



February 18, 2026

Methyl Co., Ltd.  
Stephanie Hsieh  
Assistant Manager  
7F.-2, No. 1, Guangfu S. Rd.  
Taipei, 105  
Taiwan

Re: K252098

Trade/Device Name: PA3X Detachable Safety Sleeve Syringe (with needle) (SC-23ED / SD-23ED)  
Regulation Number: 21 CFR 880.5860  
Regulation Name: Piston Syringe  
Regulatory Class: Class II  
Product Code: MEG, FMI  
Dated: January 16, 2026  
Received: January 16, 2026

Dear Stephanie Hsieh:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 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 Management System Regulation (QMSR) (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](mailto: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)

K252098

Device Name

PA3X Detachable Safety Sleeve Syringe (with needle) (SC-23ED / SD-23ED)

Indications for Use (Describe)

This product is designed for medical applications, specifically to administer injections or extract body fluids. It can be used to inject drug solutions into tissues or aspirate body fluids. To prevent the possibility of needle pricks, the safety device can be engaged to secure the injection needle within a removable outer sleeve.

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.

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## **510(k) SUMMARY – K252098**

Prepared in accordance with 21 CFR 807.92

### **I. Submitter Information**

**Submitter:** Methyl Co., Ltd.

**Address:** 7F-2, No.1, Kuang-Fu South Road, Taipei 105, Taiwan

**Contact Person:** Stephanie Hsieh

**Date Prepared:** February 13, 2026

**510(k) Number:** K252098

**Type of Submission:** Traditional 510(k)

### **II. Device Identification**

**Trade Name:** PA3X Detachable Safety Sleeve Syringe (with needle) (SC-23ED / SD-23ED)

**Common Name:** Safety Syringe with Needle

**Classification Name:** Piston Syringe; Hypodermic Single Lumen Needle

**Regulation Numbers:** 21 CFR 880.5860; 21 CFR 880.5570

**Regulatory Class:** Class II

**Product Codes:** MEG; FMI

### **III. Predicate Device**

**Primary Predicate Device:** TERUMO® SurGuard®3 Hypodermic Syringe with Safety Needle

**510(k) Number:** K113422

**Regulation Numbers:** 21 CFR 880.5860; 21 CFR 880.5570

**Product Codes:** MEG; FMI

### **IV. Device Description**

The PA3X Detachable Safety Sleeve Syringe is a sterile, single-use manual piston syringe with an integrated hypodermic needle and a manually activated safety mechanism intended to reduce the risk of needlestick injuries following use.

The device consists of:

- Polypropylene barrel
- Polypropylene plunger
- Rubber gasket
- Polypropylene needle hub
- Stainless steel needle
- Needle cap
- Polypropylene detachable outer sleeve safety mechanism

Following injection or aspiration, the outer sleeve is manually advanced to cover and lock over the needle to provide post-use sharps protection.

The device is available in:

- 3 mL (23G × 1-inch needle)
- 5 mL (23G × 1-inch needle)

The device is sterilized using ethylene oxide and supplied sterile for single use.

## V. Indications for Use

This product is designed for medical applications, specifically to administer injections or extract body fluids. It can be used to inject drug solutions into tissues or aspirate body fluids. To prevent the possibility of needle pricks, the safety device can be engaged to secure the injection needle within a removable outer sleeve.

The intended use of the subject device is the same as that of the predicate device.

