February 8, 2021

Access Vascular Inc.
Brian Hanley
VP, R&D and Operations
175 Middlesex Turnpike Suite 1A
Bedford, Massachusetts 01730

Re: K203069
Trade/Device Name: HydroMID
Regulation Number: 21 CFR 880.5200
Regulation Name: Intravascular Catheter
Regulatory Class: Class II
Product Code: FOZ
Dated: January 4, 2021
Received: January 5, 2021

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,

For Payal Patel
Acting 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K203069

Device Name
HydroMID

Indications for Use *(Describe)*
The HydroMID is indicated for short term access (<30days) 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, parenteral 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 6mL/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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510(k) Summary – K203069

Date Prepared: **January 25, 2021**

Submitter:
Access Vascular, Inc.
175 Middlesex Turnpike
Suite 1A
Bedford, MA 01730
Tel. 781-538-6594

Contact:
Brian Hanley
Access Vascular, Inc.
Tel. 781-538-6594

Subject Device

Trade Name:	HydroMID
Common Name:	Intravascular Catheter
Regulation Number:	21CFR§880.5200
Regulation Name:	Catheter, Intravascular, Therapeutic, Short-Term Less Than 30 days
Regulatory Class:	Class II
Product Code:	FOZ
Classification Panel:	General Hospital

Primary Predicate Device

Trade Name:	BioFlo Midline Catheter
Manufacturer:	AngioDynamics Inc. (Formerly Navilyst Medical, Inc.)
510(k) Reference:	K150407
Common Name:	Intravascular Catheter
Regulation Number:	21 CFR§880.5200
Regulation Name:	Catheter, Intravascular, Therapeutic, Short-Term Less Than 30 days
Regulatory Class:	Class II
Product Code:	FOZ
Classification Panel:	General Hospital

The predicate has not been subject to a design-related recall.

Reference Device

Trade Name:	HydroPICC
Manufacturer:	Access Vascular, Inc

510(k) Reference:	K193015
Common Name:	Intravascular Catheter
Regulation Number:	21CFR§880.5970
Regulation Name:	Percutaneous, Implanted, Long-Term Intravascular Catheter
Regulatory Class:	Class II
Product Code:	LJS
Classification Panel:	General Hospital

Device Description

The HydroMID catheter is a short term (< 30 days) peripheral venous access device with a single 4F outer diameter lumen that is 20 cm in length. Midlines are usually placed in an arm vein such as the basilic, brachial, or cephalic and the tip ends below the level of the axillary line. Midline catheters are longer than peripheral IV catheters which are generally 1 to 3 inches long and shorter than peripherally inserted central catheters (PICC) which extend into the superior vena cava. This device provides an alternative to short peripheral IVs and PICCs for certain treatments.

The HydroMID catheter is comprised of radiopaque, hydrophilic base with a suture wing, Luer lock hub, and extension tube made from materials commonly used in the manufacture of catheters. The catheter has a maximum power injection flow rate of 6mL/sec. HydroMID has been shown to be effective in reducing thrombus accumulation. Reduction of thrombus accumulation was 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.

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. 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.

Substantially Equivalence Discussion

Summary of Similarities and Differences in Technological Characteristics

The proposed HydroMID Catheter is substantially equivalent to the AngioDynamics BioFlo Midline Catheter (K150407). When compared to the predicate, the proposed HydroMID Catheter has equivalent design, components and technological characteristics as well as

comparable "Indications for Use" statement. Both the propose device and the predicate device are

- available in the same size and length configuration, 4Fr diameter and 20cm length;
- rated for maximum power injection flow rate up to 6 mL/sec;
- clearly labeled as a midline catheter to aid with catheter identification;
- able to be placed without the confirmation of an X-ray (or other imaging methods);
- compatible with StatLock Stabilization device; and
- indicated for short-term (< 30 days) peripheral access for selective intravenous therapies.

