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

August 7, 2017

Merit Medical Systems, Inc.
Mr. Cory Marsh
Associate Manager, Regulatory Operations
1600 West Merit Parkway
South Jordan, Utah 84095

Re: K171362
Trade/Device Name: Merit Syringe
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston syringe
Regulatory Class: Class II
Product Code: FMF
Dated: July 7, 2017
Received: July 7, 2017

Dear Mr. Cory Marsh:

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" (21CFR 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,

for James P. Bertram -S

Lori A. Wiggin, MPT, CLT
Acting Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental 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)*

K171362

Device Name

Merit Syringe

Indications for Use *(Describe)*

The Merit Syringe is used to inject fluids into, or withdraw fluids from, the body.

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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5.0 510(k) Summary

General Provisions	Submitter Name:	Merit Medical Systems, Inc.
	Address:	1600 West Merit Parkway South Jordan, UT 84095
	Telephone Number:	(801) 316-3690
	Fax Number:	(801) 826-4112
	Contact Person:	Mr. Cory Marsh
	Date Prepared:	May 8, 2017
	Registration Number:	1721504
Subject Device	Trade Name:	Merit Syringe
	Common/Usual Name:	Piston Syringe
	Classification Name:	Syringe, Piston
	Regulatory Class:	2
	Product Code:	FMF
	21 CFR §:	880.5860
	Review Panel:	General Hospital
Predicate Device	Trade Name:	BD Single Use, Hypodermic Syringe
	Common/Usual Name:	Piston Syringe
	Classification Name:	Syringe, Piston
	Regulatory Class:	2
	Premarket Notification:	K110771
	Manufacturer:	BD Medical – Medical Surgical Systems
	Product Code:	FMF
	21 CFR §:	880.5860
	Review Panel:	General Hospital
Device Description	The Merit Syringe contains a calibrated hollow barrel into which is inserted a closely fitted, ratcheted plunger, and tip or seal. The barrel contains an ISO 594-2 compliant fixed male luer connector, which is compatible with ISO 594-2 compliant female luer hubs.	
Indications for Use	The Merit Syringe is used to inject fluids into, or withdraw fluids from, the body. The Indications for Use statement for the Merit Syringe is not identical to the predicate device; however, the differences do not alter the intended therapeutic use of the device nor do they affect the performance of the device relative to the predicate. The subject and	

predicate device have the same intended use to inject fluids into, or withdraw fluids from, the body, as stated in 21 CFR 880.5860.

Comparison to Predicate Device

The proposed Merit Syringe incorporates the same Intended Use, materials, similar design and principle of operation as the predicate device. Differences between the devices include the nominal capacity and plunger design. Performance testing of the subject device was completed against FDA recognized consensus standards ISO 7886-1 and ISO 594-2.

Attribute	Subject Device – Merit Syringe	Predicate Device – BD Single Use, Hypodermic Syringe
Basic Design	Standard three-piece piston syringe constructed using the same barrel and tip material as the predicate device. The subject device utilizes a single-piece molded ratcheted plunger. Fitting offered with male luer lock connector.	Standard three-piece piston syringe constructed with a clear hollow barrel into which is inserted a closely fitting movable plunger and tip/seal. Fitting offered with male luer lock connector.
Material	The barrel is constructed from polypropylene; the plunger from polypropylene; the seal is made of silicone.	The barrel is constructed from polypropylene; the plunger from polypropylene; the seal is made of silicone.
Principle of Operation	Manually operated by advancing and withdrawing the plunger within the barrel.	Manually operated by advancing and withdrawing the plunger within the barrel.
Operational Volume	Operational volume of 10 mL.	Operational volume of 1, 3, and 5 mL.
Graduation	Printed with accurate graduation lines that are compliant with ISO 7886-1.	Printed with accurate graduation lines that are compliant with ISO 7886-1.
Indications for Use / Intended Use	The Merit Syringe is used to inject fluids into, or withdraw fluids from, the body.	The BD Single Use, Hypodermic Syringe is intended for use by health care professionals for general purpose fluid aspiration/injection.

