



Food and Drug Administration
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December 7, 2015

Merit Medical Systems, Inc.
Mr. Cory Marsh
Senior Regulatory Affairs Specialist
1600 W Merit Parkway
South Jordan, Utah 84095

Re: K152783
Trade/Device Name: Merit 20 mL Syringe
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: II
Product Code: FMF
Dated: November 6, 2015
Received: November 9, 2015

Dear Mr. 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" (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 yours,

 Tina Kiang
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for 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

Indications for Use

510(k) Number (if known)

K152783

Device Name

Merit 20 mL Syringe

Indications for Use (Describe)

The Merit Medical 20 mL 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 of Preparation:	September 24, 2015
Registration Number:	1721504	

Subject Device	Trade Name:	Merit 20 mL Syringe
	Common/Usual Name:	Merit 20 mL Syringe
	Classification Name:	Piston Syringe

Predicate Device	Trade Name:	Merit 20 mL Syringe
	Classification Name:	Piston Syringe
	Premarket Notification:	K111091
	Manufacturer:	Merit Medical Systems, Inc.

Classification	Class 2
	21 CFR § 880.5860
	FDA Product Code: FMF
	Review Panel: General Hospital

Intended Use	The Merit Medical 20 mL Syringe is used to inject fluids into, or withdraw fluids from, the body.
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Device Description	The Merit 20 mL Syringe contains a calibrated hollow barrel into which is inserted a closely fitted movable plunger and tip or seal. The barrel contains an ISO 594-1/2 compliant fixed male luer connector, which is compatible with ISO 594-1/2 compliant female luer hubs.
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This submission addresses a minor material change to the silicone plunger tip/seal. The indications for use, principle of operation, and technological characteristics of the subject device are identical to the predicate device. The subject device is substantially equivalent to the predicate device.

**Comparison to
Predicate
Device**

Attribute	Predicate Device 20 mL Syringe	Subject Device 20 mL Syringe
Design	Standard three piece piston syringe constructed with a clear hollow barrel into which is inserted a closely fitting movable plunger and tip/seal.	Standard three piece piston syringe constructed with a clear hollow barrel into which is inserted a closely fitting movable plunger and tip/seal.
Material	The barrel is constructed from clear cyclo-olefin polymer; the plunger from polycarbonate or ABS material; the seal is made of silicone elastoseal material.	The barrel is constructed from clear cyclo-olefin polymer; the plunger from polycarbonate or ABS material; the seal is made of silicone elastoseal material.
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 20 mL.	Operational volume of 20 mL.
Graduation	Printed with accurate graduation lines that are numbered at 5 mL increments (5, 10, 15, 20), with graduation marks every 1 mL.	Printed with accurate graduation lines that are numbered at 5 mL increments (5, 10, 15, 20), with graduation marks every 1 mL.
Intended Use	The Merit 20 mL Syringe is used to inject fluids into, or withdraw fluids from, the body.	The Merit 20 mL Syringe is used to inject fluids into, or withdraw fluids from, the body.

Merit performed a risk analysis on the impact of the modifications made to the subject 20 mL Syringe. A cross-functional team, including members with clinical experience in the use of the type of device, assessed the potential clinical hazards to ensure risks have been addressed. Appropriate control and prevention mechanisms were defined to mitigate the risks. Design verification testing of the subject 20 mL Syringe was conducted to mitigate risks identified from the risk analysis and to comply with the following international standards/documents:

**Performance
Tests**

- ISO 7886-1:1993, *Sterile hypodermic syringes for single use – Part 1: Syringes for manual use [Including Technical Corrigendum 1 (1995)]*
- 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*
- 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 10993-7:2008, *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 delayed type hypersensitivity*
- 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
- AAMI TIR 28:2009, *Product adoption and process equivalency for ethylene oxide sterilization*
- 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*

Summary level test results have been provided in this submission and demonstrate that the subject 20 mL Syringe met the predetermined acceptance criteria applicable to the performance of the device.

**Summary of
Substantial
Equivalence**

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