Additionally, the proposed HydroMID Catheter contains a hydrophilic material formed into the catheter shaft of the device that reduces the accumulation of thrombus. The same hydrophilic material is used in the Access Vascular cleared HydroPICC device (K193015) without modification to any material characteristic and thus testing associated with the material of the catheter is being leveraged from the reference predicate (K193015). HydroPICC has been shown to be effective in reducing thrombus accumulation. Reduction of thrombus accumulation was 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. Both the proposed device and the HydroPICC reference device are

- demonstrative of enhanced resistance to blood component (platelet and thrombus) accumulation

Finally, all sterility (with the exception of residual testing which was repeated), packaging, biocompatibility and MRI compatibility testing is being leveraged from the reference predicate, the Access Vascular cleared HydroPICC device (K193015), since the only physical device change for the proposed HydroMID Catheter and its accessories are related to length.

Non-Clinical Test Conclusion

The non-clinical testing of the proposed device was leveraged from the reference device. The following non-clinical testing was the only testing that was actually performed to the proposed device due to the differences in length of the propose device and the reference device:

- Internal product specification
- Catheter length and length change
- Power Injection
- Sterility testing (EO/ECH residuals test repeated).

Characteristic	HydroMID Catheter Access Vascular Proposed Device	AngioDynamics BioFlo Midline Catheter (K150407) Predicate Device	HydroPICC Catheter (K193015) Access Vascular Reference Device
Intended Use	Intended for short-term access to the peripheral venous system	Same as proposed device	Intended for short- or long-term peripheral access to the central venous system for intravenous therapy.
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. 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.	Same as proposed device	HydroPICC is 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. HydroPICC is rated for a Maximum Power Injection Flow Rate of 3.5mL/sec.
Intended Population	Adult and Pediatric use	Adult and Pediatric use (some sizes)	For Adult Use Only
Device Class	Class II	Class II	Same as proposed device
Product Code	FOZ	FOZ	LJS

Regulation Number	21 CFR 880.5200	Same as proposed device	21 CFR 880.5970
Prescription Device	Yes	Same as proposed device	Same as proposed device
Catheter Type	Midline Catheter	Midline Catheter	Peripherally Inserted Central Catheter (PICC)
Catheter Shaft Material	Radiopaque hydrophilic polyol (Same as HydroPICC K193015)	Radiopaque Polyurethane with Endexo Material	Same as proposed device
Suture Wing	Polyurethane	Polyurethane	Same as proposed device
Extension Tubing	Polyurethane	Polyurethane	Same as proposed device
Clamp	Natural Acetal and Polyurethane	Natural Acetal and Polyurethane	Same as proposed device
Luer	Polyvinyl Chloride	Substantially equivalent: Polyetherimide	Same as proposed device
Key Device Components	Catheter Shaft, Suture Wing, Extension Tube, Luer Hub, Clamp	Substantially equivalent: Catheter Shaft, Suture Wing, Extension Tube, Luer Hub, Oversleeve, Clamp	Same as proposed device
Outside Diameter French Size	4Fr (1.40mm) (Post Hydrated)	Substantially equivalent: 3Fr (1.02mm), 4Fr (1.40mm), 5Fr (1.68mm)	Same as proposed device
Outside Diameter as supplied	1.30mm (Supplied Dehydrated)	1.40mm	Same as proposed device
Usable/Effective Length	20 cm	Substantially equivalent: 10 cm and 20 cm	55 cm
Number of Lumens	Single Lumen (SL)	Substantially equivalent: Single Lumen (SL) and Dual Lumen (DL)	Same as proposed device
Flow Rate	6mL/sec	Same as proposed device	3.5mL/sec
X-Ray Confirmation Required	No	No	Yes
Identified as Midline	Yes	Yes	No -PICC Line
Catheter Shaft Design	Reverse Taper	Same as proposed device	Same as proposed device

Available Kit Configuration	MST Kit (IR Convenience Kit)	Substantially equivalent: Catheter Kit, MST Kit (IR Convenience Kit), Max. Barrier	Same as proposed device
How Supplied	Sterile, Single-Patient Use	Same as proposed device	Same as proposed device
Hydratable (Hydration Required)	Yes	No	Yes- same as the proposed device.
Catheter Preparation Saline Flush	Yes	Yes	Yes

The performance evaluation of the propose HydroMID Catheter included testing conducted in accordance with the following FDA Guidance Documents, and international standards:

- FDA's "Guidance on Premarket Notification [510(k)] Submissions for Short-Term and Long-Term Intravascular Catheters";
- 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"

Conclusion

Based upon successful results of testing and response to questions posed within FDA's 510(k) Decision Making tree, the proposed device is determined to be substantially equivalent to the predicate device.