October 18, 2023

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

Re: K231907
Trade/Device Name: Medline Safety Insulin and TB Syringes
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: Class II
Product Code: FMF, MEG
Dated: July 21, 2023
Received: July 21, 2023

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, Juliane C. Lessard -S

Juliane C. Lessard, Ph.D.
Director
DHT3C: Division of Drug Delivery and
General Hospital Devices,
and Human Factors
OHT3: Office of Gastrorenal, ObGyn,
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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)*
K231907

Device Name
Medline Safety Insulin and TB Syringes

Indications for Use *(Describe)*
The Medline Safety Insulin Syringe is intended for the delivery of U-100 insulin. The needle stick prevention feature of the device, once activated, guards against accidental needle-sticks.

The Medline TB (Tuberculin) Syringe is intended for the delivery of tuberculin. The needle stick prevention feature of the device, once activated, guards against accidental needle-sticks.

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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K231907- 510(k) SUMMARY

Submitter / 510(k) Sponsor

Medline Industries, LP
Three Lakes Drive
Northfield, IL 60093

Contact Person

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

Summary Preparation Date

October 19th 2023

Type of 510(k) Submission

Traditional

Device Name / Classification

Trade Name: Medline Safety Insulin and TB Syringes
Common Name: Tuberculin and Insulin Safety Syringes
Classification Name: Syringe, Antistick and Syringe, Piston
Product Code: MEG and FMF
Classification Panel: General Hospital
Regulatory Class: II
Regulation Number: 21 CFR 880.5860

Predicate Device

Predicate Device: K061492, Kendall Monoject® Magellan Insulin and Tuberculin Safety Syringe

Device Description

The Medline Safety Insulin Syringe is a sterile, single-use device, intended for prescription-use only, and is labeled for delivery of U-100 Insulin. The proposed device consists of the following components: (1) a syringe barrel with a permanently attached single lumen needle; (2) a plunger; (3) a needle cap; and (4) a manually operated safety feature (i.e. shield) at the needle end of the syringe. The proposed device functions by mechanical action to deliver insulin. The syringe consists of a plunger that fits within the syringe barrel. The plunger can be linearly pulled and pushed along the inside of the barrel, allowing the syringe to take in and dispense insulin through the needle. The segmented safety shield is designed to be extended over the needle and locked. Activation is performed by a manual operation by extending

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the shield to cover the needle. Once activated, the safety shield is securely and permanently locked with a twisting motion. The Medline Safety Insulin Syringe barrel contains major and minor graduated ink markings and will be available in a 1 ml (100 units), and 0.5 ml (50 units) syringe volumes with three different needle gauge sizes.

The Medline TB Syringe is a sterile, single-use device, intended for prescription-use only, and is labeled for Tuberculin use. The proposed device consists of the following components: (1) a syringe barrel with a permanently attached single lumen needle; (2) a plunger; (3) a needle cap; and (4) a manually operated safety feature (i.e. shield) at the needle end of the syringe. The proposed device functions by mechanical action to deliver tuberculin. The syringe consists of a plunger that fits within the syringe barrel. The plunger can be linearly pulled and pushed along the inside of the barrel, allowing the syringe to take in and dispense tuberculin through the needle. The segmented safety shield is designed to be extended over the needle and locked. Activation is performed by a manual operation by extending the shield to cover the needle. Once activated, the safety shield is securely and permanently locked with a twisting motion. The syringe barrel contains graduated markings, with major graduation markings every 0.05mL and minor graduation markings every 0.01mL. The Medline TB Syringe will be available in a 1 mL syringe volume with three different needle sizes.

Indications for Use

The Medline Safety Insulin Syringe is intended for the delivery of U-100 insulin. The needle stick prevention feature of the device, once activated, guards against accidental needle-sticks.

The Medline TB (Tuberculin) Syringe is intended for the delivery of tuberculin. The needle stick prevention feature of the device, once activated, guards against accidental needle-sticks.

Summary of Technological Characteristics

TABLE 1: COMPARISON OF PROPOSED AND PREDICATE DEVICES

Device Characteristic	**Proposed Device** Medline Safety Insulin and TB Syringes K231907	**Predicate Device** Kendall Monoject Magellan and Tuberculin Insulin Safety Syringe K061492	**Comparison Analysis**
Product Code	MEG and FMF	FMF	*Similar-* *See comment #1*
Regulation Number	21CFR 880.5860	21CFR 880.5860	Same
Intended Use	Insulin Syringe: The device is intended for the delivery of U-100 insulin. The needle stick prevention feature of the device, once activated, guards against accidental needle-sticks.	Insulin Syringe: The device is intended for the delivery of U-100 insulin. The needle stick prevention feature of the device, once activated, guards against accidental needle-sticks.	Same

