January 28, 2026

Vena Medical Holdings Corp.
Joseph De Croos
Director, Quality Assurance & Regulatory Affairs
809 Wellington St., Unit 2
Kitchener, ON N2H 5L6
Canada

Re: K253842
Trade/Device Name: Vena MicroAngioscope™ System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: LYK
Dated: December 1, 2025
Received: December 2, 2025

Dear Joseph De Croos:

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,

Aneesh S. Deoras -S

Aneesh Deoras
Assistant Director
Division of Cardiac Electrophysiology,
Diagnostics, and Monitoring Devices
Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K253842

Please provide the device trade name(s).

Vena MicroAngioscope™ System

Please provide your Indications for Use below.

The Vena MicroAngioscope™ System is indicated for the visualization and diagnosis of vascular disease within the peripheral and coronary vessels.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) Summary

I. SUBMITTER INFORMATION

Applicant / Manufacturer Name and Address:	Vena Medical Holdings Corp. 809 Wellington St N, Unit 2 Kitchener, ON N2H 5L6, Canada
Sponsor Contact:	Joseph De Croos, Director of Regulatory Affairs 519-897-6654 joseph@venamed.ca
Date Prepared:	December 1, 2025

II. SUBJECT DEVICE

Trade Name:	Vena MicroAngioscope™ System
Common or Usual Name:	Angioscope
Classification Name:	Endoscope and accessories
Regulation Number:	21 CFR §876.1500
Regulatory Class:	Class II
Classification Product Code:	LYK

III. PREDICATE DEVICE

Trade Name:	4.5F ImageCath® Coronary Angioscope, Model COV45
510(k) Number:	K952638

IV. REFERENCE DEVICE

Trade Name:	Vena MicroAngioscope™ System
510(k) Number:	K251767

V. DEVICE DESCRIPTION

The Vena MicroAngioscope System consists of two main components: the Vena MicroAngioscope™ (MA) and the Vena Camera Control Unit (CCU).

The Vena MA is a full-color, forward-viewing, imaging angioscope intended to be used in conjunction with fluoroscopy to aid in vascular interventions. Designed to be used either with a parent catheter or balloon irrigation, it has a working length of 160 cm with a diameter of 3 French (0.040”) at the distal tip and 2.7 French (0.036”) at the proximal end. A radiopaque marker band is positioned at the distal tip of the device. The device features a lighting system surrounding a high-resolution video endoscope which provides real-time, high-resolution imaging inside blood vessels. This allows for direct, accurate

visualization of vascular structures and pathologies, enabling precise interventions. The proximal end consists of a bifurcated joint for connection to an LED illumination source and a camera connector of the Vena CCU. This angioscope must be connected to the Vena CCU to acquire images and emit light. The Vena MicroAngioscope is the sterile, single use applied part of the Vena MicroAngioscope System.

The Vena CCU is a compact, reusable imaging processor designed to interface with the MA to provide power, process images, and output live video. Housed in a durable metal enclosure, the CCU features a front panel interface with a dedicated camera connector for enabling visualization and an LED connector for powering the integrated illumination system. The unit includes two control buttons: one for capturing still images and another for recording video. The CCU requires the Vena MicroAngioscope to be attached to the front connectors for operation. Real-time imaging is transmitted via an HDMI output, allowing seamless integration with external monitors, while a USB port enables image and video storage. To maintain sterility in the angiosuite, the CCU is designed to be fully draped during procedures. Additionally, the CCU can be grounded by connecting to the equipotential grounding pin. By providing high-quality image processing and intuitive controls, the Vena CCU enables enhanced visualization and procedural efficiency in vascular interventions.

VI. INDICATION FOR USE

The Vena MicroAngioscope™ System is indicated for the visualization and diagnosis of vascular disease within the peripheral and coronary vessels.

VII. TECHNOLOGICAL CHARACTERISTICS AND PRODUCT FEATURE COMPARISON TO SUBJECT DEVICE

Feature	Subject Device Vena MicroAngioscope™ System	Predicate Device 4.5F ImageCath® Coronary Angioscope, Model COV45	Reference Device Vena MicroAngioscope™ System
Regulatory Clearance	Pending	K952638	K251767
FDA Classification	Class II	Same	Same
Product Code(s)	LYK, DQY	LYK	Same
Regulation Number	876.1500	Same	Same
Regulation Name	Angioscope	Same	Same
Anatomical Locations	Peripheral & Coronary	Same	Peripheral
Indication for Use	The Vena MicroAngioscope™ System is indicated for the visualization and diagnosis of vascular disease within	The 4.5F ImageCath® Coronary Angioscope is a flexible fiberoptic device indicated for use in the direct visualization and	The Vena MicroAngioscope™ System is indicated for the observation of the interior

