January 31, 2018

Merit Medical Systems, Inc.
Cory Marsh
Assoc. Manager, Regulatory Affairs
1600 W Merit Parkway
South Jordan, Utah 84045

Re: K173601
Trade/Device Name: Merit Syringe
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: Class II
Product Code: FMF
Dated: November 20, 2017
Received: November 21, 2017

Dear 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.

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.

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)*
K173601

Device Name

Merit Syringe

Indications for Use *(Describe)*

The Merit Syringe is used to inject fluids into, and 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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Department of Health and Human Services
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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."

5.0 510(k) Summary K173601

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:	November 20, 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:	Welmed Hypodermic Syringe
	Classification Name:	Syringe, Piston
	Regulatory Class:	2
	Product Code:	FMF
	21 CFR §:	880.5860
	Premarket Notification:	K070936
	Manufacturer:	Welmed, Inc.
Device Description	The Merit Syringe contains a calibrated hollow barrel into which is inserted a closely fitted movable plunger and tip or O-Ring. 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, and withdraw fluids from, the body.	
Comparison to Predicate Device	The proposed Merit Syringe incorporates the same intended use, as well as similar materials, design and principle of operation as the predicate Welmed Hypodermic Syringe. Any differences in materials used or operating volume are supported by the subject device's compliance with FDA recognized standards ISO 7886-1 and ISO 594-2. The subject device is substantially equivalent to the predicate device.	

Comparison to Predicate Device cont'd

Attribute	Subject Device – Merit Syringe	Predicate Device – Welmed Syringe
Design	Standard three-piece piston syringe constructed with a clear hollow barrel into which is inserted a closely fitting movable plunger and tip or O-Ring. Fitting offered with male luer lock.	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.
Material	The barrel is constructed from clear polycarbonate; the plunger from ABS material; the seal or O-Ring is made of silicone material.	Materials used in the manufacture of the Welmed syringe are typically used in the manufacture of general-purpose syringes.
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 0.25, 1, 3, 6, 10, 20, 30 and 60 mL.	Operational volume of 1, 3, 5, 10, 20, 30, and 60 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.
Intended Use	The Merit Syringe is used to inject fluids into, and withdraw fluids from, the body.	The intended use of the Welmed piston syringe is to inject fluids into, and withdraw fluids from, the body.

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,*

Performance Data cont'd	*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 [including: technical corrigendum 1 (2009)].* • AAMI TIR 28:2009*, Product adoption and process equivalency for ethylene oxide sterilization* • ISO 11137-1:2006, *Sterilization of Health Care Products – Radiation – Part 1: Requirements for Development, Validation and Routine Control of a Sterilization Process for Medical Devices [Including: Amendment 1 (2013)]* • ISO 11137-2:2013, *Sterilization of health care products – Radiation – Part 2: Establishing the sterilization dose* • 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 F756-08:2008, *Standard Practice for Assessment of Hemolytic Properties of Materials* • AAMI/ANSI ST72:2011/(R)2016, *Bacterial Endotoxins – Test methods, routine monitoring, and alternatives to batch testing* • United States Pharmacopeia 37, National Formulary 32, 2014 *<151> Pyrogen Test* • 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*

Performance Data cont'd

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	Performance – Freedom from air and liquid leakage past piston
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 considered 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, the Welmed Hypodermic Syringe, K070936.