November 7, 2022

VascuPatent Medical (Shenzhen) Co. Ltd.
c/o Dr. Diana Hong
General Manager
Mid-Link Consulting Co., Ltd
P.O. Box 120-119
Shanghai, Guangdong 200120
China

Re: K222679
Trade/Device Name: Vericor Support Catheter
Regulation Number: 21 CFR 870.1210
Regulation Name: Continuous Flush Catheter
Regulatory Class: Class II
Product Code: KRA
Dated: September 14, 2022
Received: September 14, 2022

Dear Diana Hong:

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,

Gregory W. O'connell -S
Digitally signed by Gregory W. O'connell -S
Date: 2022.11.07 10:50:26 -05'00'

Gregory O'Connell
Assistant Director
DHT2C: Division of Coronary
and Peripheral Intervention Devices
OHT2: Office of Cardiovascular 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: K222679

Device Name
Vericor Support Catheter

Indications for Use *(Describe)*
The Vericor Support Catheter is intended for use in small vessel or superselective anatomy for diagnostic and interventional procedures, including peripheral use.

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

This 510(k) Summary is being submitted in accordance with requirements of Title 21, CFR Section 807.92.

The assigned 510(k) Number: K222679

1. Date of Preparation: 09/02/2022

2. Sponsor Identification

VascuPatent Medical (Shenzhen) Co. Ltd.
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3. Designated Submission Correspondent

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4. Identification of Proposed Device

Trade Name: Vericor Support Catheter
Common Name: Continuous Flush Catheter

Regulatory Information
Classification Name: Continuous flush catheter
Classification: II
Product Code: KRA
Regulation Number: 21CFR 870.1210
Review Panel: Cardiovascular

Indication for Use:
The Vericor Support Catheter is intended for use in small vessel or superselective anatomy for diagnostic and interventional procedures, including peripheral use.

Device Description
The Vericor Support Catheter with hydrophilic coating is a braided, kink-resistant catheter designed to facilitate wire guide exchange, wire guide support and to provide a conduit for the delivery of saline solutions or diagnostic contrast agents. The Vericor Support Catheter will be available in three catheter lengths which are 90 cm, 135 cm and 150 cm. The proposed device is a single-lumen catheter. The hub of the catheter incorporates standard luer adapter to facilitate the attachment of accessories. The outer surface of the distal catheter has a hydrophilic coating. The catheter has three radiopaque markers at the distal end to facilitate fluoroscopic visualization. The device is provided in single use and sterile.

5. Identification of Predicate Devices

Predicate Device
510(k) Number: K160884
Product Name: CXI Support Catheter

6. Non-Clinical Test Conclusion

Non clinical tests were conducted to verify that the proposed device met all design specifications and was found to be Substantially Equivalent (SE) to the predicate device. The testing was conducted with methods and criteria (as applicable) for compliance with the following standards:

- ISO 10993-4: 2017 Biological evaluation of medical devices-Part 4: Selection of tests for interactions with blood
- ISO 10993-5: 2009 Biological evaluation of medical devices-Part 5: Tests for in vitro cytotoxicity

- ISO 10993-7:2008 Biological evaluation of medical devices-Part 7: Ethylene oxide sterilization residuals
- ISO 10993-10: 2010 Biological evaluation of medical devices-Part 10: Tests for irritation and skin sensitization
- ISO 10993-11: 2017 Biological evaluation of medical devices-Part 11: Tests for systemic toxicity
- USP <85> Bacterial Endotoxins Test
- ASTM F756-17, Standard Practice for Assessment of Hemolytic Properties of Materials
- ASTM F2382-18, Standard Test Method for Assessment of Circulating Blood-Contacting Medical Device Materials on PTT
- ASTM D4169-16, Standard Practice for Performance Testing of Shipping Containers and System
- ASTM F1886/F1886M-16, Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection
- ASTM F1929-15, Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration
- ASTM F88/F88M-15, Standard Test Method for Seal Strength of Flexible Barrier Materials
- ISO 10555-1: 2013, Intravascular catheters - Sterile and single-use intravascular catheters - Part 1: General requirements [Including AMENDMENT 1 (2017)]
- ISO 80369-7: 2021, Small-bore connectors for liquids and gases in healthcare applications - Part 7: Connectors for intravascular or hypodermic applications
- USP<151>, Pyrogen Test
- USP<788>, Particulate Matter in Injections
- ASTM F640-20, Standard Test Methods for Determining Radiopacity for Medical Use
- ASTM F2606-08, Standard Guide for Three-Point Bending of Balloon-Expandable Vascular Stents and Stent Systems

