



November 4, 2025

Merit Medical Systems, Inc.
Kirk McIntosh
Senior Regulatory Affairs Specialist
1600 West Merit Parkway
South Jordan, Utah 84095

Re: K250853

Trade/Device Name: Merit Syringe
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: Class II
Product Code: FMF
Dated: October 3, 2025
Received: October 6, 2025

Dear Kirk McIntosh:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see <https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products>); 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance>) and CDRH Learn (<https://www.fda.gov/training-and-continuing-education/cdrh-learn>). 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 (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Shruti N. Mistry -S

Shruti Mistry

Assistant Director

DHT3C: Division of Drug Delivery and General
Hospital Devices, and Human Factors

OHT3: Office of Gastrorenal, ObGyn,

General Hospital, and Urology Devices

Office of Product Evaluation and Quality

Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K250853

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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K250853 Merit Syringe 510(k) Summary

General Provisions	Submitter Name:	Merit Medical Systems, Inc.
	Address:	1600 West Merit Parkway South Jordan, UT 84095
	Telephone Number:	(801) 316-3695
	Contact Person:	Kirk McIntosh
	Date Prepared:	November 4, 2025
	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

Primary Predicate	Trade Name:	Merit Syringe
	Common/Usual Name:	Piston Syringe
	Classification Name:	Syringe, Piston
	Regulatory Class:	2
	Product Code:	FMF
	21 CFR §:	880.5860
	Premarket Notification:	K173601

Device Description	<p>The Merit Syringe a standard three-piece piston syringe intended for general purpose injection and aspiration by a qualified clinician. The syringe is constructed of a calibrated, hollow, clear polycarbonate barrel into which is inserted a closely fitted movable ABS plunger with black silicone rubber piston seal (tip). The barrel is marked with standard graduations per ISO 7886-1 requirements and contains an ISO 80369-7 compliant fixed male luer, small-bore connector. The subject device is single use and is available in either an ethylene oxide (EO) or gamma-sterile configuration.</p>
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Indications for Use	<p>The Merit Syringe is used to inject fluids into, and withdraw fluids from, the body.</p>
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Comparison to Predicate Device

The subject device is substantially equivalent to the predicate device based on an identical Indications for Use statement, the same basic performance and safety profile, principle of operation, fundamental design principles, similar materials of construction, and manufacturing technology.

The primary reason for submitting this Special 510(k) is the addition of a silicone tip/seal material formulation that has not been previously used in a similar syringe legally marketed by Merit Medical. This change has been evaluated through biocompatibility and performance testing.

Performance Data

FDA guidance and recognized consensus standards have been established for Piston Syringes under FDA Product Code FMF and 21 CFR 880.5860. Performance testing of the subject Merit Syringe was conducted per results of risk analysis and based on the requirements of the following international standards:

- ISO 7886-1:2017 *Sterile hypodermic syringes for single use – Part 1: Syringes for manual use*
 - ISO 10993-1:2018, *Biological Evaluation of Medical Devices Part 1: Evaluation and Testing within a risk management process*, and FDA guidance *Use of International Standard ISO 10993-1, “Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process”* (2020).
 - ISO 10993-4: 2017, *Biological Evaluation of Medical Devices Part-4: Selection of Tests for Interactions with Blood*
 - ISO 10993-5:2009 (Amd, 2017), *Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity*
 - ISO 10993-10:2021, *Biological evaluation of medical devices – Part 10: Tests for skin sensitization*
 - ISO 10993-11:2017, *Biological evaluation of medical devices – Part 11: Tests for systemic toxicity*
 - ISO 10993-23:2021, *Biological evaluation of medical devices – Part 23: Tests for irritation*
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Safety & Performance Tests

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility testing

The subject Merit Syringe is categorized as externally communicating medical devices with indirect blood contact for a limited (<24 hours) duration.

The biocompatibility evaluation for the subject Merit Syringe was conducted in accordance with ISO 10993-1 (2018), *Biological Evaluation of Medical Devices- Part 1: Evaluation and testing within a risk management process* and the FDA guidance document, *Use of International Standard ISO 10993-1, “Biological evaluation of medical*

devices – Part 1: Evaluation and testing within a risk management process” (2020). The battery of testing included the following tests:

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

Performance Testing-Bench

The subject Merit Syringe was tested per the requirements of the FDA recognized ISO 7886-1 consensus standard applicable to the change to the syringe tip/seal material. Applicable testing from the standard included:

- Fit of Piston
- Liquid Leakage
- Air leakage
- Separation of Piston/Plunger (Tip Detachment)
- Force to Operate Piston

The results of the testing demonstrated that the subject Merit Syringe met the predetermined acceptance criteria applicable to the safety and effectiveness of the device when compared to the predicate device.

Summary of Substantial Equivalence

Based on the indications for use, design, safety and performance testing, the subject Merit Syringe meets the requirements that are considered essential for their intended use and is substantially equivalent to the predicate Merit Syringe, K173601, manufactured by Merit Medical Systems, Inc.
