February 16, 2024

Medline Industries, LP
Kelsey Closen
Regulatory Affairs Specialist
Three Lakes Drive
Northfield, Illinois 60093

Re: K230235
Trade/Device Name: Medline Luer Lock Syringes
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: Class II
Product Code: FMF
Dated: February 13, 2024
Received: February 14, 2024

Dear Kelsey Closen:

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.

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
Division of Drug Delivery and
General Hospital Devices, and Human Factors
Office of Gastrorenal, ObGyn,
General Hospital, and Urology Devices
Office of Product Evaluation and Quality
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K230235

Device Name
Medline Luer Lock Syringes

Indications for Use *(Describe)*
Medline Luer-Lock Syringes are intended for use by healthcare professionals for general purpose fluid aspiration/ injection. Intended for manual use.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

Medline Industries, LP
Three Lakes Drive
Northfield, IL 60093

K230235 510(k) SUMMARY
[AS REQUIRED BY 21CFR807.92(c)]

Submitter / 510(k) Sponsor
Medline Industries, LP
Three Lakes Drive
Northfield, IL 60093

Registration Number: 1417592

Contact Person
Contact Person: Kelsey Closen, Regulatory Affairs Specialist
Phone: 847-949-2283
Email: KClosen@medline.com

Summary Preparation Date
February 16th 2024

Type of 510(k) Submission
Traditional

Device Name / Classification
Trade Name: Medline Luer Lock Syringes
Common Name: Piston Syringe
Classification Name: Syringe, Piston
Product Code: FMF
Classification Panel: General Hospital
Regulatory Class: II
Regulation Number: 21 CFR 880.5860

Predicate Device
BD Plastipak Syringe, K182589

Device Description
Medline Luer Lock Syringes are Rx, sterile, non-pyrogenic, single use syringes intended to be used to inject fluids into or withdraw fluids from, the body. The syringe consists of a luer lock tip, graduated barrel, a plunger rod and stopper. The barrel has gradient markings (mL) and the male luer lock tip allows the user to attach to a hypodermic needle or administration line. The plunger is pulled back to aspirate fluids or depressed to inject or expel fluids. Medline Luer Lock Syringes are available in 3mL, 5mL, 10mL, 20mL, 30mL and 60mL.

Medline Industries, LP
Three Lakes Drive
Northfield, IL 60093

.

Indications for Use

Medline Luer-Lock Syringes are intended for use by healthcare professionals for general purpose fluid aspiration/ injection. Intended for manual use.

Summary of Technological Characteristics

TABLE 1: COMPARISON OF PROPOSED AND PREDICATE DEVICES

Device Characteristic	Proposed Device	Predicate Device	Comparison Analysis
Product Name	Medline Luer Lock Syringe	BD Plastipak Syringe	N/A
510(k) Reference	K230235	K182589	N/A
Product Owner	Medline Industries, LP	Becton, Dickinson and Company	N/A
Product Code	FMF	FMF	Same
Intended Use / Indications for Use	Medline Luer-Lock Syringes are intended for use by healthcare professionals for general purpose fluid aspiration/ injection. Intended for manual use.	The BD Plastipak™ Syringe is intended for single use by health care professionals for general purpose fluid aspiration/injection	Same
Mode of Action	Intended for manual use	Intended for manual use and use with power driven syringe pumps	Different – *Medline syringe will be used for manual use. This does not raise new question of safety and effectiveness.*
Regulation Number	21 CFR 880.5860	21 CFR 880.5860	Same
Syringe Type	Piston Syringe	Piston Syringe	Same
Design Features	- Luer Lock - Graduated Barrel - 3 parts: Piston, Barrel, Stopper	- Luer Slip or Luer Lock - Graduated Barrel - 3 parts: Piston, Barrel, Stopper	Different- *Medline Luer Lock Syringe will not be offered in Luer Slip*
Nozzle/Tip Type	Luer Lock, ISO 80369-7	Luer Lock, ISO 80369-7	Same
Barrel Markings Specs	- Graduated Scale	- Graduate Scale	Same
Gradation Legibility	- Bold Markings	- Bold Markings	Same
Material	- Barrel = Polypropylene	- Barrel = Polypropylene	Different – *The raw material of the Stopper varies slight between the proposed and predicate device. This does not*

