September 27, 2023

Merit Medical Systems, Inc.
Garry Courtney
Principal Regulatory Affairs Specialist
1600 West Merit Parkway
South Jordan, Utah 84095

Re: K232609
Trade/Device Name: Micro Ace™ Advanced Micro Access System
Regulation Number: 21 CFR 870.1310
Regulation Name: Vessel Dilator For Percutaneous Catheterization
Regulatory Class: Class II
Product Code: DRE
Dated: August 28, 2023
Received: August 28, 2023

Dear Garry Courtney:

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.

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,

Misti L. Malone -S

Misti Malone, PhD
Assistant Director
DHT2C: Division of Coronary
and Peripheral Intervention Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

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)*
K232609

Device Name
Micro Ace™ Advanced Micro Access System

Indications for Use *(Describe)*
The Micro Ace™ Advanced Micro Access System is intended for percutaneous placement of a 0.035" (0.89mm) or 0.038" (0.97mm) guidewire into the vascular system.

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

General Provisions	Submitter Name: Address: Telephone Number: Contact Person: Date Prepared: Registration Number:	Merit Medical Systems, Inc. 1600 West Merit Parkway South Jordan, UT 84095 (801) 208-4583 Garry A. Courtney 08/28/2023 1721504
Subject Device	Trade Name: Common/Usual Name: Classification Name: Regulatory Class: Product Code: 21 CFR §: Review Panel:	Micro Ace™ Advanced Micro Access System Percutaneous Catheterization System Dilator, Vessel, for Percutaneous Catheterization 2 DRE 870.1310 Cardiovascular
Predicate Device	Trade Name: Classification Name: Premarket Notification: Manufacturer: This predicate has not been subject to a design-related recall.	Merit MAK® (Mini Access Kit) Dilator, Vessel, for Percutaneous Catheterization K031691 Merit Medical Systems, Inc.
Reference Device	K091584 (Submission that allowed for modifications to K031691 where stainless steel wires and nitinol wires were modified to include palladium tips). The K091584 submission did not obsolete the design with platinum tips that was cleared with K031691.	

Device Description	The Merit Micro Ace™ Advanced Micro Access System (hereafter referred to as Micro Ace™) provides access to the vascular system and facilitates the placement of a 0.035" (0.89mm) or 0.038" (0.97mm) guide wire. The system is available in 4 French and 5 French sizes – and includes the coaxial introducer-dilator pair, a 21 gauge needle and a 0.018" (0.46mm) guide wire. The introducer-dilator assembly that is included in each kit is 10 cm effective length. The system will be offered with optional guidewires: • Some catalog codes will include a nitinol wire with platinum guide wire tips; • Some catalog codes will be offered with a stainless steel wire with platinum guidewire tips.
Indications for Use	There is no change in the Indications for Use Statement from the predicate to the subject device. The Merit Micro Ace™ Advanced Micro Access System is intended for percutaneous placement of a 0.035" (0.89mm) or 0.038" (0.97mm) guidewire into the vascular system.

Comparison to Predicate Device

The design and technological characteristics of the subject modified Micro Ace™ are substantially equivalent to those of the predicate Mini Access Kit (MAK). The subject device has the same basic design as the predicate device. The differences between the predicate MAK® device and the subject/modified Micro Ace™ device are as follows:

- The introducer sheath is changed from high-density polyethylene (HDPE) sheath to a coiled design with a thermoplastic elastomer jacket;
- A marker band is added to the introducer sheath to aid visibility when used under fluoroscopy.

The comparison between the subject and the predicate devices is based on the following:

- Same intended use
- Same indications for use
- Same sterilization methods
- Same packaging scheme
- Same fundamental technology/principles of operation
- Similar material types (all meet ISO 10993 biocompatibility requirements)
- Equivalent design

No performance standards have been established under Section 514 of the Food, Drug and Cosmetic Act for these devices. Performance testing of the subject Micro Ace™ was conducted based on the risk analysis - and based on the requirements of the following international standard:

1. ISO 10555-1:2013, *Intravascular Catheters – Sterile and single-use catheters – Part 1: General requirements.*
2. EN ISO 11070 2014/A1:2018, *Sterile Single-Use Intravascular Catheter Introducers.*
3. ISO 10993-1:2018, *Biological Evaluation of Medical Devices Part 1: Evaluation and Testing within a risk management process,* and FDA guidance *Required Biocompatibility Training and Toxicology Profiles for Evaluation of Medical Devices*.

Biocompatibility testing was conducted to assess the biocompatibility profile of the finished device because a new material is used in the construction of the coiled sheath. Because the sheath is a patient-contacting component, the appropriate tests were performed for the classification: *Externally Communicating Device with Circulating Blood Contact for a Limited Duration (≤ 24 hours).*

4. ISO 14971:2019, *Medical Devices – Application of Risk Management to Medical Devices*.

   This standard is referenced because the Special 510(k) is submitted with the recognition that a declaration of conformity to design controls is required, and to effectively utilize design controls and prepare the submission, a risk assessment is required to better understand potential risks that might be associated with product modifications – and then conduct appropriate verification and validation testing to support those modifications.

Safety & Performance: Verification, Validation and Biocompatibility

The tests listed below were performed to demonstrate that the modified device meets product specification criteria, and to demonstrate there were no unacceptable risks associated with the changes made to the device.

The tests were performed on both 4F and 5F Micro Ace™ products. Further, the testing was performed on sterile devices (following ethylene oxide processing) and aged devices. All samples were manufactured in accordance with existing and validated processes, and when sterile, are representative of product that Merit Medical intends to commercialize.

All tested samples met pre-established performance criteria and were deemed acceptable.

Design Verification Studies

- Leak Test
- Marker Band-to-Tip Length
- Effective Use Length
- Introducer OD
- Introducer ID
- Dilator Drag
- Introducer Stiffness
- Sheath Kink Force
- Sheath Kink Distance
- Tip Insertion Force
- Sidewall Compression
- Sheath Hub Tensile
- Radiopacity

Design Validation Studies

- Clinician feedback following assessment of design changes.

Biocompatibility Studies

- Cytoxicity Study – ISO Elution Method
- Intracutaneous Irritation Study
- Sensitization – ISO Guinea Pig Maximum Sensitization Test
- Acute Systemic Toxicity – Study in Mice
- Pyrogen Study – USP Rabbit, Material Mediated
- Hemolysis Study – Extract and Direct Material Contact
- Partial Thromboplastin Time – Assay with Comparison Article
- Heparinized Blood Platelet and Leukocyte Count Assay
- Complement Activation (SC5b-9)Assay with Comparison Article

Summary of Substantial Equivalence	Based on the indications for use, design, materials, safety and performance testing (verification and validation), and materials, the subject Micro Ace™ Advanced Micro Access System is deemed to be *substantially equivalent* to the predicate device, the MAK® (Mini Access Kit), K031691. Both the subject device and the predicate device are legally manufactured by Merit Medical Systems, Inc.