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	TB Syringe: The device is intended for the delivery of Tuberculin. The needle stick prevention feature of the device, once activated, guards against accidental needle-sticks.	TB Syringe: The device is intended for the delivery of Tuberculin. The needle stick prevention feature of the device, once activated, guards against accidental needle-sticks.	
Design Features	-Manually operated safety feature to prevent accidental needle sticks. -Graduation markings	-Manually operated safety feature to prevent accidental needle sticks. -Graduation markings	Same
Mechanism of Action	Insulin Syringe: Mechanical delivery of U-100 insulin. Needle-stick prevention feature is mannually activated by the user by a finger-tip or thumb operation. TB Syringe: Mechanical delivery of tuberculin. Needle-stick prevention feature is manually activated by the user by a finger-tip or thumb operation	Insulin Syringe: Mechanical delivery of U-100 insulin. Needle-stick prevention feature is mannually activated by the user by a finger-tip or thumb operation. TB Syringe: Mechanical delivery of tuberculin. Needle-stick prevention feature is manually activated by the user by a finger-tip or thumb operation	Same
Components	Sterile Syringe Single lumen needle Safety sheild/feature	Sterile Syringe Single lumen needle Safety sheild/feature	Same
Prescription vs. OTC	Prescription Use Only	Prescription Use Only	Same
Sterile vs. Non-Sterile	Sterile	Sterile	Same
Sterilization Method	EO	EO	Same
Shelf life	5 years	5 years	Same
Single Use vs. Reusable	Single Use	Single Use	Same
Non-pyrogenic	Yes	Yes	Same
Size Configurations	Insulin Syringes: 1ml Syringe w/ Needle, 29G x 0.5in 1ml Syringe w/ Needle, 30G x 5/16in *1ml Syringe w/ Needle, 31G x 5/16in* ***1ml Syringe w/ Needle, 31G x 6mm*** 0.5ml Syringe w/ Needle, 29G x 0.5in 0.5ml Syringe w/ Needle, 30G x 5/16in *0.5ml Syringe w/ Needle, 31G x 5/16in* ***0.5ml Syringe w/ Needle, 31G x 6mm*** TB Syringes:	Insulin Syringes: 1ml Syringe w/ Needle, 29G x 0.5in 1ml Syringe w/ Needle, 30G x 5/16in 0.5ml Syringe w/ Needle, 29G x 0.5in 0.5ml Syringe w/ Needle, 30G x 5/16in 0.3ml Syringe w/ Needle, 29G x 0.5in 0.3 ml Syringe w/ Needle, 30G x 5/16in TB Syringes: 1 mL syringe w/ needle 25Gx5/8" (0.508mm x 1.6cm)	Different – See comment # 2 ***Reference agency cleared 1ml syringes with needle in 31G x6mm and 0.5ml syringe with needle, 31G x6mm (K220061)***

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	1 mL Tuberculin Safety Syringe with Needle, 25Gx5/8" (0.508 x 1.6 cm) *1 mL Tuberculin Safety Syringe with Needle, 27Gx1/2" (0.356 mm x 1.3 cm)* 1 mL Tuberculin Safety Syringe with Needle, 28 G x 1/2" (0.356 mm x 1.3 cm	1 mL syringe w/ needle, 28 Gx1/2" (0.356mm x 1.3cm)	
Lubricant	Silicone	Silicone	Same
Needle Cap Color	Insulin: Orange TB: Red, Grey and Brown	Insulin: Orange TB: Orange, Red, Brown and Grey	Similar – see comment #3
Device Materials (barrel and shield)	Polypropylene and Polyethylene	Polypropylene and Polyethylene	Same

Discussions of differences in technological characteristics

- *Comment #1 Medline also has MEG as a product code since the proposed devices make an anti-stick claim. Both of these product codes are defined by the same FDA regulation number (21 CFR 880.5860), and this difference does not impact Medline's ability to claim substantial equivalence.*

- *Comment # 2- Reference device cleared TB syringe 1mL with needle, 27Gx ½", Insulin syringe 1mL with needle 31G x 5/16" and 0.5ml, 31Gx5/16" (K153537). Reference device cleared 1mL syringes with needle in 31Gx 6mm (k220061). The addition of 27Gx1/2", Insulin syringe 1mL with needle 31G x 5/16" and 0.5ml 31G x5/16 including the 1ml with needle in 31Gx6mm does not raise different questions of safety and effectiveness than the predicate device.*

- *Comment #3- The TB syringe cap colors are different among the proposed device and predicate device. Biocompatibility on the caps was conducted and supports that this difference does not impact the safety and effectiveness of the device to claim substantially equivalent to the predicate.*

Shelf Life and Sterilization

The proposed Medline Safety Insulin and TB Syringe is terminally sterilized by Ethylene Oxide (EO). The sterilization validation for the proposed device has been conducted in accordance with ISO 11135:2014, *Sterilization of Health Care Products – Ethylene Oxide – Requirements for Development, Validation, and Routine Control of a Sterilization Process for Medical Devices*, to ensure a Sterility Assurance Level (SAL) of 1 x 10^{-6}. The proposed device has also been evaluated for EO and Ethylene Chlorohydrin (ECH) residuals in accordance with ISO 10993-7:2008(R)2012, *Biological Evaluation of Medical Devices – Part 7: Ethylene Oxide Sterilization Residuals.*

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Additionally, in accordance with ASTM F1980-16, *Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices*, aging studies have been conducted to verify a five-year shelf life of the subject device and ensure that its functionality and sterility are successfully maintained throughout the duration of this shelf life. For additional information on the sterilization and shelf life of the proposed device, please refer to Section 14 of this submission. Test articles also underwent transportation-testing method, ISTA-3A:2008 and underwent a drop, vibration with top load, vibration without top load and a second drop test. After distribution stimulation, the test articles were tested to ASTM F1929:2015, Resistance to Dye Penetration.