Feature	Subject Device Vena MicroAngioscope™ System	Predicate Device 4.5F ImageCath® Coronary Angioscope, Model COV45	Reference Device Vena MicroAngioscope™ System
	the peripheral and coronary vessels.	diagnosis of disease within the peripheral and coronary vascular system.	of blood vessels of the peripheral vasculature.
Material	Commonly used medical grade plastics, glass, silicon, epoxy, stainless steel	Consists of light and image transmitting fiber bundles (glass) contained within a catheter body. Polyethylene sleeve PTFE-coated, stainless steel containing polymethyl methacrylate, illumination fibers and silica image fibers	Same
Tip Shape	Straight	Same	Same
Radiopaque Markers	Distal Tip has radiopaque marker band	Same	Same
Coating	None	Same	Same
Field of View	127 degrees	55 degrees	Same
Direction of View	0 degrees	Same	Same
Working Length	1600mm	1300mm	Same
Insertion Tube Diameter	1mm	1.5mm	Same
Shaft Diameter	0.9mm	1.5mm	Same
Angulation System	none	Same	Same
Channel Diameter	none	0.014"	Same
Accessories Supplied	Camera Control Unit, Power Cable, HDMI Cable, Sterile Drape	Camera system, light source, Sterile Drape, distensible cuff	Same
How Supplied	Sterile, single use	Same	Same
Sterilization Method	EO	Same	Same
Sterility Assurance Level	10 to the -6	Same	Same

VIII. PERFORMANCE DATA

The Vena MA System was verified and validated in accordance with 21 CFR §820.30. The following tests were completed to demonstrate substantial equivalence and that any technological differences do not raise new or different questions of safety and effectiveness. The device successfully passed all testing, and the results demonstrate the device is safe, effective, and performs as well or better than the predicate device.

Performance Bench Testing

- CCU Unit – Compatibility/ Functionality/Recording/Capture
- Color
- Connector Insertion and Removal Force
- Delivery and Retrieval Force
- Dimensional Verification
- Distortion
- Depth of Field
- Field of View
- Direction of View
- Illumination Intensity
- Image Intensity Uniformity
- Image Latency
- Kink Resistance
- Marker Band Position
- Particulate
- Photobiological Safety
- Resolution
- Signal to Noise Ratio
- Simulated Use (Validation)
- Simulated Use (Verification)
- Tensile Test
- Tip Flexibility
- Torqueability
- Visual Inspection
- Water Ingress

Packaging & Labeling Testing

- Accelerated Aging
- Labeling Validation
- Labeling Verification
- Package and Transit Testing

Biocompatibility

- Acute System Toxicity
- Cytotoxicity
- Pyrogenicity
- Sensitization (Maximization)

- Intracutaneous Reactivity
- Hemolysis
- Complement Activation
- Standard Thrombogenicity

The passing biocompatibility testing results demonstrate that the subject device meets biological safety requirements per ISO 10993-1.

Sterilization

The Vena MicroAngioscope™ is sold sterile, for single use and single patient only. The Vena MA is sterilized using 100% Ethylene Oxide (EO) gas to achieve a sterility assurance level of 10^{-6} in compliance with ISO 11135:2014, "Sterilization of Health-Care Products - Ethylene Oxide - Requirements for The Development, Validation and Routine Control of a Sterilization Process for Medical Devices".

Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing in accordance with IEC 60601-1, IEC 60601-1-2, IEC 60601-2-18 and IEC 60601-4-2.

Software Verification and Validation Testing

Software verification and validation testing in accordance with IEC 62304.

Animal Study

No animal testing was required to support this 510(k) as the indications for use and technology are substantially equivalent to those of the predicate device.

Clinical Studies

No clinical testing was required to support this 510(k) as the indications for use and technology are substantially equivalent to those of the predicate device.

IX. CONCLUSIONS

The performance tests have concluded that the Vena MicroAngioscope System, is substantially equivalent in its intended use, design, material, performance, and the underlying scientific technology used, to the predicate device. Non-clinical bench, packaging & labeling, and biocompatibility testing demonstrates that the Vena MicroAngioscope System meets specifications and performs as intended and that any technological differences do not raise new or different questions of safety and effectiveness.