May 22, 2024

Merit Medical Systems, Inc.
Gamaliel Figueroa
Manager, Regulatory Affairs
1600 West Merit Parkway
South Jordan, Utah 84095

Re: K233268
Trade/Device Name: Impress Angiographic Catheter
Regulation Number: 21 CFR 870.1200
Regulation Name: Diagnostic intravascular catheter
Regulatory Class: Class II
Product Code: DQO
Dated: September 28, 2023
Received: September 29, 2023

Dear Gamaliel Figueroa:

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,

Gregory W. O'connell -S

Digitally signed by Gregory W. O'connell -S
Date: 2024.05.22 09:46:10 -04'00'

Gregory O'Connell
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

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)*
K233268

Device Name
Impress Angiographic Catheter

Indications for Use *(Describe)*
The Impress Angiographic Catheter is designed to be used for delivering radiopaque media to selected sites in the vascular system in conjunction with routine diagnostic procedures. Angiographic catheters with marker bands may also be used for anatomical measurements.

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.

K233268 510(k) Summary

General Provisions	Submitter Name:	Merit Medical Systems, Inc.
	Address:	1600 West Merit Parkway South Jordan, UT 84095
	Telephone Number:	(801) 208-4583
	Contact Person:	**Garry A. Courtney**
	Date Prepared:	09/28/2023
	Registration Number:	1721504
Subject Device	Trade Name:	Impress Angiographic Catheter
	Common/Usual Name:	Angiographic Catheter
	Classification Name:	Diagnostic Intravascular Catheter
	Regulatory Class:	2
	Product Code:	DQO
	21 CFR §:	870.1200
	Review Panel:	Cardiovascular
Predicate Devices	**Predicate 1**	
	Trade Name:	Merit Impress Angiographic Catheter
	Classification Name:	Diagnostic Intravascular Catheter
	Premarket Notification:	K191608
	Manufacturer:	Merit Medical Systems, Inc.
	Predicate 2	
	Trade Name:	Merit Impress Angiographic Catheter
	Classification Name:	Diagnostic Intravascular Catheter
	Premarket Notification:	K053171
	Manufacturer:	Merit Medical Systems, Inc.
	The predicate devices have not been subject to design-related recall and/or field actions.	
Reference Device	No reference devices are identified for this submission.	

Device Description	The Merit Impress Angiographic Catheters with/without hydrophilic coating are intravascular diagnostic catheters that are intended for the administration of contrast for conducting fluoroscopic studies. The catheters are available in a variety of 4F and 5F wire-braided and non-braided configurations ranging in length from 40cm to 125cm. The device may include a marker band to assist anatomical measurements. The devices are available in a variety of tip shapes to cater to variations in physician preference and patient anatomy. The catheters consist of a shaft with a molded hub assembly. It is the shaft that may be offered with or without a wire-braided reinforcement. The distal tip of the device is tapered for efficient volume flow and dispersion of the contrast media. The distal tip is flexible so as to minimize the potential for vessel trauma.
Indications for Use	There is no change in the Indications for Use Statement from the predicate devices to the subject device. The Impress Angiographic Catheter is designed to be used for delivering radiopaque media to selected sites in the vascular system in conjunction with routine diagnostic procedures. Angiographic catheters with marker bands may also be used for anatomical measurements.

Comparison to Predicate Device

The design and technological characteristics of the subject modified Impress Angiographic Catheters are equivalent to the predicate Impress Angiographic Catheters. The only differences between the subject catheters and the predicate catheters are that different materials are used in the subject (modified) devices:

- The material used in the construct of the **catheter tip** is changing from one Pebax 5533 formula (SP01) to a different material, Pebax 5533 (SA01 MED). The use of the new Pebax material is fully supported by verification and validation studies, and an extensive biocompatibility assessment.

- The material used in the construct of the **catheter shaft** is changing from one Pebax 7233 formula (SP01) to a different Pebax 7233 formula (SA01 MED). The use of the new Pebax material is fully supported by verification and validation studies, and an extensive biocompatibility assessment.

- The material used in the construct of the **HUB** is changing from a polycarbonate/Xylex resin to polycarbonate resin without Xylex. The use of the polycarbonate resin is fully supported by verification and validation studies, and an extensive biocompatibility assessment.

- The adhesive used in the construct of the **HUB** is changing from cyanoacrylate adhesive to Loctite 4306 adhesive. The use of the new Loctite adhesive is fully supported by verification and validation studies, and an extensive biocompatibility assessment.

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 labeling
- Same design
- Same fundamental technology/principles of operation
- Similar material types (all meet ISO 10993 biocompatibility requirements)

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

1. ISO 10555-1:2013-1, *Intravascular Catheters – Sterile and single-use catheters – Part 1: General requirements.*

2. ISO 80369-7:2021, *Small Bore Connectors for Liquids and Gases in Healthcare Applications – Part 7: Connectors for Intravascular or Hypodermic Applications*.

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*.

4. ISO 10993-4:2017, *Biological Evaluation of Medical Devices Part 4: Selection of Tests for Interaction with Blood.*

5. ISO 10993-5:2009, *Biological Evaluation of Medical Devices Part 5: Tests for In-Vitro Cytotoxicity*

6. ISO 10993-10:2021, *Biological Evaluation of Medical Devices Part 10: Tests for Irritation and Skin Sensitization*

7. ISO 10993-11:2017, *Biological Evaluation of Medical Devices Part 11: Tests for Systemic Toxicity*

8. ASTM F756-13*, Tests for Interaction with Blood: Assessment of Hemolytic Properties of Materials*

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

Safety & Performance Tests

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

The tests were performed on both representative Impress Catheter samples. Further, the testing was performed on sterile devices (following ethylene oxide processing) and aged devices (3-year simulated). All samples were manufactured in accordance with existing and validated processes and 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

- Shaft O.D. meets Specifications
- Confirmation of Working Length Catheter
- Pressure Assessment for Maximum Flow Rate
- Static Pressure Rating
- Force at Break - Tensile; Hub-to-Shaft
- Peak Tensile; Hub-to-Shaft
- I.D. of Assembly / Compatibility with Mandrel
- Hub Defects Assessment
- Kinking Assessment of Strain Relief
- Printing on Hub
- Stiffness/Torque-ability after 37°C water bath
- Catheter Flex Assessment
- Shaft O.D. after Hydration of Hydrophilic Coating in water bath
- Coating Degradation
- Tip Free of Defects
- Tip Curves adherence to templates
- Friction Assessment of Coated Shafts
- Overall Assessment for defects
- Leak Test
- Air Leakage to Hub Assembly

	Design Validation Studies Clinician feedback following assessment of design changes were collected for the following: • Optical Density • Catheter Push-ability • Catheter Track-ability • Catheter Torque-ability • Kink Resistance • Catheter Stiffness • Tip Flexibility • Catheter Compatibility • Withdrawal from Model • Simulated Use in accord with IFU • Useability Assessment Biocompatibility Studies • Cytotoxicity • Intracutaneous Irritation (Extract) • Sensitization – ISO Guinea Pig Maximization • Acute Systemic Toxicity • Pyrogenicity – Material Mediated: Rabbit Study • Hemolysis • Complement Activation (SCb5-9) • In Vitro Blood Loop Assay w/ Comparison Article (3xAnimal)
Summary of Substantial Equivalence	Based on the intended use, product indications, design, materials, safety and performance testing (verification and validation), and materials, the subject Impress Angiographic Catheters are deemed to be *substantially equivalent* to the predicate Impress Angiographic Catheters (K191608 and K053171). Both the subject devices and the predicate devices are legally manufactured by Merit Medical Systems, Inc.