydroPICC Single-Lumen Catheter. There is no change to the remainder of the indications for use for the device: The Hydro catheter lines incorporate MIMIX® Technology, an anti-thrombogenic bulk hydrogel material, designed to minimize the risk of thrombus formation on the device surfaces. In vitro studies have demonstrated that both the external surfaces and internal fluid pathways of the catheter effectively reduce thrombus accumulation and thrombotic occlusions. This reduction in thrombus accumulation is achieved due to the catheter's steric barrier. The clinical impact has not been evaluated in human clinical trials. This device is not intended for the treatment of existing vein thrombosis.	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. Maximum Power Injection Flow Rate: 4Fr Single Lumen, 20cm: 6 mL/sec	Substantially equivalent.
Device Classification	II	II	Same
Product Code	FOZ	FOZ	Same
Regulation	21 CFR 880.5200	21 CFR 880.5200	Same
Prescription Device	Yes	Yes	Same
Intended population	Adult and Pediatric Use	Adult and Pediatric Use	Same
Catheter Type	Midline Catheter	Midline Catheter	Same
Catheter Outer Diameter French Size	4 French (1.40mm) (Post Hydrated)	4 French (1.40mm) (Post Hydrated)	Same
Catheter Outer Diameter as supplied	1.30 mm (Supplied dehydrated)	1.30 mm (Supplied dehydrated)	Same

Specification	***HydroMID* Single Lumen *(K243458)* Subject device**	**HydroMID (K220772) Access Vascular Inc. Primary Predicate Device**	**Same / Different between Proposed and Predicate?**
Catheter Inner Diameter	1mm	1mm	Same
Useable Length	20 cm	20 cm	Same
Priming Volume	< 1.0mL	< 1.0mL	Same
Guidewire Compatibility	Ø.018"	Ø.018"	Same
Catheter Shaft Design	Taper	Taper	Same
Number of Lumens	1	1	Same
Key Device Components	Catheter shaft, suture wing, extension tube, Luer hub	Catheter shaft, suture wing, extension tube, Luer hub	Same
Implant Time	Short term	Short term	Same
Use with Power Injection and Specified Flow Rate	Yes 6mL/s	Yes 6mL/s	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
Catheter Markings	Markings (every cm)	Markings (every cm)	Same

Discussion of Similarities and Differences

Indications for Use:

Rationale Supporting 21 CFR 807.92(a)(5) for a Change in Indications for Use

1. Technological Characteristics and Performance Data: The proposed devices, HydroPICC DL and SL, and HydroMID SL, incorporate MIMIX® Technology, which is designed to minimize thrombus formation. This technology is present in the predicate devices but was not highlighted in their indications for use statements. In vitro studies have demonstrated that the external surfaces and internal fluid pathways of the catheter effectively reduce thrombus accumulation and thrombotic occlusions.

2. Safety and Effectiveness: The proposed devices have been shown to be safe and effective for their intended use. The reduction in thrombus formation can potentially lead to fewer complications, such as thrombotic events, which are common concerns with catheter use. Although no direct link between these testing methods and clinical outcomes has been conclusively established, the laboratory data provide a strong basis for the proposed indications.

3. Comparison with Predicate Devices The predicate devices, HydroPICC (K193015), HydroMID (K220772), and HydroPICC-251 5F DL Catheter (K213550), are 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. The proposed devices offer additional benefits due to the explicit incorporation of MIMIX® Technology in their indications for use statements, which was not previously mentioned for the predicate devices.

4. Intended Use and Indications The intended use of the proposed devices aligns with that of the predicate devices, with the added benefit of reduced thrombus formation. 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.

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 DL and SL and HydroMID SL catheters, with their advanced MIMIX® Technology, offer significant improvements in terms of reducing thrombus formation. These enhancements, supported by robust laboratory 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

The proposed devices, HydroPICC Single Lumen and Dual Lumen and HydroMID Single Lumen have identical technological characteristics as the predicate device(s) identified above. These characteristics include design, material, chemical composition, and principle of operation**.**

Non-Clinical and/or Clinical Tests Summary & Conclusions

The following tests were completed to demonstrate device safety and efficacy with respect to the predicate devices:

Test Description/Title	Test Summary	Results
Assessment of PICC Catheter Thrombosis in an *in vitro* Model	Evaluate the reduction of thrombus on Hydro-Line catheters compared to polyurethane devices	PASS
Thrombosis Accumulation Report	Assessment of PICC catheter thrombosis in an in-vitro model aimed to evaluate the reduction of thrombus and bacterial accumulation on HydroPICC catheters compared to traditional devices	PASS
In Vitro Thrombosis Study with Saline Conditioning	Assess PICC catheter thrombosis, incorporating preconditioning prior to flow-induced thrombosis using a multi-phase model	PASS
In Vitro Assessment of PICC Thrombus	Assess thrombus accumulation on the exterior surface of select PICC devices using an in vitro blood loop model (BLM)	PASS
In Vitro Assessment of Catheter Thrombotic Occlusion	Study comparing pressures requires to remove thrombotic occlusion of 4F PICC samples using an in-vitro blood flow model	PASS
Blood Loop Analysis of HydroPICC Against Competitors	Determine and compare the quantitative thrombogenicity of subject device relative to existing commercial standard and non-thrombogenic devices using in-vitro blood loop testing	PASS
Sterigenics Sterilization Validation	Describes the catheter to have no inhibitory characteristics per ISO 11737-2:2019	PASS

Test Description/Title	Test Summary	Results
Exhaustive Recovery Assessment of Catheter Thrombosis in an In-Vitro Blood Flow Model	Determine thrombosis differences of catheter materials in whole blood under thrombotic conditions.	PASS

This 510(k) submission provides comprehensive data demonstrating the safety and efficacy of the Hydro Catheter Line, which includes the HydroMID and HydroPICC devices, available in both single and dual lumen configurations. Rigorous testing protocols were employed to evaluate these devices' performance under various conditions, ensuring they meet all applicable regulatory standards. The submission includes in vitro testing, which substantiates 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 HydroMID and HydroPICC devices are substantially equivalent to the predicate device(s).

Upon reviewing the information provided in this submission and comparing the intended use, principle of operation and overall technological characteristics, the Hydro Line of Catheters with the addition to the indications for use is substantially equivalent to existing legally marketed devices.