Performance Data	FDA guidance and recognized consensus standards have been established for Piston Syringes under FDA Product Code FMF and 21 CFR 880.5860. A battery of tests was performed based on the requirements of the below recognized consensus standards and guidance, as well as biocompatibility, sterilization, and packaging standards and guidance. Conformity to these standards demonstrates that the proposed Merit Syringe met the standards' established acceptance criteria for the device. • ISO 7886-1:1993, *Sterile hypodermic syringes for single use – Part 1: Syringes for manual use [Including Technical Corrigendum 1 (1995)]* • 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 10993-7:2008, *Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals* • AAMI TIR 28:2009*, Product adoption and process equivalency for ethylene oxide sterilization* • ISO 11607-1:2006, *Packaging for Terminally Sterilized Medical Devices – Part 1: Requirements for Materials, Sterile Barrier Systems and Packaging Systems [Including: Amendment 1 (2014)]* • ASTM D4169-14: 2014, *Standard Practice for Performance Testing of Shipping Containers and Systems* • ASTM F1980-07:2007, *Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices (Reapproved 2011)* • ISO 2233:2000, *Packaging – Complete, filled transport packages and unit loads – Conditioning for testing* • ISO 10993-1:2009, *Biological evaluation of medical devices - Part 1: Evaluation and Testing within a risk management process [Including: Technical Corrigendum 1 (2010)]* • ISO 10993-4:2002 (Amd.1:2006)*, Biological evaluation of medical devices - Part 4: Selection of tests for interactions with blood [Including: Amendment 1(2006)]* • 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 10993-11:2006, *Biological evaluation of medical devices – Part 11: Tests for systemic toxicity* • ASTM F756-08:2013, *Standard Practice for Assessment of Hemolytic Properties of Materials* • AAMI/ANSI ST72:2011, *Bacterial Endotoxins – Test methods, routine monitoring, and alternatives to batch testing* • United States Pharmacopeia 39, National Formulary 34, <*151*> *Pyrogen Test* (2016)

- FDA Guidance, *Guidance on the Content of Premarket Notification [510(k)] Submissions for Piston Syringes, April 1993*
- FDA Guidance, The New 510(k) Paradigm – Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications, March 1998
- FDA Guidance, Recognition and Use of Consensus Standards, September 2007
- FDA Guidance, Use of International Standard ISO 10993-1, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing within a risk management process, June 2016

Performance Bench Testing
The Merit Syringe complies with the FDA recognized consensus standards ISO 7886-1 and ISO 594-2, as outlined within this submission. Results of the testing demonstrate that the subject device met the acceptance criteria sufficient for its intended use. Testing included the following from these standards:

ISO 7886-1	
Cleanliness	Graduated Scale
Limits for acidity or alkalinity	Barrel
Limits for extractable metals	Piston/Plunger Assembly
Lubricant	Nozzle
Tolerance on Graduated Capacity (based on graduation scale)	Performance – Freedom from air and liquid leakage past piston
Tolerance on Graduated Capacity (based on audible/tactile use)	
ISO 594-2	
Gauging	Unscrewing torque
Liquid leakage	Ease of assembly
Air leakage	Resistance to overriding
Separation force	Stress cracking

Biocompatibility testing
The biocompatibility evaluation for the Merit Syringe was conducted in accordance with the FDA Guidance Document “Use of International Standard ISO-10993, ‘Biological Evaluation of Medical Devices Part 1: Evaluation and Testing within a Risk Management Process,’” June 16, 2016, 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. Testing included the following: • Cytotoxicity • Sensitization • Irritation • Acute Systemic Toxicity • Pyrogenicity • Hemolysis The Merit Syringe is an externally communicating device with indirect blood contacting for a duration of less than 24 hours.
Summary of Substantial Equivalence	Based on the intended use, materials, design, and performance testing, the Merit Syringe meets the requirements that are considered essential for its intended use and is considered substantially equivalent to the predicate device.