August 30, 2023

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

Re: K231246
Trade/Device Name: Ventrax Delivery System
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: July 28, 2023
Received: July 31, 2023

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 (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,

Rachel E. Neubrander -S

Rachel Neubrander
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)*
K231246

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(K) Summary

Applicant Name:	Merit Medical Systems, Inc.
Applicant Address:	1600 West Merit Parkway South Jordan UT 84095
Contact:	Jenny Soderquist, phone: 801-208-4579, email: jenny.soderquist@merit.com
Prepared Date:	July 28, 2023
Trade Name:	Ventrax™ Delivery System (VTR851)
Common Name:	Percutaneous catheter
Classification:	Catheter, percutaneous
Regulation Number:	870.1250
Procode:	DQY
Predicate Device:	K202610

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 Systems 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.

INTENDED USE/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.

TECHNOLOGICAL COMPARISON

The technological characteristics of the subject device are substantially equivalent to those of the predicate device. The indications for the subject device and the predicate device are the same. The subject device has the same basic design as the predicate device in that it consists of Sheath tubing, hub, sidearm, and stopcock and is provided with a pigtail and a straight dilator and a guidewire. The difference between the subject and the predicate devices are found in the dimensions and materials used.

SUMMARY OF NON-CLINICAL TESTING

Verification and validation testing of the Ventrax Delivery System was conducted to ensure that the subject device is safe and effective and meets the performance specifications and user needs considered essential for its intended use. Required performance testing was determined based on risk assessment, recognized consensus standards, FDA guidance documents and the anticipated clinical environment.

CONCLUSION

Based on the indications for use, comparison of technological characteristics, and design verification and validation testing, the subject Ventrax Delivery System is substantially equivalent to the predicate device.