Summary of Non-Clinical Performance Testing

Non-clinical verification of the Medline Safety Insulin and TB Syringes has been conducted to evaluate its safety, performance, and functionality. The results of these tests have demonstrated the overall safety of the proposed device and its effectiveness in accordance with relevant test methods, and ultimately support a substantial equivalence determination. Particularly, the following was conducted to adequately demonstrate the effectiveness of the proposed device in accordance with relevant test methods cited below:

Chemical Safety Testing

- Particulate Matter Testing in accordance with USP <788> *Particulate Matter in Injections*
- Phthalate Testing
- Limulus Amebocyte Lysate (LAL) Bacterial Endotoxin Testing in accordance with USP <85> *Bacterial Endotoxin Testing*

Functional Performance Testing

- Visual Appearance Testing in accordance with ASTM F1886:2016 *Standard Test Method For Determining Integrity Of Seals For Flexible Packaging By Visual Inspection*
- Package Integrity Testing in accordance with ASTM F1929-15 *Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration*
- Seal Strength Testing in accordance with ASTM F88-21 *Test Method for Seal Strength of Flexible Barrier Materials*
- ISO 8537:2016 *Sterile Single-Use Syringes, With or Without Needles, for Insulin*
- ISO 23908:2011 *Sharps Injury Protection – Requirements and Test Methods – Sharps Protection Features for Single Use Hypodermic Needles, Introducers for Catheters and Needles Uses for Blood Sampling*
- ISO 7864:2016 *Sterile Hypodermic Needles for Single Use – Requirements and Test Methods*
- ISO 9626:2016 *Stainless Steel Needle Tubing for the Manufacturing of Medical Devices – Requirements and Test Methods*
- ISO 7886-1:2017 *Sterile Hypodermic Syringes for Single Use – Part 1: Syringes for Manual Use*

Usability Testing

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In accordance with the FDA guidance document *Medical Devices with Sharps Injury Prevention Features*, a simulated clinical use (i.e. usability) testing was conducted using the Medline Safety Insulin and TB Syringes.

Biocompatibility Testing

The biocompatibility evaluation for the Medline Safety Insulin and TB Syringes was conducted in accordance with ANSI/AAMI/ISO 10993-1:2018 *Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing within a Risk Management Process*, as recognized by FDA. The proposed device is classified as an externally communicating with prolonged, indirect blood contact. Final biocompatibility test protocols and reports are available for the Agency's review in Appendix D.

- Cytotoxicity in accordance with ISO 10993-5:2009 *Biological Evaluation of Medical Devices-Part 5: Tests for in vitro Cytotoxicity*
- Sensitization in accordance with ISO 10993-10:2010 *Biological Evaluation of Medical Devices-Part 10: Test for Irritation and Skin Sensitization*
- Irritation in accordance with ISO 10993-10:2010 *Biological Evaluation of Medical Devices-Part 10: Tests for Irritation and Skin Sensitization*
- Acute Systemic Toxicity in accordance with ISO 10993-11:2017 *Biological Evaluation of Medical Devices-Part 11: Tests for Systemic Toxicity*
- Hemolysis Assay in accordance with ASTM F756-17 *Standard Practice for Assessment of Hemolytic Properties of Materials* and ISO 10993-Part 4:2017 *Biological Evaluation of Medical Devices-Part 4: Selection of Tests for Interactions with Blood*
- Material-Mediated Pyrogenicity in accordance with USP <151> *Rabbit Pyrogen Test* as recommended in ISO 10993-11:2017 *Biological Evaluation of Medical Devices-Part 11: Tests for Systemic Toxicity*
- Subacute/ Subchronic Toxicity in accordance with ISO 10993-11:2017 *Biological Evaluation of Medical Devices-Part 11: Tests for Systemic Toxicity*
- Complement Activation in accordance with ISO 10993-4: 2017 *Biological Evaluation of Medical Devices-Part 4: Selection of Tests for Interactions with Blood.*
- Partial Thromboplastin Time in accordance with ISO 10993-4 *Biological Evaluation of Medical Devices-Part 4: Selection of Tests for Interactions with Blood.*
- Platelet and Leukocyte Counts in accordance with ISO 10993-4:2017 *Standard Biological Evaluation of Medical Devices, Part 4 – Selection of Tests for Interaction with Blood.*

Summary of Clinical Testing

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Not applicable.

Conclusion

The difference between the predicate and the subject device do not raise any new or different questions of safety or effectiveness. The Medline Safety Insulin and TB Syringes are substantially equivalent to the Kendall Monoject Magellan Insulin and Tuberculin Safety Syringe with respect to the indications for use, target populations, treatment method, and technological characteristics.