September 10, 2025

Merit Medical System Inc.
Desiree Bond
Sr. Regulatory Affairs Specialist
1600 West Merit Parkway
South Jordan, Utah 84095

Re: K252527
Trade/Device Name: Surfacer Inside-Out Access Catheter System
Regulation Number: 21 CFR 870.1342
Regulation Name: Reverse Central Venous Recanalization System
Regulatory Class: Class II
Product Code: QJH
Dated: August 11, 2025
Received: August 11, 2025

Dear Desiree Bond:

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 and the limitations described below. 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.

The OHT2: Office of Cardiovascular Devices has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must appear in the warnings section of the device's labeling: All procedures should be proctored by a Merit representative and performed by physicians who have received appropriate training and are familiar with the principles, clinical applications, complications, side effects and hazards commonly associated with interventional procedures

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification if the limitation statement described above is added to your labeling.

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,

Brian D. Pullin -S

for Bram Zuckerman, M.D.
Director
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K252527

Device Name
Surfacer Inside-Out Access Catheter System

Indications for Use *(Describe)*
The Surfacer® Inside-Out® Access Catheter System is intended to obtain central venous access to facilitate catheter insertion into the central venous system for patients with upper body venous occlusions or other conditions that preclude central venous access by conventional methods.

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
PRAStaff@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."

Introduction

In accordance with Section 510(k) of the Federal Food, Drug and Cosmetic Act, and pursuant to 21 CFR § 807.81, this Premarket Notification is being submitted to demonstrate that the subject device Surfacer Inside-Out Access Catheter System is substantially equivalent to the predicate device Surfacer Inside-Out Access Catheter System, DEN190038.

The subject of the Special 510(k) is to notify FDA of Merit's intent to distribute the Surfacer Inside-Out Access Catheter System with an amended IFU warning statement.

General Provisions

Submitter Name: Merit Medical Systems, Inc.
Address: 1600 West Merit Parkway
South Jordan, UT 84095
Telephone Number: (832) 299-5684
Contact Person: Desiree Bond
Date of Preparation: 08/07/2025
Registration Number: 1721504

Subject Device

Trade Name: Surfacer® Inside-Out® Access Catheter System
Common/Usual Name: Surfacer Inside-Out Access Catheter System
Classification Name: Cardiovascular

Predicate Devices

Trade Name: Surfacer® Inside-Out® Access Catheter System
Common/Usual Name: Surfacer Inside-Out Access Catheter System
Premarket Notification: DEN190038
Manufacturer: Merit Medical Inc.

Classification

Class II
21 CFR § 870.1342
FDA Product Code: QJH
Review Panel: Cardiovascular

Indications for Use

There is no change in the Indications for Use Statement from the predicate to the subject device.

The Surfacer® Inside-Out® Access Catheter System is intended to obtain central venous access to facilitate catheter insertion into the central venous system for patients with upper body venous occlusions or other conditions that preclude central venous access by conventional methods.

Description of the Device

The Surfacer System is designed to facilitate entry and placement of central venous access catheters within the peripheral vasculature. The Surfacer System is only sold as a kit as Model or Catalog Number 600200 and is comprised of four components: a Workstation for percutaneous access to the femoral vein; a Delivery Instrument which contains a Needle Wire and Needle Guide which is advanced to the supraclavicular space; an Exit Target which provides fluoroscopic guidance to mark the exit point; and an Exit Introducer which is introduced over the needle wire to access the central venous system. The Exit Targets are packaged with the Delivery Instrument. Once the access is obtained and a catheter is in place, the Surfacer System is removed.

Modifications Addressed in this Submission

The new Surfacer System has the same indications for use, design and technological characteristics, performance specification, and materials as the predicate Surfacer System. The difference between the subject and the predicate devices is the following warning statement in the IFU.

- Amended warning: All procedures should be proctored by a Merit representative and performed by physicians who have received appropriate training and are familiar with the principles, clinical applications, complications, side effects and hazards commonly associated with interventional procedures.

Performance Testing Summary

FDA guidance documents and recognized performance standards have been established for the Surfacer System under Section 514 of the Food, Drug and Cosmetic Act. Testing performed on the predicate device based upon the risk analysis, the requirements of the internationally recognized standards, guidance documents pertaining to the device performance, as well as biocompatibility, sterilization, and labeling standards and guidance are still applicable to the subject device. The proposed Surfacer System IFU change did not require any additional performance testing and the device continues to meet the same acceptance criteria as the predicate device.

Conclusion

Based on the indications for use, design, safety, and performance specification, the subject Surfacer System met the requirements that are considered essential for its intended use and is substantially equivalent to the predicate Surfacer System (DEN190038).