May 23, 2025

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

Re: K244047
Trade/Device Name: Navi™ Needle-free Blood Collection Device
Regulation Number: 21 CFR 862.1675
Regulation Name: Blood Specimen Collection Device
Regulatory Class: Class II
Product Code: JKA
Dated: April 28, 2025
Received: April 28, 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)*
K244047

Device Name
Navi™ Needle-free Blood Collection Device

Indications for Use *(Describe)*
The Navi™ Needle-free Blood Collection Device attaches to a peripheral intravascular catheter (PIVC) system for use to obtain venous blood specimens into a vacuum tube or syringe from adult and pediatric patients, including those with difficult intravenous access who may have small, fragile, and/or non-palpable veins.

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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K244047 - 510(K) SUMMARY

Device Name	Navi™ Needle-free Blood Collection Device	
Indications for Use	The Navi™ Needle-free Blood Collection Device attaches to a peripheral intravascular catheter (PIVC) system for use to obtain venous blood specimens into a vacuum tube or syringe from adult and pediatric patients, including those with difficult intravenous access who may have small, fragile, and/or non-palpable veins.	
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 23rd, 2025
Subject Device	Trade Name	Navi™ Needle-free Blood Collection Device
	Common Name	Blood specimen collection device
	Classification Name	Tubes, Vials, Systems, Serum Separators, Blood Collection
	Class	Class II
	Regulation Number	21 CFR § 862.1675
	Product Code	JKA
	Classification Panel	General Hospital
Predicate Device	Trade Name	PIVO™ Pro Needle-free Blood Collection Device
	Common Name	Blood specimen collection device
	Classification Name	Tubes, Vials, Systems, Serum Separators, Blood Collection
	Class	Class II
	Regulation Number	21 CFR § 862.1675
	Product Code	JKA
	510(k) Number	K230865

Device Description	The Navi™ Needle-free Blood Collection Device is a sterile packaged single use product designed to be attached to an already placed peripheral intravascular catheter (PIVC) system. The device is comprised of an inner flow tube with an atraumatic tip attached to a plunger that is advanced and retracted with the use of a slider. The slider extends through the proximal end of the housing and is connected to the plunger. A male cannula is positioned at the distal end of the housing with Luer clips configured to connect to a PIVC system. The inner flow tube is intended to be advanced distally through the PIVC into a patient blood vessel establishing fluid communication between the blood vessel and the collection assembly. The inner flow tube is designed to extend beyond the distal end of the PIVC. A lateral flexible tube with a female Luer connected to the housing provides a connection point for an evacuated tube holder or syringe to obtain a blood sample. Once complete, the inner flow tube is fully retracted back into the housing, and the device is removed from the PIVC system. The device is available in three sizes (20 GA, 22 GA and 24 GA) that are compatible with the corresponding PIVC.
Technological Characteristics	The Navi™ Needle-free Blood Collection Device is substantially equivalent in indications for use, intended use, design, materials, and function to the PIVO device, cleared via 510(k) #K230865. The following table includes a comparison of the Navi™ device to the PIVO blood collection device:

Attribute	**Predicate Device (K230865)** PIVO™ Pro Needle-free Blood Collection Device	**Subject Device (K244047)** Navi™ Needle-free Blood Collection Device	**Comparison**
Owner	Becton Dickinson Infusion Therapy Systems, Inc.	Venocare Inc.	N/A
Classification	21 CFR 862.1675 Class II JKA – Blood Specimen Collection Device	21 CFR 862.1675 Class II JKA – Blood Specimen Collection Device	Same
Indications for Use	The PIVO™ Pro Needle-free Blood Collection Device attaches to a peripheral IV catheter system for use to obtain venous blood specimens into a vacuum tube or syringe from adult and pediatric patients,	The Navi™ Needle-free Blood Collection Device attaches to a peripheral intravascular catheter (PIVC) system for use to obtain venous blood specimens into a vacuum tube or syringe from adult and pediatric patients,	Same

	including those with difficult intravenous access who may have small, fragile, and/or non-palpable veins.	including those with difficult intravenous access who may have small, fragile, and/or non-palpable veins.	
Intended Use	Venous blood draw	Venous blood draw	Same
Patient Interface	Separately placed commercially available peripheral IV catheter	Separately placed commercially available peripheral IV catheter	Same
PIV Attachment	Clip-to-connect	Push-connect	Different. Simulated use testing was done on the device to show that this difference does not raise new questions of safety or effectiveness.
Blood Collection Attachment	Female Luer to Blood Transfer Device or Syringe	Female Luer to Blood Transfer Device or Syringe	Same
Blood Control Mechanism	Cap on female luer and clamp on flexible tubing	User activated discontinuous lumen, clamp on extension tubing	Different. Performance and Simulated use testing were done on the device to show that this difference does not raise new questions of safety or effectiveness.
Tubing	Transparent Flexible	Transparent Flexible	Same
Primary Components Dimensions and Material Composition			
ISO 10993-1 Biocompatibility Contact Type Duration	Body Contact: Externally communicating device Contact: Circulating blood Contact Duration: Limited (A) (<24 hrs)	Body Contact: Externally communicating device Contact: Circulating blood Contact Duration: Limited (A) (<24 hrs)	Same
Housing	Polycarbonate	Polycarbonate	Same
Inner Flow Tube (Cannula)	Polyimide	Polyimide	Same

