May 16, 2025

Venocare, Inc.
% Mark Smutka
Regulatory Consultant
Daniel & Daniel, LLC.
PO Box 129
Minden, Nevada 89423

Re: K243105
Trade/Device Name: Ruby Intravascular Catheter
Regulation Number: 21 CFR 880.5200
Regulation Name: Intravascular catheter
Regulatory Class: Class II
Product Code: FOZ
Dated: May 9, 2025
Received: May 12, 2025

Dear Mark Smutka:

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,

Porsche Bennett
For 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.

510(k) Number *(if known)*
K243105

Device Name
Ruby Intravascular Catheter

Indications for Use *(Describe)*

The RUBY Intravascular Catheter is inserted into a patient's vascular system to sample blood, monitor blood pressure, or administer fluids intravenously. The device may be used with consideration given to adequacy of vascular anatomy, appropriateness of the solution being infused, and duration of therapy. The RUBY Intravascular Catheter is suitable for use with power injectors.

The RUBY Intravascular Catheter is indicated for use in pediatric patients (with body mass higher or equal to 10 kg) and adults.

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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K243105- 510(K) SUMMARY

Device Name	RUBY™ Intravascular Catheter	
Submitter Information	**Submitter Name**	Venocare Inc.
	Contact Person	Raul Leyte-Vidal
	Telephone Number	786.870.4020
	Address	3750 NW 87th Avenue, Suite 260 Doral, FL 33178
	Date of Preparation	May 16th, 2025
Subject Device	**Trade Name**	RUBY™ Intravascular Catheter
	Common Name	Catheter, Intravascular, therapeutic, short-term less than 30 days
	Classification Name	Intravascular catheter
	Class	Class II
	Regulation Number	21 CFR § 880.5200
	Product Code	FOZ
	510(k) Number	K243105
	Classification Panel	General Hospital
Predicate Device	**Trade Name**	AccuCath™ Intravascular Catheter
	Common Name	Catheter, Intravascular, therapeutic, short-term less than 30 days
	Classification Name	Intravascular catheter
	Class	Class II
	Regulation Number	21 CFR § 880.5200
	Product Code	FOZ
	510(k) Number	K162894
Device Description	The RUBY™ Intravascular Catheter consists of a radiopaque catheter having a usable length of 1.30 inches in 20-gauge size. The device is a single use, sterile intravascular catheters designed to be inserted into a patient 's vascular system to sample blood, monitor pressure, or administer fluids intravenously. The RUBY™ Intravascular Catheter's hub has a blood control valve mechanism that automatically activates to stop the blood flow in the catheter hub when the needle is removed from the catheter during initial insertion by the clinician. Blood flow from the catheter is restricted immediately after needle retraction until a secure luer connection has been made. The RUBY™ Intravascular Catheter is provided with a catheter guiding element with an atraumatic tip	

	design positioned within the formed lumen between the catheter and the needle and connected to a slider used to deploy and retract the catheter guiding element; a flashback chamber to enhance flashback visualization, and a safety container that prevents sharp injuries.
Intended Use	The RUBY™ Intravascular Catheter is intended to be inserted in the patient's vascular system for short-term use to sample blood, monitor blood pressure, or administer fluids intravenously.
Indications for Use	The RUBY Intravascular Catheter is inserted into a patient's vascular system to sample blood, monitor blood pressure, or administer fluids intravenously. The device may be used with consideration given to adequacy of vascular anatomy, appropriateness of the solution being infused, and duration of therapy. The RUBY Intravascular Catheter is suitable for use with power injectors. The RUBY Intravascular Catheter is indicated for use in pediatric patients (with body mass higher or equal to 10kg) and adults.

Technological Characteristics:

The key differences between the subject device when compared to the predicate device are as follows:
1. Difference in the axial position of the catheter guiding element (guidewire in predicate) to the outside of the needle instead of inside of the lumen of the needle.
2. Difference in the catheter guiding element design and composition. RUBY™ Intravascular Catheter uses both metallic and polymeric materials to create a guiding element vs. nitinol for the predicate device.
3. Difference in the needle surface geometries

Technological Characteristics Comparison Table			
	Predicate Device Accucath Intravascular Catheter (K162894)	**Subject Device** RUBY Intravascular Catheter (K243105)	**Comparison**
Indications for Use	The AccuCath Intravascular Catheter is inserted into a patient's vascular system to sample blood, monitor blood pressure, or administer fluids intravenously. This device may be used with consideration given to adequacy of vascular anatomy, appropriateness of the solution being infused, and duration of	The RUBY Intravascular Catheter is inserted into a patient's vascular system to sample blood, monitor blood pressure, or administer fluids intravenously. The device may be used with consideration given to adequacy of vascular anatomy, appropriateness of the solution being infused, and duration of therapy. The RUBY Intravascular	Different. Added intended use for – pediatric and adults weighing > 10kg. Biocompatibility testing done on device shows that this change does not introduce new questions of safety or effectiveness.

