November 6, 2018

Merit Medical Systems, Inc
John Skousen
Senior Regulatory Affairs Specialist
1600 W Merit Parkway
South Jordan, Utah 84095

Re: K182216
Trade/Device Name: Merit Syringe
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: Class II
Product Code: FMF
Dated: August 13, 2018
Received: August 15, 2018

Dear John Skousen:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Tina Kiang -S

Tina Kiang, Ph.D.
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K182216

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

K182216 510(k) Summary

General Provisions	Submitter Name:	Merit Medical Systems, Inc.
	Address:	1600 West Merit Parkway South Jordan, UT 84095
	Telephone Number:	(801) 316-3724
	Fax Number:	(801) 826-4112
	Contact Person:	Dr. John Skousen
	Date Prepared:	August 13, 2018
	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:	Merit 20 mL Syringe
	Common/Usual Name:	Piston Syringe
	Classification Name:	Syringe, Piston
	Regulatory Class:	2
	Premarket Notification:	K152783
	Manufacturer:	Merit Medical Systems, Inc.
	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 movable plunger and tip. The barrel contains a fixed male luer connector, which is compatible with female luer hubs.	
Indications for Use	The Merit Syringe is used to inject fluids into, or withdraw fluids from, the body.	
Comparison to Predicate Device	A technological comparison table is provided below that compares the subject device and predicate device. The proposed Merit Syringe incorporates the same Intended Use with identical materials, similar design, and identical principle of operation as the predicate device: the Merit 20 mL Syringe (K152783). The only differences are the dimensional aspects and volume capacity compared to the predicate device. Performance testing of the subject device was completed against FDA recognized consensus standards ISO 7886-1 and ISO 594-2.. These differences between the subject device and predicate device, do not raise different questions of safety and effectiveness.	

Comparison to Predicate Device

Attribute	Subject Device – Merit Syringe	Predicate Device – Merit 20 mL Syringe	Comparison
Design	Standard three-piece piston syringe constructed with a clear hollow barrel into which is inserted a closely fitting plunger and tip/seal. Fitting offered with male luer lock connector. Design is consistent with dimensions of a 1 mL syringe.	Standard three-piece piston syringe constructed with a clear hollow barrel into which is inserted a closely fitting plunger and tip/seal. Fitting offered with male luer lock connector. Design is consistent with dimensions of a 20 mL syringe.	Same general design except the operational volume
Material	The barrel is constructed from clear cyclo-olefin polymer; the plunger from polycarbonate or ABS material; the seal is made of silicone; the lubricant is silicone.	The barrel is constructed from clear cyclo-olefin polymer; the plunger from polycarbonate or ABS material; the seal is made of silicone; the lubricant is silicone.	Same
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.	Same
Operational Volume	Operational volume of 1 mL.	Operational volume of 20 mL.	Different
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.	Different graduations but both follow same standard
Indications for Use / Intended Use	The Merit Syringe is used to inject fluids into, or withdraw fluids from, the body.	The Merit Medical 20 mL Syringe is used to inject fluids into, or withdraw fluids from, the body.	Same

Non-Clinical Testing	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. • ISO 7886-1: 2017, *Sterile hypodermic syringes for single use – Part 1: Syringes for manual use* • ISO 594-2:1998, *Conical fittings with 6% (Luer) taper for syringes, needles and certain other medical equipment – Part 2: Lock fittings* • AAMI TIR 28:2009*, Product adoption and process equivalency for ethylene oxide sterilization* • FDA Guidance, *Guidance on the Content of Premarket Notification [510(k)] Submissions for Piston Syringes, April 1993* • 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 **Device Biocompatibility:** The Merit Syringe is an externally communicating device with indirect blood contacting for a duration of less than 24 hours. The materials used in the subject device in its final finished form are identical to the materials used in the predicate device, cleared under K152783. Therefore, testing provided in K081361 demonstrated the biocompatibility of the subject device for the intended use. The biocompatibility endpoints that were previously evaluated under K152783 are the following: • Cytotoxicity • Sensitization • Irritation • Acute Systemic Toxicity • Pyrogenicity • Hemocompatibility **Device Sterilization :** The subject device is a sterile, non-pyrogenic, single use 1 ml syringe sterilized by EO, with a 3 year shelf life. It is packaged in an EVA blister/Tyvek pouch. The subject device was adopted into exisiting validated sterility process per AAMI TIR: 2009: Adoption and Process Equivalency for Ethylene Oxide Sterilization. The sterility process was cleared under K152783 and was validated under K152783 using: • 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 11607-1:2006, *Packaging for Terminally Sterilized Medical Devices – Part 1: Requirements for Materials, Sterile Barrier Systems and Packaging Systems [Including: Amendment 1 (2014)]*: **Device Performance Bench Testing** The Merit Syringe performance was tested in accordance with the FDA recognized consensus standards ISO 7886-1:2017 and ISO 594-2:1998.

	Results of the testing demonstrate that the subject device met the pre-determined acceptance criteria and supports the 3 year shelf life of the device.
Non-Clinical Testing	A risk analysis was conducted in accordance with ISO 14971: 2007 – Medical devices — Application of risk management to medical devices. In all non-clinical testing, the pre-determined acceptance criteria was met.
Summary of Substantial Equivalence	Differences between the technological characteristics of the subject device as compared to the predicate do not raise different questions of safety and effectiveness. The performance of the device is supported by non-clinical testing and risk management activities. The Merit Syringe is Substantially Equivalent (SE) to the Merit 20 mL Syringe, cleared under K152783.