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

November 4, 2016

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

Re: K161921
Trade/Device Name: SwiftNINJA Microcatheter
Regulation Number: 21 CFR 870.1210
Regulation Name: Continuous Flush Catheter
Regulatory Class: Class II
Product Code: KRA
Dated: September 30, 2016
Received: October 3, 2016

Dear Luke 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. 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)*
K161921

Device Name

SwiftNINJA Microcatheter

Indications *(Describe)*

This microcatheter is intended for general intravascular use, including peripheral and coronary vasculature. Once the sub-selective region has been accessed, the microcatheter can be used for the controlled and selective infusion of diagnostic, embolic, or therapeutic materials into the vasculature. The catheter should not be used in the cerebral vessels.

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.

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510(k) Summary - K161921

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:	09/30/2016
	Registration Number:	1721504
Subject Device	Trade Name:	SwiftNINJA® Microcatheter
	Common/Usual Name:	Continuous Flush Catheter
	Classification Name:	Catheter, Continuous Flush
	Regulatory Class:	2
	Product Code:	KRA
	21 CFR §:	870.1210
	Review Panel:	Cardiovascular
Primary Predicate Device	Trade Name:	Merit Microcatheter
	Classification Name:	Continuous Flush Catheter
	Premarket Notification:	K082613
	Manufacturer:	Merit Medical Systems, Inc.
	This predicate has not been subject to a design-related recall.	
Secondary Predicate Device	Trade Name:	Micrus® Courier Enzo™ Microcatheter
	Classification Name:	Diagnostic intravascular catheter
	Premarket Notification:	K072526, K070456
	Manufacturer:	Micrus Endovascular Corporation
Device Description	The SwiftNINJA® Microcatheter is a 2.9 Fr (proximal) / 2.4 Fr (distal) microcatheter with a steerable/articulating distal tip. Articulation is achieved via a steering dial at the proximal handle which allows the operator to manipulate the tip up to 180 degrees in opposing directions. The steering dial and steerable tip are connected via two operating wires. The wires are located on both lateral walls of the catheter shaft with a connection point on the	

	distal catheter. Tension is applied to either one of the wires by turning the steering dial for manipulation of the tip direction. Once the direction of steerable tip is determined, the steering dial lock may be used for maintaining the intended direction. The outer surface of the distal segment of the microcatheter shaft is coated with a hydrophilic coating designed to facilitate the introduction of the microcatheter into the vasculature.
Indications for Use	*This microcatheter is intended for general intravascular use, including peripheral and coronary vasculature. Once the sub-selective region has been accessed, the microcatheter can be used for the controlled and selective infusion of diagnostic, embolic, or therapeutic materials into the vasculature. The catheter should not be used in the cerebral vessels.* The Indications for Use statement for the SwiftNINJA Microcatheter is identical to the predicate device.
Comparison to Predicate Device	The SwiftNINJA Microcatheter is similar in design and technological characteristics to the Merit Microcatheter (primary predicate) and the Micrus Courier Enzo Microcatheter (secondary predicate). The comparison between the subject, primary predicate, and secondary predicate devices is based on the following: • Same intended use • Same Indications for Use • Similar material types that meet ISO 10993 biocompatibility requirements • Same sterilization methods • Same fundamental technology/principle of operation between the subject and predicate devices.
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 SwiftNINJA Microcatheter was conducted based on the risk analysis and based on the requirements of the following international standards: • ISO 10555-1: 2013, *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.*

- BS EN 20594-1_1994/ISO 594-1:1986, *Conical fittings with a 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.*
- 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 10993-1:2009, *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 10993-4:2002 (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 F756-13:2013, *Standard practice for assessment of hemolytic properties of materials*
- United States Pharmacopeia 38, National Formulary 33, 2015 <151> Pyrogen Test
- ISO 11607-1: 2009/Amd.1:2014, *Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems.*
- ISO 11607-2: 2006/Amd.1:2014, *Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing and assembly processes.*
- ISO 2233:2000, *Packaging – Complete, filled transport packages and unit loads – Conditioning for testing.*
- ASTM D4169-14:2014, *Standard practice for performance testing of shipping containers and systems*

- ASTM F2096-11:2011, *Standard Test Method for Detecting Gross Leaks in Medical Packaging by Internal Pressurization (Bubble Test)*
- ASTM F1929-98:1998 (Reapproved 2004), *Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration.*
- ASTM F640-12:2012, *Standard test methods for determining radiopacity for medical use*.

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility testing
The biocompatibility evaluation for the SwiftNINJA Microcatheter 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 battery of testing included the following tests:

- Cytotoxicity
- Sensitization
- Irritation
- Acute Systemic Toxicity
- Pyrogenicity
- Genotoxicity
- Hemolysis
- Thrombogenicity
- Complement Activation

The SwiftNINJA Microcatheter is considered tissue contacting for a duration of less than 24 hours.

Performance Data cont.

<u>Performance Testing-Bench</u>

- Gauging
- Liquid leakage under high static pressure conditions
- Air leakage
- Separation force
- Unscrewing torque
- Ease of assembly
- Resistance to overriding
- Stress cracking
- Visual inspection

	• Dimensional inspection • Catheter body tensile strength / elongation • Catheter tip tensile strength / elongation • Catheter body to hub tensile strength • Catheter burst to failure • Power injection • Dead space (priming volume) • Microcatheter guide wire passage • Tip articulation / dial spring functionality / dial lock knob • Multiple articulation (fatigue test) • Radiodetectability • Freedom from damage under high dynamic pressure conditions • Catheter body fatigue • Shaft radius of collapse with guide wire • Shaft radius of collapse without guide wire • Kink resistance • Lubricious coating effectiveness • Lubricious coating coverage • Torque to failure • Design validation • Negative pressure collapse • Embolic Delivery • Particulate No clinical or pre-clinical testing was conducted to evaluate the substantial equivalence of this device.
Summary of Substantial Equivalence	Based on the Indications for Use, design, safety and performance testing, the subject SwiftNINJA Microcathetermeets the requirements that are considered essential for its intended use and is substantially equivalent to the predicate device, the Merit Microcatheter, K082613.