DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

October 31, 2016

Merit Medical Systems, Inc.
Ms. Angela Brady
Senior Regulatory Affairs Specialist
1600 West Merit Parkway
South Jordan, UT 84095

Re: K162777
Trade/Device Name: Squirt Fluid Delivery System
Regulation Number: 21 CFR 870.1210
Regulation Name: Continuous Flush Catheter
Regulatory Class: Class II
Product Code: KRA
Dated: September 30, 2016
Received: October 4, 2016

Dear Ms. Brady:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Brian D. Pullin -S

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K162777

Device Name
Squirt Fluid Delivery System

Indications for Use *(Describe)*
The Squirt Fluid Delivery System is intended for the controlled administration of thrombolytic agents into the peripheral vasculature.

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.

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510(k) Summary

General Provisions	Submitter Name: Address: Telephone Number: Fax Number: Contact Person: Date of Preparation: Registration Number:	Merit Medical Systems, Inc. 1600 West Merit Parkway South Jordan, UT 84095 (801) 316-4818 (801) 316-4878 Angela Brady September 30, 2016 1721504
Subject Device	Trade Name: Common/Usual Name: Classification Name: Regulatory Class: Product Code: 21 CFR §: Review Panel:	Squirt® Fluid Delivery System Fluid Delivery System Catheter, Continuous Flush II KRA 870.1210 74 Cardiovascular
Predicate Device	Trade Name: Classification Name: Premarket Notification: Manufacturer: The predicate has not been subject to a design-related recall.	Squirt® Fluid Delivery System Catheter, Continuous Flush K981417 Merit Medical Systems, Inc.
Device Description	The Squirt® Fluid Delivery System is a hand held instrument to provide consistent, forceful, pulsed injections for optimal thrombolysis procedures. It's designed to be attached to a syringe and a catheter, to infuse controlled administration of thrombolytic agents into the peripheral vasculature.	
Indications for Use	The Squirt® Fluid Delivery System is intended for the controlled administration of thrombolytic agents into the peripheral vasculature. There is no change in the Indications for Use Statement from the predicate to the subject device.	

Comparison to Predicate Device	The technological characteristics of the subject Squirt® Fluid Delivery System are identical to the predicate device. Both devices use the same components and materials, with the exception of the O-Ring within the rotator assembly that is bonded on the end of the Squirt® Fluid Delivery System which has undergone a chemical formulation change in the subject device. The indications for use, principle of operation, and technological characteristics of the subject device are identical to the predicate device. Both devices have the same mode of operation and indication for use.
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 Squirt® Fluid Delivery System was conducted based on the risk analysis and based on the requirements of the following international standards: • ISO 8536-4:2010, *Infusion equipment for medical use – Part 4: Infusion sets for single use, gravity feed* • ISO 8536-10:2015, *Infusion equipment for medical use – Part 10: Accessories for fluid lines for single use with pressure infusion equipment* • ISO 11135:2014*, Sterilization of health care products – Ethylene oxide – Requirements for 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 10993-4:2002 (Amd.1:2006)*, 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 10993-11:2006, *Biological evaluation of medical devices – Part 11: Tests for systemic toxicity* • ASTM F756-13, *Standard Practice for Assessment of Hemolytic Properties of Materials* • United States Pharmacopeia 38, National Formulary 33, 2015 <151> Pyrogen Test • AMMI TIR 28:2009, *Product adoption and process equivalency for ethylene oxide sterilization*

Safety & Performance Tests cont.	Performance Testing • Merit Rotational Torque Test • Merit Hydrostatic Pressure Test • Merit Vacuum Leak Test • ISO 8536-4 Chemical Requirements • ISO 8536-10 Particulate • ISO 8536-10 Leakage Biocompatibility • Cytotoxicity • Sensitization • Irritation • Acute Systemic Toxicity • Pyrogenicity • Hemocompatibility • Chemical Characterization The results of the testing demonstrated that the subject Squirt® Fluid Delivery System met the predetermined acceptance criteria and thus is substantially equivalent to the predicate device.
Summary of Substantial Equivalence	Based on the indications for use, design, and performance testing, the subject Squirt® Fluid Delivery System meets the requirements that are considered essential for its intended use and is substantially equivalent to the predicate device, the Squirt® Fluid Delivery System, K981417 manufactured by Merit Medical Systems, Inc.