## VI. Comparison of Technological Characteristics

Characteristic	Subject Device	Primary Predicate Device (K113422)	Same/Different
Manufacturer	Methyl Co., Ltd.	TERUMO (PHILIPPINES) CORPORATION	N/A
Product Name	PA3X Detachable Safety Sleeve Syringe	TERUMO® SurGuard®3 Hypodermic Syringe with Safety Needle	N/A
Model Number	SC-23ED, SD-23ED	SG3-series (multiple models)	N/A
K Number	K252098	K113422	N/A
Regulation Number	21 CFR 880.5860; 21 CFR 880.5570	21 CFR 880.5570; 21 CFR 880.5860	Same
Product Code	MEG, FMI	MEG, FMI	Same
Indications for Use	This product is designed for medical applications, specifically to administer injections or extract body fluids. It can be used to inject drug solutions into tissues or aspirate body fluids. To prevent the possibility of needle pricks, the safety device can be engaged to secure the injection needle within a removable outer sleeve.	The TERUMOO SurGuard®3 Safety Needle device is intended for use in the aspiration and injection of fluids for medical purposes. The TERUMO SurGuard®3 Safety Needle is compatible for use with standard luer slip and luer lock syringes. Additionally, after withdrawal of the needle from the body, the attached needle safety	Same

		shield can be manually activated to cover the needle immediately after use to minimize risk of accidental needlestick	
Configuration	Barrel, plunger, gasket, needle hub, needle cap, injection needle, outer sleeve	Barrel, plunger, gasket, needle cap, needle tube, needle hub, sheath lock	Different
Syringe Volume	3mL, 5mL	3mL, 5mL, 10mL	Different
Connection Type	Luer Slip	Luer Slip and Luer Lock	Different
Needle Gauge	23G	18G, 20G, 21G, 22G, 23G, 25G	Different (subset)
Needle Length	1"	1", 1½", 2"	Different (subset)
Needle Wall Type	Regular wall	Thin wall	Different
Materials: Needle Cap	PP	PP	Same
Materials: Safety Mechanism Component	Outer sleeve (PP)	Sheath lock (PP)	Different (design); Same (material)
Materials: Injection Needle	SUS 304 Stainless Steel	Stainless Steel	Same
Materials: Needle Hub	PP	PP	Same
Materials: Barrel	PP	PP	Same
Materials: Gasket	Rubber	Rubber	Same
Materials: Plunger	PP	PP	Same
DEHP/PVD/BPA Free	Yes	Yes	Same
Latex Free	Yes	Yes	Same
Sterilization Method	Ethylene Oxide (EO)	Radiation	Different
Shelf Life	3 years	5 years	Different

Performance Standards: Syringe Performance	ISO 7886-1:2017	ISO 7886-1:2017	Same
Performance Standards: Needle Performance	ISO 7864:2016; ISO 9626:2016	ISO 7864:2016; ISO 9626:2016	Same
Performance Standards: Luer Connector	ISO 80369-7:2021	ISO 80369-7:2021	Same
Performance Standards: Sharps Protection	ISO 23908:2024	ISO 23908	Same
Biocompatibility: Cytotoxicity	No cytotoxicity (ISO 10993-5)	No cytotoxicity	Same
Biocompatibility: Irritation	No intracutaneous reactivity (ISO 10993-23)	No intracutaneous reactivity	Same
Biocompatibility: Sensitization	No sensitization (ISO 10993-10)	No sensitization	Same
Biocompatibility: Systemic Toxicity	No systemic toxicity (ISO 10993-11)	No systemic toxicity	Same
Biocompatibility: Hemolysis	No hemolysis (ISO 10993-4)	No hemolysis	Same
Biocompatibility: Pyrogen	No pyrogen (USP <151>, <85>)	No pyrogen	Same

## **VII. Discussion of Differences**

### ***Indications for Use***

The subject device Indications for Use statement contains minor wording differences compared to the predicate device; however, both devices are intended for the aspiration and injection of fluids for medical purposes with an integrated safety mechanism to reduce needlestick injuries. Both devices are classified under the same regulations and product codes. The wording differences do not alter the fundamental intended use and do not raise new questions of safety and effectiveness when compared to the predicate device.

### ***Safety Mechanism Design***

The subject device utilizes a detachable outer sleeve safety mechanism, whereas the predicate device employs a hinged sheath lock mechanism. Although the mechanical configurations differ, both designs provide manually activated post-use needle coverage and are constructed of similar polymeric materials. Performance testing conducted in accordance with recognized sharps injury protection

standards demonstrates effective needle shielding and activation reliability. The difference in safety mechanism design does not alter the intended use or fundamental protective function and does not raise new questions of safety and effectiveness when compared to the predicate device.

