December 7, 2022

Access Vascular, Inc.
Brian Hanley
VP, R&D and Operations
749 Middlesex Turnpike
Billerica, Massachusetts 01821

Re: K220772
Trade/Device Name: HydroMID 4F Single Lumen Midline Catheter
Regulation Number: 21 CFR 880.5200
Regulation Name: Intravascular catheter
Regulatory Class: Class II
Product Code: FOZ
Dated: November 4, 2022
Received: November 7, 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,

David Wolloscheck, Ph.D.
For Joyce M. Whang, Ph.D.
Acting 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)*
K220772

Device Name
HydroMID 4F Single Lumen Midline Catheter

Indications for Use *(Describe)*
The HydroMID 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.

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

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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K220772 510(k) Summary

Preparation Date: December 7, 2022

Submitter:
Access Vascular Inc.
749 Middlesex Turnpike
Billerica, MA 01821

Contact:
Brian M. Hanley
VP, R&D and Operations
Phone: 781.538.6594 x101
bhanley@accessvascularinc.com

Subject Device

Trade Name:	HydroMID 4F Single Lumen Midline Catheter
Regulation Name:	Intravascular Catheter
Regulation Number:	21 CFR 880.5200
Common Name:	Catheter, Intravascular, therapeutic, Short-Term less than 30 days
Regulatory Class:	Class II
Product Code:	FOZ
Manufacturer:	Access Vascular Inc
Manufacturer ERN:	3015060232

Predicate Device

Trade Name:	HydroMID 4F Single Lumen Catheter
Manufacturer:	Access Vascular
510(k) Number:	K203069
Regulation Name:	Intravascular Catheter
Regulation Number:	21 CFR 880.5200
Common Name:	Catheter, intravascular, therapeutic, Short-Term less than 30 days
Regulatory Class:	Class II
Product Code:	FOZ

Reference Device

Trade Name:	BioFlo Midline Catheter
510(k) Number:	K161866

The reference devices are provided because they are a comparable midline catheter, with catheter markings.

Description of Use

HydroMID

The HydroMID catheter is a 4 French, single lumen midline catheter comprised of a radiopaque, hydrophilic catheter with a suture wing, Luer lock hub, and extension tube 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 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 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

The HydroMID 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.

Maximum Power Injection Flow Rate:

-4Fr Single Lumen, 20cm: 6 mL/sec

Comparison of Technological Characteristics with the Predicate Device

The Proposed Devices and Predicate Devices, respectively, are similar in indications for use, intended use, technological characteristics, and principles of operation.

The differences between the Proposed Device and the Predicate Device are minor and raise no different questions of safety and effectiveness, thus it was concluded that the Proposed Device is substantially equivalent to the Predicate Device. In accordance with 21CFR807.92(a)(6) a summary of how the technological characteristics of the Proposed Device compares to the Predicate Device is provided below.

Specification	**HydroMID 4F Single Lumen Access Vascular Inc. Subject Device**	**HydroMID-142 4F Access Vascular Inc. Predicate Device K203069**	**Comparison**
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 4F Single Lumen Access Vascular Inc. Subject Device	HydroMID-142 4F Access Vascular Inc. Predicate Device K203069	Comparison
Indications for Use	The HydroMID 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. Maximum Power Injection Flow Rate: -4Fr Single Lumen, 20cm: 6 mL/sec	The HydroMID 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. Therapies not appropriate for midline catheters include continuous vesicant therapy, parental nutrition, infusates with pH less than 5 or greater than 9, and infusates with an osmolarity greater than 600mOsm/L. HydroMID is rated for a Maximum Power Injection Flow Rate of 6 mL/sec.	Difference – see comment #1: The Infusion Nurses Society (INS) standards language slightly changed, but intended use is still the same.
Warnings	Do Not use midline catheter for continuous vesicant therapy, PN, or infusates with extremes of pH or osmolarity	Therapies not appropriate for midline catheters include continuous vesicant therapy, parental nutrition, infusates with pH less than 5 or greater than 9, and infusates with an osmolarity greater than 600mOsm/L	Difference – see comment #1: The INS standards language slightly changed, but intended use is still the same.
Device Classification	Class II	Class 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

