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 17, 2014

Merit Medical Systems, Incorporated
Ms. Mridi Kumathe
1600 West Merit Parkway
South Jordan, UT 84095

Re: K142636
Trade/Device Name: Merit 10mL Syringe
Regulation Number: 21 CFR 880.5860
Regulation Name: Merit 10mL Syringe
Regulatory Class: II
Product Code: FMF
Dated: 9/15/2014
Received: 9/17/2014

Dear Ms. Kumathe:

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 Small Manufacturers, International and Consumer Assistance 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 Small Manufacturers, International and Consumer Assistance 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 yours,

Erin I. Keith, M.S.
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)*
K142636

Device Name
Merit 10mL Syringe

Indications for Use *(Describe)*
The Merit 10mL 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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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."

5.0 510(k) Summary K142636

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) 208-4712 (801) 253-6921 Mridi Kumathe 09/15/2014 1721504
Subject Device	Trade Name: Common/Usual Name: Classification Name:	Merit 10mL Syringe Merit 10mL Syringe Piston Syringe
Predicate Device	Trade Name: Classification Name: Premarket Notification: Manufacturer:	Merit 20mL Syringe Syringe, Piston K111091 Merit Medical Systems, Inc.
Classification	Class 2 21 CFR § 880.5860 FDA Product Code: FMF Review Panel: General Hospital	
Intended Use	The Merit 10mL Syringe is used to inject fluids into, or withdraw fluids from, the body.	
Device Description	The Merit 10mL Syringe is a device consisting of a calibrated hollow barrel into which is inserted a closely fitted movable plunger and seal. The barrel contains a male Luer lock connector (which conforms to ISO 594-1 & 2 standards) which is compatible for attaching devices with standard female Luer hubs.	
Comparison to Predicate Device	The indications for use, principle of operation and technological characteristics of the subject device are identical to the predicate device. Both devices have been designed and tested to ensure compliance with the same set of consensus standards listed below. The subject device (Merit 10mL Syringe) is substantially equivalent to the predicate device (Merit 20mL Syringe).	

Safety & Performance Tests	FDA guidance and recognized performance standards have been established for "piston syringes" under Section 514 of the Food, Drug and Cosmetic Act. FDA Guidance Document "*Guidance on the Content of Premarket Notification [510(k)] Submissions for Piston Syringes,* April 1993" was consulted in the preparation of this 510(k) submission. A battery of tests was performed based on the requirements of the below recognized performance standards, as well as biocompatibility, sterilization, and labeling standards and guidance. Conformity to these standards demonstrates that the subject Merit 10mL Syringe met the standards' established acceptance criteria applicable to the safety and efficacy of the device. Performance testing was conducted based on the risk analysis and based on the requirements of the following international consensus standards/documents: • ISO 7886-1:1993*, Sterile hypodermic syringes for single use – Part 1: Syringes for manual use [Including Technical Corrigendum 1 (1995)]* • 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 10993-7:2008*, Biological Evaluation of Medical Devices, Part 7: Ethylene Oxide Sterilization Residuals* • AAMI TIR 28, *Product Adoption and Process Equivalency for Ethylene Oxide Sterilization* • 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 10993-10:2010, *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* • United States Pharmacopeia 37, National Formulary 32, 2014 <151> Pyrogen Test

Safety & Performance Tests cont.

Performance Testing-Bench

ISO 7886-1

- Cleanliness
- Sufficient/excessive Lubricant
- Capacity Tolerance
- Graduated Scale
- Scale - Uniformity
- Scale - Evenly spaced
- Scale - Vertical Alignment
- Scale - Increments
- Scale - Vertical Print
- Scale - Length
- Scale - Position
- Capacity 10% > Nominal
- Finger Grips
- Piston/Plunger Assembly
- Piston fit in Barrel
- Fiducial line on Barrel
- Nozzle Placement
- Nozzle Lumen
- Dead Space
- Liquid Leak Test
- Air Leak Test
- Acidity / Alkalinity
- Extractable Metals

ISO 594-2

- Luer Gauging
- Liquid Leak Test
- Air Leak Test
- Separation Force
- Unscrewing torque
- Ease of assembly
- Resistance to overriding
- Stress Cracking

Merit's Risk Analysis

- Plunger Seal Detachment Test
- Ink Adhesion Test

Biocompatibility

- Cytotoxicity
- Sensitization
- Irritation
- Acute Systemic Toxicity
- Pyrogenicity
- Hemocompatibility

The results of the testing demonstrated that the subject Merit 10mL Syringe met the predetermined acceptance criteria applicable to the safety and efficacy of the device.

Summary of Substantial Equivalence

Based on the indications for use, design, safety and performance testing, the subject Merit 10mL Syringe meets the requirements that are considered essential for its intended use and is substantially equivalent to the predicate device, the Merit 20mL Syringe, K111091 manufactured by Merit Medical Systems, Inc..