### ***Syringe Volume***

The subject device is available in 3 mL and 5 mL volumes, whereas the predicate device includes an additional 10 mL configuration. The subject device volumes represent a subset of the predicate device's available configurations. Performance testing conducted in accordance with ISO 7886-1 demonstrates compliance with dimensional accuracy, leakage resistance, and functional performance requirements. This difference does not raise new questions of safety and effectiveness when compared to the predicate device.

### ***Connection Type***

The subject device is available with a Luer Slip connection only, while the predicate device offers both Luer Slip and Luer Lock configurations. The subject device has been evaluated for compliance with ISO 80369-7 requirements for small-bore connectors. The absence of a Luer Lock option represents a subset configuration and does not alter the intended use or raise new questions of safety and effectiveness when compared to the predicate device.

### ***Needle Specifications***

The subject device is available in a 23G × 1-inch configuration, whereas the predicate device includes additional gauge and length options. The subject device specifications fall within the predicate device's available range. Testing conducted in accordance with ISO 7864 and ISO 9626 demonstrates compliance with applicable dimensional and mechanical requirements. These differences represent a subset of the predicate configurations and do not raise new questions of safety and effectiveness when compared to the predicate device.

### ***Sterilization Method***

The subject device is sterilized using ethylene oxide, while the predicate device is sterilized using radiation. Ethylene oxide sterilization has been validated in accordance with ISO 11135 to achieve a sterility assurance level of  $10^{-6}$ . Both sterilization methods are recognized for single-use sterile medical devices. This difference does not raise new questions of safety and effectiveness when compared to the predicate device.

### ***Shelf Life***

The subject device demonstrates a 3-year shelf life, compared to the predicate device's 5-year shelf life. The shelf-life claim is supported by stability and aging studies conducted in accordance with applicable standards. The shorter shelf life does not raise new questions of safety and effectiveness when compared to the predicate device.

## **VIII. Non-Clinical Testing**

Testing demonstrates compliance with the following recognized standards:

### **Performance Standards**

- ISO 7886-1:2017 – Sterile hypodermic syringes for single use — Part 1: Syringes for manual use
- ISO 7864:2016 – Sterile hypodermic needles for single use — Requirements and test methods
- ISO 9626:2016 – Stainless steel needle tubing for the manufacture of medical devices — Requirements and test methods
- ISO 23908:2024 – Sharps injury protection — Requirements and test methods
- ISO 80369-7:2021 – Small-bore connectors for liquids and gases in healthcare applications — Part 7: Connectors for intravascular or hypodermic applications

### **Biocompatibility Standards**

- ISO 10993-1:2018 – Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process
- ISO 10993-5 – Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity
- ISO 10993-4 – Biological evaluation of medical devices — Part 4: Selection of tests for interactions with blood
- ISO 10993-10 – Biological evaluation of medical devices — Tests for skin sensitization
- ISO 10993-23 – Biological evaluation of medical devices — Tests for irritation
- ISO 10993-11 – Biological evaluation of medical devices — Part 11: Tests for systemic toxicity

### **Sterilization and Shelf-Life Standards**

- 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
- ASTM F1980 – Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
- USP <85> – Bacterial Endotoxins Test
- USP <151> – Pyrogen Test
- USP <788> – Particulate Matter in Injections

Testing demonstrated compliance with applicable requirements.

## **IX. Conclusion**

The subject device has the same intended use and fundamental scientific technology as the predicate device (K113422). Identified differences in safety mechanism design, available configurations, sterilization method, and shelf life have been evaluated through appropriate testing and do not raise new questions of safety or effectiveness when compared to the predicate device.

The PA3X Detachable Safety Sleeve Syringe is substantially equivalent to the predicate device.