Specification	HydroMID 4F Single Lumen Access Vascular Inc. Subject Device	HydroMID-142 4F Access Vascular Inc. Predicate Device K203069	Comparison
Catheter Outer Diameter French Size	4Fr (1.40mm) (Post Hydrated)	4Fr (1.40mm) (Post Hydrated)	Same
Catheter Outer Diameter as supplied	1.30mm (Supplied Dehydrated)	1.30mm (Supplied Dehydrated)	Same
Catheter Inner Diameter	1mm	1mm	Same
Useable Length	20 cm	20 cm	Same and 20 cm
Priming Volume	< 1.0mL	< 1.0mL	Same
Guidewire Compatibility	Ø.018”	Ø.018”	Same
Catheter Shaft Design	Taper	Taper	Same
Number of Lumens	Single Lumen (SL)	Single Lumen (SL)	Same
Key Device Components	Catheter Shaft, Suture Wing, Extension Tube, Luer Hub, Clamp	Catheter Shaft, Suture Wing, Extension Tube, Luer Hub, Clamp	Same
Short or Long Term Access	Short	Short	Same
Use with Power Injection and Specified Flow Rate	Yes 6mL/sec	Yes 6mL/sec	Same
Catheter Materials	Radiopaque hydrophilic polyol catheter with Copper Phthalocyanine Blue 15:1 catheter markings, Luer lock hub, polyurethane extension tubing, and suture wing	Radiopaque hydrophilic polyol catheter with Luer lock hub, polyurethane extension tubing, and suture wing	Difference – see comment #2: Copper Phthalocyanine Blue 15:1 material is added to the outer surface of the catheter shaft to incorporate catheter markings as supported by bench testing and biocompatibility testing.
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)	None	Difference – see comment #3: Catheter markings are added to the subject device to assist the user in positioning the

Specification	HydroMID 4F Single Lumen Access Vascular Inc. Subject Device	HydroMID-142 4F Access Vascular Inc. Predicate Device K203069	Comparison
			catheter and monitoring catheter migration

The purpose of listing the K161866 reference device in this submission is intended to provide information that PICC catheters with distance markings are effective in assisting users in both positioning the catheter and monitoring catheter migration. In prior Access Vascular submission K203069 we utilized the BioFlo Midline device a predicate device and demonstrated substantial equivalence despite minor differences in technological characteristics (i.e. catheter shaft material).

Comment #1 – Removal of statement about therapies not appropriate for midlines

The proposed HydroMID Catheter indication for use statement removes mention of restricted therapies for midline catheters to align with slight changes to INS standards without impacting the intended use. The proposed indication for use is identical to other marketed midline catheters. A warning was related to therapies not appropriate for midline catheters include those requiring central access. The difference between the subject device and the predicate device are minor and do not raise any different question of safety and effectiveness.

Comment #2 – Addition of Copper Phthalocyanine Blue 15:1 material

Materials of construction of the HydroMID Catheter with catheter markings are the same as those of the HydroMID catheter (K203069), with minor changes to accommodate the introduction of catheter markings. Bench testing and biocompatibility testing was done to support the addition of the ink used in the catheter distance markings. The difference between the subject device and predicate device are minor and do not raise any different question of safety and effectiveness as determined through testing.

Comment #3 – Addition of Catheter Markings

The addition of catheter markings to the subject device assists the user in positioning the catheter and monitor catheter migration. This change is proposed in response to user feedback and is consistent with currently marketed Midline catheters. Testing included bench testing and biocompatibility testing. The difference between the subject device and predicate device are minor and do not raise any different question of safety and effectiveness as determined through testing.

The HydroMID is used for the same intended use in the same anatomical location using the same principles of operation as the predicate device. Therefore, the HydroMID can be considered substantially equivalent to the predicate device.

Performance Data

All necessary performance testing has been conducted on the HydroMID to assure substantial equivalence to the predicate devices and to demonstrate the device performs as intended. All testing was performed on test units representative of finished devices.

The device passed the following tests, which were conducted in accordance with noted

standards:

Test	Consensus Standard/FDA Guidance/Description
Bench testing, including • Catheter length testing • Catheter marking spacing • Surface continuity • In-life durability testing	Confirm that the device meets intended product specifications
Biocompatibility testing	FDA Final Guidance Document, "Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" (September 2020)

The following standards were used to support testing:

- 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 11135:2014 Sterilization of Healthcare Products – Ethylene Oxide – Requirements for the Development, Validation, and Routine Control of a Sterilization Process for Medical Devices
- AAMI TIR28:2016 Product Adoption and Process Equivalence for Ethylene Oxide Sterilization
- ISO 15223-1:2016 – Symbols to be used with medical device labels, labelling, and information to be supplied - Part 1: General Requirements
- ISO 10993-1: 2018 - Biological evaluation of medical devices – Evaluation and testing within a risk management process
- ISO 10993-4: 2017 - Biological evaluation of medical devices – Selection of tests for interactions with blood
- ISO 10993-5: 2009 - Biological evaluation of medical devices – Tests for in vitro cytotoxicity
- ISO 10993-10: 2010 - Biological evaluation of medical devices – Tests for irritation and skin sensitization
- ISO 10993-12: 2021 - Biological evaluation of medical devices – sample preparation and reference materials

Conclusion:

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