Technological Characteristics Comparison Table			
	Predicate Device Accucath Intravascular Catheter (K162894)	**Subject Device** RUBY Intravascular Catheter (K243105)	**Comparison**
	therapy. The AccuCath IV Catheter is suitable for use with power injectors.	Catheter is suitable for use with power injectors. The RUBY Intravascular Catheter is indicated for use in pediatric patients (with body mass higher or equal to 10kg) and adults.	
Commercial Name	AccuCath™ Intravascular Catheter	RUBY™ Intravascular Catheter	N/A
Duration of Use	Short term (< 30 days)	Short term (< 30 days)	Same
Shelf-Life	1.4 years	6 months	Different. Shelf-life testing shows that this change does not introduce new questions of safety and effectiveness.
Device Components	Catheter Length: 1.25 and 2.25 inches Catheter Diameter: 18, 20, 22 GA	Catheter Length: 1.30 inches Catheter Diameter: 20 GA	Different. Performance testing done on the device shows that this change does not introduce new questions of safety and effectiveness.
	Needle Length: 1.25 and 2.25 inches Needle Diameter: 18GA Catheter – 20GA Needle 22GA Catheter – 24GA Needle 20GA Catheter – 22GA Needle	Needle Length: 1.30 inches Needle Diameter: 20GA Catheter– 22GA Needle	Different. Performance testing done on the device shows that this change does not introduce new questions of safety and effectiveness.
	Guidewire Length: > 1.25 Inches Guidewire diameter:	Catheter Guiding Element Length: > 1.30 inches	Different. Simulated use testing was done on the device to show that this difference does not raise

Technological Characteristics Comparison Table			
	Predicate Device Accucath Intravascular Catheter (K162894)	**Subject Device** RUBY Intravascular Catheter (K243105)	**Comparison**
	.008 inches (20/22GA) .010 inches (18GA)	Catheter Guiding Element diameter: .007 inches (20GA)	new questions of safety and effectiveness.
	Catheter Luer	Catheter Luer	Different. Simulated use testing was done on the device to show that this difference does not raise new questions of safety and effectiveness.
	Needle Safety Housing	Needle Safety Housing	Same
	Needle Cover	Needle Cover	Same
	Support tubes	Support tubes	Different. Simulated use testing was done on the device to show that this difference does not raise new questions of safety and effectiveness.
	Spring	Spring	Same
	Porous Plug	Porous Plug	Same
	Button	Button	Same
	Slider	Slider	Different. Simulated use testing was done on the device to show that this difference does not raise new questions of safety and effectiveness.
Means of Insertion	Percutaneous, over a guidewire	Percutaneous, over a catheter guiding element	Different. Simulated use, performance, and biocompatibility testing was done on the device to show that this difference does not raise new questions of safety and effectiveness.
Insertion Site	Peripheral	Peripheral	Same
Device Materials	Catheter Shaft: Pebax	Catheter Shaft: TPU	Different. Simulated use, performance, and biocompatibility testing

Technological Characteristics Comparison Table			
	Predicate Device Accucath Intravascular Catheter (K162894)	**Subject Device** RUBY Intravascular Catheter (K243105)	**Comparison**
			was done on the device to show that this difference does not raise new questions of safety and effectiveness.
	Needle: Stainless Steel	Needle: Stainless Steel	Same
	Guidewire: Nitinol	Catheter Guiding Element: Nitinol and Pebax	Different. Simulated use, performance, and biocompatibility testing was done on the device to show that this difference does not raise new questions of safety and effectiveness.
	Catheter Luer: TPU	Catheter Luer: TPU	Same
	Needle Safety Housing: Polycarbonate	Needle Safety Housing: Polycarbonate	Same
	Needle Cover: Polypropylene	Needle Cover: Polypropylene	Same
	Support Tubes: Stainless Steel	Support Tubes: Stainless Steel	Same
	Spring: Stainless Steel	Spring: Stainless Steel	Same
	Porous Plug: PTFE	Porous Plug: PTFE	Same
	Button: Polycarbonate	Button: Polycarbonate	Same
	Slider: Polycarbonate	Slider: Polycarbonate	Same
Catheter Proximal Configuration	Luer Connection	Luer Connection	Same
Catheter Distal Configuration	Open Ended	Open Ended	Same
Number of Lumens	Single Lumen	Single lumen	Same

