January 15, 2025

Merit Medical Systems, Inc.
Jenny Soderquist
Regulatory Affairs Specialist II
1600 West Merit Parkway
South Jordan, Utah 84095

Re: K242873
Trade/Device Name: Ventrax™ Delivery System
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: September 20, 2024
Received: September 23, 2024

Dear Jenny Soderquist:

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,

Alexandra K. Manaras -S

For Kalkidan A. Molla
Acting Assistant Director
DHT2B: Division of Circulatory Support, Structural and Vascular 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 *(if known)*
K242873

Device Name
Ventrax Delivery System

Indications for Use *(Describe)*
The Ventrax Delivery System is intended to provide a pathway through which devices are introduced within the chambers and coronary vasculature of the heart.

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.

Ventrax Delivery System

510(k) Summary: K242873

General Provisions	Submitter Name:	Merit Medical Systems, Inc.
	Address:	1600 West Merit Parkway South Jordan, UT 84095
	Telephone Number:	(801) 208-4579
	Fax Number:	(801) 208-3365
	Contact Person:	Jenny Soderquist
	Date Prepared:	December 16, 2024
	Registration Number:	1721504
Subject Device	Trade Name:	Ventrax™ Delivery System
	Common/Usual Name:	Percutaneous catheter
	Classification Name:	Catheter, Percutaneous
	Regulatory Class:	II
	Product Code:	DQY
	21 CFR §:	870.1250
	Review Panel:	Cardiovascular
Predicate Device	Trade Name:	Ventrax™ Delivery System
	Classification Name:	Catheter, Percutaneous
	Premarket Notification:	K231246
	Manufacturer:	Merit Medical Systems, Inc.
Reference Device	No reference devices were used in this submission.	
Device Description	The Ventrax™ Delivery System is designed to provide a conduit to deliver diagnostic and therapeutic catheters to specific heart chambers and locations. It provides support for positioning and maintaining the position of catheters at specific locations in the heart. The sheath may be used for percutaneous entry. The system consists of four components: a sheath, a pigtail dilator, a straight dilator and a J-tipped Amplatz guidewire. **VENTRAX™ DELIVERY SYSTEM COMPONENTS** A. 8.5F Guiding Sheath Introducer: provides a conduit to deliver diagnostic and therapeutic catheters to specific heart chambers and locations. The sheath has an integrated valve to restrict blood loss, and a sideport for flushing and withdrawing blood. B. Mating Pigtail Dilator: designed to conform to the sheath introducer inner diameter, has a tapered tip, has a pigtail at the distal end to assist aortic valve crossing, has an integrated valve to restrict blood loss, and has a sideport for flushing. C. Mating Straight Dilator: designed to conform to the sheath introducer inner diameter and has a tapered tip. Usage of this straight dilator is optional. This straight dilator is intended to be used only when access is unsuccessful after using the mating pigtail dilator. D. 0.035” X 220cm J-tipped Amplatz guidewire: provide path for sheath and dilator advancement.	

Indications for Use	The Ventrax™ Delivery System is intended to provide a pathway through which devices are introduced within the chambers and coronary vasculature of the heart. There is no change in the Indications for Use Statement from the predicate to the subject device.
Comparison to Predicate Device	The subject device and predicate device are similar in design and technological characteristics and are substantially equivalent. The basis of comparison between them is based on the following: • Same Clinical Use • Same Indications for Use • Same Basic Design • Same fundamental technology/principal of operation • Same Sterilization Method • Same intended use The following technological differences exist between the subject device and the predicate device: • Slight Packaging Difference • Different (similar) material types that meet ISO 10993-1 • Similar Labeling The labeling, packaging and material differences are considered technological differences but do not raise different questions of safety or efficacy compared to the predicate.
Performance Data	A battery of tests was performed based upon the risk assessment and requirements of the following internationally recognized standards and guidance documents pertaining to the device performance, as well as biocompatibility, sterilization, and labeling standards and guidance. Conformity to these standards demonstrates that the proposed subject device meets the acceptance criteria established by the standards as they apply to the device safety and effectiveness. • ISO 13485 – Quality management systems – Requirements for regulatory purposes • ISO 14971 – Application of Risk Management to Medical Devices • ISO 11070 – Sterile Single-Use Intravascular Introducers, Dilators and Guidewires • ISO 80369-7 – Connectors for Intravascular or Hypodermic Applications • ISO 80369-20 – Common Test Methods • IEC 62366-1 - Medical Devices - Part 1: Application of Usability Engineering to Medical Devices • ISO 10993-1 - Biological Evaluation of Medical Devices -- Part 1: Evaluation and Testing Within A Risk Management Process • ISO 10993-3 - Biological Evaluation of Medical Devices - Part 3: Tests for Genotoxicity, Carcinogenicity and Reproductive Toxicity

