December 14, 2020

Merit Medical Systems, Inc.
Elizabeth Lazaro
Sr. Regulatory Affairs Specialist
1600 West Merit Parkway
South Jordan, UT 84095

Re: K202610
Trade/Device Name: Ventrax™ Delivery System
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: November 10, 2020
Received: November 12, 2020

Dear Elizabeth Lazaro:

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,

For 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K202610

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary K202610

General Provisions	Submitter Name:	Merit Medical Systems, Inc.
	Address:	1600 West Merit Parkway South Jordan, UT 84095
	Telephone Number:	(610) 651 -5093
	Contact Person:	Elizabeth Lazaro
	Date Prepared:	September 04, 2020
Subject Device	Trade Name:	Ventrax™ Delivery System
	Common/Usual Name:	Delivery System
	Classification Name:	Percutaneous Catheter
	Regulatory Class:	II
	Product Code:	DQY
	21 CFR §:	870.1250
	Review Panel:	Cardiovascular
Predicate Device	Trade Name:	AMPLATZER® TorqVue® Delivery System
	Classification Name:	Percutaneous Catheter
	Premarket Notification:	K072313
	Manufacturer:	AGA Medical Corporation
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 guiding sheath introducer may be used for percutaneous entry. The System consists of four components: a sheath, a pigtail dilator, a straight dilator and a J-tipped guidewire. Ventrax™ Delivery System Components A. 8.5F Guiding Sheath Introducer: provide a conduit to deliver diagnostic and therapeutic catheters within the chambers and coronary vasculature of the heart. 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. J- tipped InQwire®Amplatz Guidewire 0.035" X 180cm provides pathway 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.
Comparison to Predicate Device	Summary of the technological characteristics of the Ventrax™ Delivery System and the AMPLATZER® TorqVue® Delivery System are based on the following: • Similar Indications for Use • Similar materials • Similar design • Same sterilization method • Same fundamental technology / principle of operation The Ventrax™ Delivery System is substantially equivalent to the predicate device, Amplatzer ®TorqVue ®Delivery System cleared by K072313, both delivery systems are designed to facilitate access within the chambers and coronary vasculature of the heart.
Performance Data	Performance testing of the Ventrax™ Delivery System was conducted based on the risk analysis and when applicable on the requirements of the following 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 **ASTM D1469-2016** Standard Practice for Performance Testing of Shipping Containers and Systems **ISO 11070:2014** Sterile Single-Use Intravascular Introducers, Dilators and Guidewires **ISO 594-1:1986**

Performance Data cont.	Conical Fittings with a 6% (Luer) Taper for Syringes, Needles and Certain of Other Medical Equipment – Part 1: General Requirements **ISO 594-2:1988** Conical Fittings with a 6% (Luer) Taper for Syringes, Needles, and Certain Other Medical Equipment - Part 2: Lock Fittings **ISO 10993-1:2018** Biological Evaluation of Medical Devices -- Part 1: Evaluation and Testing Within A Risk Management Process **ISO 10993-7:2008 (R2016)** Biological Evaluation of Medical Devices - Part 7: Ethylene Oxide Sterilization Residuals **ISO 2233:2000 (R2016)** Packaging - Complete, Filled Transport Packages and Unit Loads – Conditioning for Testing **ASTM D999-08 (R2015)** Standard Test Methods for Vibration Testing of Shipping Containers **ASTM F 2096-11 (R2019)** Standard Test Method for Detecting Gross Leaks in Packaging by Internal Pressurization (bubble Test) **AAMI TIR 28:2016** Product Adoption and Process Equivalence for Ethylene Oxide Sterilization **IEC 62366-1:2016** Medical Devices - Part 1: Application of Usability Engineering to Medical Devices **AAMI ISO 11607:2019** Packaging for Terminally Sterilized Medical Devices- Part 1: Requirements for Materials, Sterile Barrier Systems and Packaging Systems **ASTM F1929:2015** Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration **ASTM F 88/F88M 2015** Standard Test Method for Seal Strength of Flexible Barrier Materials **ASTM F 1980 2016** Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices **ASTM D 5265 2009 R2016** Standard Test Method for Bridge Impact Testing **ISO 10993-3:2014** Biological Evaluation of Medical Devices - Part 3: Tests for Genotoxicity, Carcinogenicity and Reproductive Toxicity **ISO 10993-4 :2017** Biological Evaluation of Medical Devices – Part 4: Selection of Tests for Interactions with Blood **ISO 10993-5:2009-06 (R2017)**

Biological Evaluation of Medical Devices - Part 5: Teste for In Vitro Cytotoxicity
ISO10993-10:2010 (R2016)
Biological Evaluation of Medical Devices - Part 10: Tests for Irritation and Skin Sensitization
ISO 10993-11:2017
Biological Evaluation of Medical Devices - Part 11: Tests for Systemic Toxicity
ISO 10993-12:2012
Biological Evaluation of Medical Devices - Part 12: Sample Preparation and Reference Materials
ISO 14971:2019
Application of Risk Management to Medical Devices
AAMI ST72 :2019
Bacterial Endotoxins-test Methods, Routine Monitoring, And Alternatives to Batch Testing
AAMI TIR28:2016
Product Adoption and Process Equivalence for Ethylene Oxide Sterilization
The following performance data was provided in support of the substantial equivalence determination.

Performance Data cont

Biocompatibility testing
The biocompatibility evaluation for the Ventrax™ Delivery System was conducted in accordance with the FDA Blue Book Memorandum #G95-1 "Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing,'" May 1, 1995, and International Standard ISO 10993-1 "Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process," as recognized by FDA. The battery of testing included the following tests:

- Cytotoxicity
- Sensitization
- Irritation
- Acute Systemic Toxicity
- Pyrogenicity
- Hemocompatibility - Hemolysis Complete
- Hemocompatibility - Complement Activation
- Hemocompatibility - Thrombogenicity

The Ventrax™ Delivery System is considered an externally communicating device with circulating blood contact for a limited (< 24 hours) duration

Performance Data cont.	Performance Testing-Bench • Label Adherence and Condition • Tube OD • Sheath Tip to Dilator Gap • Straight Dilator Radiopacity • Sheath Curve • Pigtail Dilator Curve, Pre-Use • Sheath and Pigtail Dilator Curve Orientation • Dilator Tip ID • Simulated Use – Insertion through Simulated Tissue • Simulated Use Testing- Device Exchange Through Sheath • Dilator and Sheath Assembly • Dilator Protrusion Length • Pigtail Dilator Curve, Post-Use • Guidewire Backloading through Pigtail Dilator Valve • HVA Attachment • Sheath Valve Damage • High Pressure Water Leak Testing • Dilator Joint Strengths • Sheath Free Length • Sheath Marker Band Location • Hemostasis Valve Liquid Leak Test (Short and Long Term) • Sheath Joint Strengths • Sheath Hub Thru-Hole ID • Sheath Tip Radiopacity Test • Sheath Tip ID • Sheath Tip Pull Test • Sheath Shaft Tensile Strength
Performance Data cont	
Summary of Substantial Equivalence	Based on the indications for use, design, safety and performance testing, the Ventrax™ Delivery System meets the requirements that are considered essential for its intended use and is substantially equivalent to the predicate device, the Amplatzer® TorqVue® Delivery System, K072313 manufactured by AGA Medical Corporation.