August 7, 2020

Merit Medical Systems, Inc
Spriha Pandey
Regulatory Affairs Specialist I
1600 West Merit Parkway
South Jordan, Utah 84095

Re: K193082
Trade/Device Name: Fountain ValveTip Infusion Catheter
Regulation Number: 21 CFR 870.1210
Regulation Name: Continuous Flush Catheter
Regulatory Class: Class II
Product Code: KRA
Dated: July 9, 2020
Received: July 10, 2020

Dear Spriha Pandey:

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
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)*
K193082

Device Name
Fountain ValveTip Infusion Catheter

Indications for Use *(Describe)*
The Fountain ValveTip Infusion System is intended to administer infusions of various therapeutic solutions into the peripheral vasculature of a patient.

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 - K193082

General Provisions	Submitter Name:	Merit Medical Systems, Inc.
	Address:	1600 West Merit Parkway South Jordan, UT 84095
	Telephone Number:	(801) 316-3845
	Fax Number:	(801) 826-4174
	Contact Person:	Mr. Jesse Nelson
	Date Prepared:	August 7, 2020
	Registration Number:	1721504
Subject Device	Trade Name:	Fountain ValveTip Infusion Catheter
	Common/Usual Name:	Infusion Catheter
	Classification Name:	Catheter, Continuous Flush
	Regulatory Class:	II
	Product Code:	KRA
	21 CFR §:	870.1210
	Review Panel:	Cardiovascular
Predicate Device	Trade Name:	Fountain Infusion Catheter and Occluding Guide Wire
	Classification Name:	Catheter, Continuous Flush
	Premarket Notification:	K974067
	Manufacturer:	Merit Medical Systems, Inc.

Device Description	The Fountain ValveTip Infusion Catheter is intended to administer infusions of various therapeutic solutions into peripheral vasculature of a patient. The Fountain ValveTip Infusion Catheter has infusion holes at the distal end. These infusion holes allow for passage of thrombolytic fluid. The infusion segment of the catheter is indicated by two radiopaque marker bands. These marker bands can provide the user the means for positioning the infusion length at a desired location with the blood vessel. The Fountain ValveTip Infusion Catheter uses a valve at the distal tip to seal the catheter to facilitate flow through the catheter and spray distribution through the infusion holes. The valve allows the catheter to track over a 0.035" guide wire to facilitate placement of the catheter. The Fountain ValveTip Catheter is available in 4 and 5 French including usable lengths from 45 cm to 135 cm and infusion segments length from 5cm to 50 cm. The usable length and Infusion lengths are the same as the predicate device configuration and will have same functional infusing characteristics. This device is provided with the following Merit device which is already marketed in the US (Class II Exempt): • AccessPLUS™ Hemostasis Valve
Indications for Use	The Fountain ValveTip Infusion System is intended to administer infusions of various therapeutic solutions into the peripheral vasculature of a patient. *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 510(k) is the addition of a valve on the distal tip of the catheter predicate device under 510(k), K974067 and eliminate the use of the occluding wire.

Performance Data	No performance standards have been established under Section 514 of the Food, Drug and Cosmetic Act for these devices. Performance testing of the subject Fountain ValveTip Infusion Catheter was conducted based on the risk analysis and based on the requirements of the following international standard: • ISO 11135-1:2014, Sterilization Of Health-care Products - Ethylene Oxide - Requirements For The Development, Validation And Routine Control Of A Sterilization Process For Medical Devices • ISO 10993-1:2009, 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, May 1, 1995 • ISO 10993-3:2014, Biological Evaluation of Medical Devices – Part 3: Tests for Genotoxicity, Carcinogenicity and Reproductive Toxicity • ISO 10993-4:2017, Biological evaluation of medical devices – Part 4: Selection of tests for interaction with blood • ISO 10993-5:2009, Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity • ISO 10993-7:2008, Biological evaluation of medical devices — Part 7: Ethylene oxide sterilization residuals • 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 • ISO 10993-12, 2012 Biological Evaluation of Medical Devices – Part 12: Sample preparation and reference materials • BS EN ISO 11607-1:2006 Packaging for Terminally Sterilized Medical Devices. Part 1: Requirements for materials, sterile barrier systems, and packaging systems. • ASTM F 2096-11 Standard Test Method for Detecting Gross Leaks in Medical Packaging by Internal Pressurization (Bubble Test) • ASTM F756:2017 Standard practice for Assessment of Hemolytic Properties of Materials • ANSI AAMI ST72:2011, Bacterial endotoxins - Test methods, routine monitoring, and alternatives to batch testing • USP 41,NF 36 (USP), GP <151>, Pyrogen Test (2018) • ASTM F 1929-15 Standard Test Method for Detecting Seal Leaks in porous Medical Packaging by Dye Penetration • ASTM D 4169-16 Standard Practice for Performance Testing of Shipping Containers and Systems • ASTM F640-12 Standard Test Methods for determining Radiopacity for medical use Product Specific Standards: • ISO 10555-1:2013(E) - Intravascular Catheters – Sterile And Single-Use Catheters - Part 1: General requirements

- ISO 10555-3:2013 - Intravascular catheters — Sterile and single-use catheters — Part 3: Central venous catheters
- ISO 594-1:1996(E) - Conical Fittings with 6% (Luer) Taper for Syringes, Needles and Certain Other Medical Equipment – Part 1:General Requirements
- ISO 594-2:1998(E) - Conical Fittings with 6% (Luer) Taper for Syringes, Needles and Certain Other Medical Equipment – Part 2: Lock Fittings

Safety & Performance Tests cont.

Biocompatibility Testing

The biocompatibility evaluation for the Fountain ValveTip Infusion Catheter was conducted in accordance with the ISO 10993-1 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” (CDRH’s biocompatibility as recognized by FDA). The battery of testing included the following tests:

- Cytotoxicity
- Sensitization
- Irritation
- Acute Systemic Toxicity
- Pyrogenicity
- Genotoxicity
- Hemolysis
- Thrombogenicity
- Complement Activation
- Subacute/Subchronic Toxicity
- Implantation

The Fountain ValveTip Infusion Catheter is considered as an externally communicating device with circulating blood contact for a prolonged 24 hours – 30 days.

Performance Testing-Bench

Bench Testing (Safety & Performance Tests)

- French size
- Usable length
- Surface
- Compatible Guide Wire
- Valve- shall not damage guide wire
- The guidewire shall not damage the valve
- Valve penetration and drag force
- Valve leak test
- Kink test

	• Radio-detectability • Tensile force, tip attachment test • ISO-594-2, Gauge test • ISO-594-2, Liquid leakage test • ISO-594-2, Air leakage test • ISO-594-2, Separation force • ISO-594-2, Unscrewing Torque • ISO-594-2, Ease of assembly • ISO-594-2, Resisting to overriding • ISO-594-2, Stress Cracking **Design Validation** • Simulated use testing • Penetration force • Drag force • Trackability • Tip stiffness • Leakage out of tip The results of the testing demonstrated that the subject Fountain ValveTip Infusion Catheter met the predetermined acceptance criteria.
Summary of Substantial Equivalence	Based on the indications for use, design, and performance testing, the Fountain ValveTip Infusion Catheter meets the requirements that are considered essential for its intended use and is substantially equivalent to the predicate device, the Fountain Infusion Catheter and Occluding Guide Wire, K974067. manufactured by Merit Medical Systems, Inc.