- ISO 10993-4 - Biological Evaluation of Medical Devices - Part 4: Selection of tests for Interactions with blood
- ISO 10993-5 - Biological Evaluation of Medical Devices - Part 5: Tests for In Vitro Cytotoxicity
- ISO 10993-10 - Biological Evaluation of Medical Devices - Part 10: Tests for Irritation and Skin Sensitization
- ISO 10993-11 - Biological Evaluation of Medical Devices - Part 11: Tests for Systemic Toxicity
- ISO 10993-12 - Biological Evaluation of Medical Devices - Part 12: Sample Preparation and Reference Materials
- AAMI ST72 - Bacterial Endotoxins-test Methods, Routine Monitoring, And Alternatives To Batch Testing
- ISO 11135 - Sterilization of Health-care Products - Ethylene Oxide - Requirements for The Development, Validation and Routine Control of a Sterilization Process For Medical Devices
- ISO 10993-7 - Biological Evaluation of Medical Devices - Part 7: Ethylene Oxide Sterilization Residuals
- AAMI TIR 28 - Product Adoption and Process Equivalence for Ethylene Oxide Sterilization
- ASTM D999-08 - Standard Test Methods for Vibration Testing of Shipping Containers
- ASTM D5265-23 – Standard test method for bridge impact testing
- ASTM F 2096-11 - Standard Test Method for Detecting Gross Leaks in Packaging by Internal Pressurization (bubble Test)
- ASTM D4169 - Standard Practice for Performance Testing of Shipping Containers and Systems
- ISO 2233 - Packaging - Complete, Filled Transport Packages and Unit Loads – Conditioning for Testing.
- AAMI ISO 11607 - Packaging for Terminally Sterilized Medical Devices Part 1: Requirements for Materials, Sterile Barrier Systems and Packaging Systems
- ASTM F1929 - Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging By Dye Penetration
- ASTM F 88/F88M - Standard Test Method for Seal Strength of Flexible Barrier Materials
- ASTM F 1980 - Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility Testing

The biocompatibility evaluation for the Ventrax Delivery System was conducted in accordance with the FDA guidance document: Use of International Standard ISO-10993-1, “Biological Evaluation of Medical Devices Part 1: Evaluation and Testing Within a Risk Management Process” and International Standard ISO 10993-1 “Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process”.

- Cytotoxicity
- Sensitization

- Irritation
- Acute Systemic Toxicity
- Pyrogenicity
- Genotoxicity
- Hemolysis
- Thrombogenicity
- Complement Activation

The Ventrax Delivery System met the biocompatibility requirements for externally communicating device with circulating blood contact for a limited (< 24 hours) duration.

The results of the following performance tests demonstrated that the subject Ventrax Delivery System met the acceptance criteria applicable to the safety and efficacy of the device.

Performance Data (Continued)

Design Verification (Performance) Testing conducted:

- Sheath Curve
- Sheath Curve Orientation
- Sheath OD
- Sheath Free Length
- Sheath Marker Band Location
- Sheath Hub ID
- Insertion Testing
- Pressure Leak Test
- Sheath Tip ID
- Sheath Tip Tensile
- Sheath Hub Tensile
- Sheath Shaft Tensile – Transition 1
- Sheath Shaft Tensile – Transition 2
- Sheath Shaft Tensile – Transition 3
- Sheath Shaft Tensile – Transition 4
- Sheath Side Port Tubing Tensile Test
- Sheath Kink Resistance
- Sheath Liner Adhesion
- Simulated Use Design Validation – Clinician

Packaging testing

- • Visual Inspection
- • Dye Penetration
- • Underwater Bubble Emission Testing
- • Burst Testing
- • Engineering Evaluation

Summary of Substantial Equivalence	Based on the indications for use, design, safety, and performance testing, the subject Ventrax Delivery System meets the requirements that are considered essential for its intended use and is substantially equivalent to the predicate device, the Ventrax Delivery System K231246