The results of performance testing conducted on the Vericor Support Catheter demonstrate that it performs as designed, is suitable for its indication for use and is equivalent in performance to the identified predicate device. A summary of the tests performed is provided in the table below:

Test	Test Method Summary	Results and Conclusion
Visual inspection	Observe the catheter by naked eyes or under microscope of X2.5 magnification for any structural or mechanical damage.	The catheter met acceptance criteria.
Corrosion Resistance	The proposed device was evaluated per ISO 10555‑1:2013. To demonstrate that the device meets the corrosion resistance.	Corrosion resistance met acceptance criteria.
Dimensional verification	Verify dimensions using specified measurement tools. Record measurements.	Size verification met acceptance criteria.
Flowrate	The proposed device was evaluated per ISO 10555-1:2013. To demonstrate that the device	The flowrate of the Vericor catheter size verification met

determination test	meets the flowrate requirements.	acceptance criteria.
Compatibility test	Simulated use testing with compatible devices in a vascular model was performed.	The device can be used as intended.
Simulated use	Simulated use testing in a vascular model was performed	The device can be used as intended.
Power injection	The proposed device was evaluated per ISO 10555‑1:2013. To demonstrate that the device meets the power injection requirements.	The catheters were free of leakage, rupture or other failure modes during power injection test, and the test result met acceptance criteria.
Torque transmission	Fix the distal end of the catheter and rotate the proximal.	Torque transmission met acceptance criteria.
Air leakage	The proposed device was evaluated per ISO 10555‑1 to demonstrate that the product meets the hub aspiration air leakage requirements.	No air leakage
Liquid leakage	The proposed device was evaluated per ISO 10555‑1. To demonstrate that the device meets the liquid leakage under pressure requirements.	No liquid leakage
Static burst pressure	Burst pressure tests were performed at pressures greater than the maximum injection pressures.	Burst pressure met acceptance criteria.
Friction of coating	The test simulates the change in coating friction of the product before and after use	Friction met acceptance criteria
Coating integrity	After simulating the use with compatible devices, the coating is dyed and observe coating defects with magnification.	Coating integrity met acceptance criteria.
Flexibility	The proposed device was evaluated per ASTM F2606-2008. To demonstrate that the device meets the flexibility requirements.	Tip flexibility met acceptance criteria.
Kink resistance	One end of the test piece was fixed on the stator of kink resistance fixture, and the other was fixed on the mover that could move axially in a fixture. The radius gradually decreased when the mover moves axially. Recorded the total length of the catheter body with fixed ends.	Kink resistance met acceptance

Peak tensile force	Use a tensile test machine to apply a tensile load to the sample and determine whether the maximum tensile force meets the acceptance criteria.	Peak tensile force met acceptance criteria.
Catheter tip twist to damage test	Fixed the end of the tip with a Torsional Meter. Rotated the proximal end of the catheter until the tip or body deformed or failed	Tip twist met acceptance
Radiopacity	The radiopaque marker on the catheter tip should be visible under X - ray.	The radiopaque marker on the catheter tip is visible under X - ray.
Catheter body axial compression test	The lower jaw clamped the fixture, and the upper jaw clamped one test piece of the catheter. Recorded the force-deflection curve and peak force value of the catheter body during test.	Catheter body axial force met acceptance criteria.
Delivery and retrieval forces test	The proposed device was evaluated per FDA Guidance - Non-Clinical Engineering Tests and Recommended Labeling for Intravascular Stents and Associated Delivery Systems. To demonstrate that the device meets the delivery and retrieval requirements.	Deliver and retrieval force met acceptance criteria.
Particulate testing	After simulating the use with compatible devices, determine the quantity and size of the particles generated.	The number and size of the particles met acceptance criteria.
Connector performance	The proposed device was evaluated per ISO 80369-7 to demonstrate that the product meets the requirements for small bore connectors.	Connector performance met acceptance criteria.

7. Clinical Test Conclusion

No clinical study is included in this submission.