Medline Industries, LP
Three Lakes Drive
Northfield, IL 60093

	- Stopper = Synthetic Rubber - Plunger = Polypropylene - Lubricant = Silicone Oil	- Stopper = thermoplastic elastomer - Plunger = Polypropylene - Lubricant = Silicone Oil	*impact the safety or performance of the device per testing.*
Design Standards	- Luer Lock tip to ISO 80369-7 - Syringe to ISO 7886-1	- Syringe to ISO 7886-1 and 7886-2	Different – *Medline Luer Lock Syringes are also designed to ISO 80369-7. This does not impact the safety or performance of the device*
Volume	3mL 5mL 10mL 20mL 30mL 60mL	3mL 20mL	Different - *Medline Luer Lock Syringes are available in additional configurations, the additional configurations do not cause any additional risks or concerns based on performance testing*
Prescription vs. OTC	Rx	Rx	Same
Shelf Life	5 years	5 years	Same
Sterilization Method	EO	EO	Same
Sterile vs. Non-Sterile	Sterile	Sterile	Same
SAL	10^{-6}	10^{-6}	Same
Disposable vs. Non-Disposable	Disposable	Disposable	Same
Single Use vs. Reusable	Single Use	Single Use	Same
Operational Principles	Three-piece piston syringe. Plunger is used to fill syringe as well as discharge the fluid for both manual and pump driven operation.	Three-piece piston syringe. Plunger is used to fill syringe as well as discharge the fluid for both manual and pump driven operation.	Same
Lubricant Composition	Silicone Oil	Silicone Oil	Same
Barrel Transparency	Clear	Clear	Same

Medline Industries, LP
Three Lakes Drive
Northfield, IL 60093

Physical and Mechanical	ISO 7886-1	ISO 7886-1 ISO 7886-2	Same
Biocompatibility	ISO 10993	ISO 10993	Same
Labeling	Complied with 21 CFR part	Complied with 21 CFR part	Same

Summary of Non-Clinical Testing

Biocompatibility Testing

The biocompatibility evaluation for the Medline Luer Lock Syringes was conducted in accordance with FDA guidance document, Use of International Standard ISO 10993, *"Biological Evaluation of Medical Devices Part 1: Evaluation and Testing",* ISO 10993-1 *Biological Evaluation of the Medical Devices – Part 1: Evaluation of Testing within a Risk Management Process."*

The following biocompatibility testing was performed:

- 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 10993-11:2017 Biological Evaluation of Medical Devices - Part 11: Tests for Systemic Toxicity
- ISO 10093-4 and ASTM F756-17 Hemolysis Assay
- USP 151 Material Mediated Pyrogenicity

Performance Testing (Bench)

Performance testing on the Medline Luer Lock Syringes was conducted for compliance with the below standards:

- ISO 7886-1:2017 Sterile hypodermic syringes for single use - Part 1: Syringes for manual Use
- ISO 80369-7: 2016 Small –Bore Connectors For Liquids and Gasses in Healthcare applications - Part 7: Connectors for intravascular or hypodermic applications

Performance Testing (Animal)

This section does not apply. No animal testing was performed.

Performance Testing (Clinical)

This section does not apply. No clinical testing was performed.

Medline Industries, LP
Three Lakes Drive
Northfield, IL 60093

Other Testing

The following additional testing was performed:

- Particulate Matter Testing in accordance with USP <788> Particulate Matter in Injections
- Limulus Amebocyte Lysate (LAL) Bacterial Endotoxin Testing in accordance with USP Bacterial Endotoxin Testing

Summary of Clinical Testing

Not applicable.

Conclusion

In accordance with 21 CFR Part 807, and based on the information provided in this premarket notification, Medline Industries, Inc. concludes that the Medline Luer Lock Syringes are as safe and as effective for their intended use as the predicate device BD Plastipak Syringe, K182589.