Proximal Tubing	Vestamid	DEHP-free PVC	Different. Simulated use, performance, and biocompatibility testing was done on the device to show that this difference does not raise new questions of safety or effectiveness.
Color	Pink Blue Yellow	Pink Blue Yellow	Same
Compatible PIVC Sizes	The device is available in three sizes: 20 GA, 22 GA, and 24 GA IV compatible. The device is compatible with the corresponding IV gauge and larger IV catheters.	The device is available in three sizes: 20 GA, 22 GA, and 24 GA IV compatible. The device is compatible with the corresponding IV gauge and larger IV catheters.	Same
Inner Flow Tube (Distal Tubing) Length	20 GA = 155.28 mm 22 GA = 155.28 mm 24 GA = 132.68 mm	20 GA = 147.07 mm 22 GA = 147.07 mm 24 GA = 121.67 mm	Different. Performance and simulated use testing were done on the device to show that this difference does not raise new questions of safety or effectiveness.
Outer Diameter (OD) of Inner Flow Tube (Cannula)	20 GA = 0.709 mm max 22 GA = 0.543 mm max 24 GA = 0.400 mm max	20 GA = 0.673 mm max 22 GA = 0.533 mm max 24 GA = 0.445 mm max	Different. Performance and simulated use testing were done on the device to show that this difference does not raise new questions of safety or effectiveness.
Sample Collection	Device attaches to female luer of PIV system, tube inserted into PIV, blood is drawn through tube into a blood transfer device	Device attaches to female luer of PIV system, tube inserted into PIV, blood is drawn through tube into a blood transfer device	Same

Packaging Material	Tyvek/PET or Nylon/Nylon	Tyvek Pouch	Different. Performance, packaging, and sterilization validations were done on the device to show that this difference does not raise new questions or safety or effectiveness.
Sterility **(Sterility Assurance Level (SAL) of 10^{-6}**	Gamma	Ethylene Oxide (EO)	Different. Sterilization validation was done on the device to show that this difference does not raise new questions of safety or effectiveness.
Single Use Only	Yes	Yes	Same
Shelf Life	1 year	6 months	Different. Performance testing over the shelf life was done with the device to show that this difference does not raise new questions of safety or effectiveness.

The Navi™ Needle-free Blood Collection Device has substantially equivalent indications for use and intended use as the PIVO device. Although there are technological differences between the two devices, the differences do not raise any new questions related to safety or effectiveness.

Summary of Performance Data	The Navi™ Needle-free Blood Collection Device was tested to demonstrate all product requirements and user needs were met. Based on the identified risks, the following tests were performed: *Applicable Standards:* • ISO 10555-1: 2013 - Intravascular catheters - Sterile and single-use intravascular catheters - Part 1: General requirements [Including AMENDMENT 1 (2017)] • 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 80369-20:2021 - Small-bore connectors for liquids and gases in healthcare applications - Part 20: Common test methods

	• TIR28: 2016 / (R) 2020 – Product adoption and process equivalence for Ethylene Oxide Sterilization. • 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 8536-14: 2016 - Infusion equipment for medical use - Clamps and flow regulators for transfusion and infusion equipment without fluid contact. • IEC 62366-1 - Medical devices - Part 1: Application of usability engineering to medical devices *Tests:* • Pressure Leak • Vacuum Leak • Pinch Clamp Leak • Dimensional • Kink Resistance • Tensile Strength • Catheter Gauge Compatibility • Catheter Perforation • Flow Rate • Hemolysis • Particulate • Cannula Advancement Force • Human Factors Testing • Design Validation Testing
Biocompatibility	*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. *Tests:* • Cytotoxicity • Irritation • Chemical Characterization • Hemolysis • Hemocompatibility • Sensitization • Particulate • Systemic Toxicity

Sterilization and Packaging	*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)] • ISO 15223-1: 2021 – Medical devices – Symbols to be used with information to be supplied by the manufacturer – Part 1: General Requirements. • 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 • ASTM F88/F88M-21 – Standard Test Method for Seal Strength of Flexible Barrier Materials. *Tests:* • Package Integrity Testing • Package Strength Testing
Summary of Substantial Equivalence	The test data obtained demonstrate that the Navi™ Needle-free Blood Collection Device meets requirements and user needs, and the device is substantially equivalent to the predicate device cleared under K230865. Differences in technological characteristics do not raise new questions of safety or effectiveness.