



January 15, 2025

Merit Medical Systems, Inc.
Niloufar Samimi
Senior Regulatory Affairs Specialist
1600 West Merit Parkway
South Jordan, Utah 84095

Re: K242229

Trade/Device Name: Micro Ace Gold 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: November 25, 2024
Received: November 26, 2024

Dear Niloufar Samimi:

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, Finn E.
Donaldson -S

Digitally signed by
Finn E. Donaldson -S
Date: 2025.01.15
11:14:59 -05'00'

Finn Donaldson
Assistant Director (Acting)
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

Enclosure

Indications for Use

510(k) Number (if known)

K242229

Device Name

Micro Ace Gold Advanced Micro Access System

Indications for Use (Describe)

The Merit Micro Ace™ Gold 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.

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

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASStaff@fda.hhs.gov

“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

General Provisions

Submitter Name: Merit Medical Systems, Inc.
Address: 1600 West Merit Parkway
South Jordan, UT 84095
Telephone Number: (385) 534-0632
Contact Person: Niloufar Samimi
Date Prepared: 11/25/2024
Registration Number: 1721504

Subject Device

Trade Name: Micro Ace™ Gold Advanced Micro Access System
Common/Usual Name: Percutaneous Catheterization System
Classification Name: Dilator, Vessel, for Percutaneous Catheterization
Regulatory Class: 2
Product Code: DRE
21 CFR §: 870.1310
Review Panel: Cardiovascular

Predicate Device

Trade Name: Merit Micro Ace™ Advanced Micro Access System
Classification Name: Dilator, Vessel, for Percutaneous Catheterization
Premarket Notification: K232609
Manufacturer: Merit Medical Systems, Inc.

This predicate has not been subject to a design-related recall.

**Device
Description**

The Merit Micro Ace™ Gold Advanced Micro Access System (hereafter referred to as Micro Ace™ Gold) provides access to the vascular system and facilitates the placement of a 0.035" (0.89mm) or 0.038" (0.97mm) guide wires. 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 guidewire 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™ Gold 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.

The design and technological characteristics of the subject modified Micro Ace™ Gold are substantially equivalent to those of the predicate Micro Ace™ Advanced Micro Access System. The subject device has the same basic design as the predicate device. The differences between the predicate Micro Ace™ Advanced Micro Access System device and the subject/modified Micro Ace™ Gold device are as follows:

- The dilator material was changed from HDPE to PEEK yellow.
- Addition of silicone coating lubricant to the shaft and tip of the introducer, to reduce insertion force.
- Dilator hub material was changed from HDPE to nylon.

Comparison to Predicate Device

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™ Gold 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.*
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.*

**Safety &
Performance:
Verification &
Validation**

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™ Gold 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

- Dilator Effective length
 - Dilator Outer Diameter
 - Dilator Tip Inner Diameter
 - Insertion Force
 - Pushability and Kink Test
 - Shaft Tensile
 - Hub Tensile
 - Dilator Tip Bend
 - Dilator Tip Fracture
-

-
- Particulate test
 - Lubricity test

Design Validation Studies

- Clinician feedback following assessment of design changes.

Biocompatibility Studies

- Cytotoxicity
- Sensitization
- Irritation
- Acute Systematic Toxicity
- Pyrogenicity
- Hemolysis
- Partial Thromboplastin Time
- Heparinized Blood Platelet and Leukocyte Count
- Complement Activation
- Extract Particulates

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™ Gold Advanced Micro Access System is deemed to be *substantially equivalent* to the predicate device, the Micro Ace™ Advanced Micro Access System, K232609. Both the subject device and the predicate device are legally manufactured by Merit Medical Systems, Inc.