8. Substantially Equivalent (SE) Comparison

Table 1 Comparison of Technology Characteristics

Item		Proposed Device	Predicate Device K160884	Remark
Classification		II	II	Same
Product Code		KRA	KRA	Same
Regulation Number		21 CFR 870.1210	21 CFR 870.1210	Same
Indication for Use		The Vericor Support Catheter is intended for use in small vessel or superselective anatomy for diagnostic and interventional procedures, including peripheral use.	The CXI ™ Support Catheter is intended for use in small vessel or superselective anatomy for diagnostic and interventional procedures, including peripheral use.	Same
Component		Hub Strain relief Distal shaft Proximal shaft Marker bands Radiopaque tip	Multi layers with hydrophilic coating Distal tip and hub	Different
Inner Diameter		0.0215inch	0.0215inch	Same
Outer Diameter		Proximal: 2.5Fr (0.83mm) Distal: 2.4Fr (0.80mm)	2.6Fr (0.87mm) 4.0Fr (1.23mm)	Different
Effective length		90cm, 135cm, 150cm	65cm, 90cm, 135cm, 150cm	Similar
Maximum Guidewire		0.018inch	0.018inch	Same
Radiopaque Marker		Yes	Yes	Same
Single Use		Yes	Yes	Same
Labeling		Conform with Part 801	Conform with Part 801	Same
Patient-contact Material				
Tip	Tip Outer Body	Polyether block amide (PEBA)	Unknown	Different
		Tungsten		
	Tip Inner Body	Polyether block amide (PEBA)		
	PTFE Liner	Poly tetra fluoroethylene (PTFE)		
Marker Band		Polyamide		
		Tungsten		
Proximal Shaft	Proximal Outer Body	Polyethylene terephthalate (PET)		
	PTFE	Poly tetra fluoroethylene (PTFE)		

	Liner			
Distal Shaft	Distal Outer Body 1	Polyamide		
		Polyether block amide (PEBA)		
	Distal Outer Body 2	Polyamide		
	PTFE Liner	Poly tetra fluoroethylene (PTFE)		
Hydrophilic Coating		Ethanol 2-Hydroxy-1-[4-(2-hydroxyethoxy) phenyl]-2-methyl-1-propanone		
		Ethanol Water Polyvinylpyrrolidone		
Hub		Polycarbonate (PC)		
Biocompatibility				
Cytotoxicity		No cytotoxicity	Conform with ISO 10993 standards	Same
Skin Sensitization		No skin sensitization		
Intracutaneous Reactivity		No irritation		
Systemic Toxicity		No systemic toxicity		
Pyrogen		No pyrogen		
Complement Activation		No significant difference to control group		
In Vivo Thromboresistance		Minimal thrombosis		
Hemolysis		No hemolysis		
Partial Thromboplastin Time		No significant difference to control group		
Sterilization		Ethylene oxide	Ethylene oxide	Same
SAL		10^{-6}	10^{-6}	Same

Analysis Different - Component

The components for the proposed device are different from predicate device. The component name for different manufacturer maybe different from each other. Each component of the proposed device is written in more detail. However, the differences in component name will not affect indication for use or raise any safety issues. In addition, a comparative performance test was conducted between the proposed device and the predicate device, and the test results showed that the performance of the two devices was

similar. Therefore, this difference does not raise new safety and efficacy issues.

Analysis Different -Outer Diameter

The outer diameter of the proposed device is different from predicate device. The proposed device is designed with unequal outer diameter, while the predicate device is designed with equal outer diameter. The predicate device has two sizes of outer diameter, while the proposed device has only one. However, the proposed proximal outer diameter is very similar to the predicate device and this difference is small. The comparative performance test was conducted between the proposed device and the predicate device, and the test results showed that the performance of the two devices was similar. Therefore, this difference does not raise new safety and efficacy issues.

Analysis Similar-Effective length

The outer diameter of the proposed device is similar to predicate device. The proposed devices are available in three effective lengths, which are 90cm, 135cm and 150cm. The predicate devices are available in four effective lengths, which are 65cm, 90cm, 135cm and 150cm. The effective length for the proposed device is covered by the range of lengths for the predicate device. Therefore, this difference does not raise new safety and efficacy issues.

Analysis Different- Patient-contact Material

The materials of subject device may be different from predicate device. However, biocompatibility and other bench tests were performed on the proposed device and the test results showed that there was no adverse effect. Therefore, this difference does not raise new safety and efficacy issues.

9. Substantially Equivalent (SE) Conclusion

Based on the comparison and analysis above, the proposed devices are determined to be Substantially Equivalent (SE) to the predicate devices.