Technological Characteristics Comparison Table			
	Predicate Device Accucath Intravascular Catheter (K162894)	**Subject Device** RUBY Intravascular Catheter (K243105)	**Comparison**
Power injection maximum flow rate	6mL/sec	6mL/sec	Same
Sterility	Provided Sterile	Provided Sterile	Same. Ethylene Oxide (EO) with Sterility Assurance Level (SAL) of 10^{-6}.
Available Packaging Configurations	Standalone Device Basic Kit	Standalone Device	Different. Not offering a Basic Kit has no effect on device safety or effectiveness or change in risk.

Safety and Performance Tests

Verification and validation tests were designed and performed in accordance with Design Controls as per 21 CFR § 820.30. The following tests were conducted per guidance documents and standards in determining the substantial equivalence of the RUBY Intravascular Catheter to the predicate AccuCath Intravascular Catheter:

Performance Testing done according to the following applicable standards

- 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 [Including: Amendment 1 (2018)]
- ISO 10555-1: 2013 - Intravascular catheters - Sterile and single-use intravascular catheters - Part 1: General requirements [Including AMENDMENT 1 (2017)]
- ISO 10555-5: 2013 - Intravascular catheters -- Sterile and single-use catheters -- Part 5: Over-needle peripheral catheters.
- ISO 7864: 2016 - Sterile hypodermic needles for single use - Requirements and test methods.
- ISO 23908: 2011 - Sharps injury protection - Requirements and test methods - Sharps protection features for single-use hypodermic needles introducers for catheters and needles used for blood sampling.
- ISO 80369-1: 2018 - Small-bore connectors for liquids and gases in healthcare applications - Part 1: General requirements
- ISO 80369-7:2021 - Small-bore connectors for liquids and gases in healthcare applications - Part 7: Connectors for intravascular or hypodermic applications

- ISO 80369-20:2015 - Small-bore connectors for liquids and gases in healthcare applications - Part 20: Common test methods
- ISO 9626: 2016 - Stainless steel needle tubing for the manufacture of medical devices - Requirements and test methods
- IEC 62366-1 - Medical devices - Part 1: Application of usability engineering to medical devices

Biocompatibility Testing done according to the following applicable standards

- ISO 10993-1: 2018 - Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
- ISO 10993-12: 2021 - Biological evaluation of medical devices - Part 12: Sample preparation and reference materials.
- ISO 10993-18: 2020 - Biological evaluation of medical devices - Part 18: Chemical characterization of medical device materials within a risk management process

Sterilization and Packaging Testing done according to the following applicable standards

- ISO 10993-7:2008 - Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals [Including: Technical Corrigendum 1 (2009) AMENDMENT 1: Applicability of allowable limits for neonates and infants (2019)]
- ASTM F2250-13: 2018 - Standard Practice for Evaluation of Chemical Resistance of Printed Inks and Coatings on Flexible Packaging Materials.
- ASTM F1980:2021 – Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices.
- ISO 11607-1: 2019 – Packaging for terminally sterilized medical devices – Part 1: Requirements for materials sterile barrier systems and packaging systems.
- ISO 11607-2: 2019 - Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming sealing and assembly processes.
- ASTM D4169-22 – Standard Practice for Performance Testing of Shipping Containers and systems
- ASTM D4332-22 – Standard Practice for Conditioning Containers Packages or Packaging Components for Testing

Shelf Life Testing

Testing of baseline and real-time aged samples supports a product shelf- life of 6 months.

Conclusion

The non-clinical tests support the substantial equivalence of the subject device for the proposed indications for use.

The differences in the technological characteristics and the intended use of the subject device and the predicate do not raise new questions of safety and effectiveness.