July 16, 2019

Merit Medical Systems, Inc.
Luke Meidell
Principal Regulatory Affairs Specialist
1600 West Merit Parkway
South Jordan, UT 84095

Re: K191608
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: June 14, 2019
Received: June 17, 2019

Dear Mr. Meidell:

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,

Gregory O'Connell
Assistant Director
Plaque Modification Devices Team
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K191608

Device Name
Impress Angiographic Catheter

Indications for Use *(Describe)*
Angiographic catheters are 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.

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510(k) Summary – K191608

General Provisions	Submitter Name:	Merit Medical Systems, Inc.
	Address:	1600 West Merit Parkway South Jordan, UT 84095
	Telephone Number:	(801) 208-4623
	Fax Number:	(801) 826-4174
	Contact Person:	Luke Meidell
	Date Prepared:	June 13, 2019
	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 Device	Trade Name:	Impress Angiographic Catheter
	Classification Name:	Diagnostic intravascular catheter
	Premarket Notification:	K093004
	Regulatory Class:	2
	Product Code:	DQO
	21 CFR §:	870.1200
	Manufacturer:	Merit Medical Systems, Inc.
Device Description	The Impress Angiographic Catheter with Hydrophilic Coating is an intravascular diagnostic catheter intended for the administration of contrast for conducting fluoroscopic studies. The catheter is available in a variety of 5F braided configurations including lengths from 40 cm to 125 cm, with or without marker bands and with hydrophilic coating. The device is available in variety of tip shapes to cater to variation in physician preference and patient anatomy. The device is intended for single use only and is supplied in a sterile configuration.	
Indications for Use	Angiographic catheters are 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.	

	Note: There is no change in the Indications for Use Statement from the predicate to the subject device.
Comparison to Predicate Device	The subject device is substantially equivalent to the predicate device based on identical indications for use statement, and same basic performance and safety profile, principle of operation, fundamental design principles, materials and manufacturing technology. The primary reason for submitting this special 510(k) is the addition of a marker band on the current Impress Angiographic Catheter with Hydrophilic Coating cleared under K093004.
Safety & Performance Tests	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 with Hydrophilic Coating was conducted based on the risk analysis and based on the requirements of the following international consensus standards: • ISO 10555-1:2013 *Intravascular catheters - Sterile and single-use catheters – Part 1: General requirements* • ISO 594-1:1986*, Conical Fittings with 6% (Luer) Taper for Syringes, Needles and Certain Other Medical Equipment - Part 1: General Requirements.* • ISO 594-2:1998*, Conical Fittings with 6% (Luer) Taper for Syringes, Needles and Certain Other Medical Equipment - Part 2: Lock fittings.* • ASTM F640-12*, Standard Test Methods for Determining Radiopacity for Medical Use* • ANSI/AAMI/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.* • ISO 10993-1:2018 *Biological Evaluation of Medical Devices Part 1: Evaluation and Testing within a risk management process*, and FDA guidance *Use of International Standard ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process" (2016).* • ISO 10993-4:2017, *Biological Evaluation of Medical Devices – Part 4: Selection of Tests for Interactions with Blood* • ISO 10993-5:2009*, Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity* • ISO 10993-10:2010, *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* • United States Pharmacopeia 41-NF36:2018, *<151> Pyrogen Test* • ASTM F756-13*, Standard Practice for Assessment of Hemolytic Properties of Materials*

Safety & Performance Tests	The following performance data were provided in support of the substantial equivalence determination. **Biocompatibility testing** The biocompatibility evaluation for the Impress Angiographic Catheter with Hydrophilic Coating 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 following testing was conducted for the catheter: • Cytotoxicity • Hemolysis The Impress Angiographic Catheter with Hydrophilic Coating is considered to be an externally communicating device with circulating blood contact for a limited (≤ 24 hours) duration. **Bench Testing** • Marker band radiopacity • Marker band position • Marker band width • Marker band integrity • Tensile – shaft at marker band and tip to shaft bond • Shaft ID/OD • Catheter length • Catheter stiffness • Kink resistance • Hydrophilic coating lubricity and coating integrity friction testing • Tip length • Burst pressure rating • Flow rate **Design Validation** • Marker band size, shape, location, surface profile, and radiopacity • Distal Tip Inspection • Guidewire compatibility • Catheter push-ability • Catheter track-ability • Kink resistance • Catheter stiffness • Catheter torque-ability • Curve retention

	• Catheter withdrawal The results of the testing do not bring up new questions of safety or effectiveness.
Summary of Substantial Equivalence	Based on the indications for use, design, safety and performance testing, the subject Impress Angiographic Catheter with Hydrophilic Coating meets the requirements that are considered essential for its intended use and is substantially equivalent to the predicate device, the Impress Angiographic Catheter, K093004 manufactured by Merit Medical Systems, Inc.