November 20, 2024

Sol-Millennium Medical Inc.
% Tanya Wang, Technical Manager
Shanghai Mind-link Consulting Co. Ltd
1399 Jiangyue Road, Minhang
Shanghai, Shanghai 201114, China

Re: K242291
Trade/Device Name: SOL-M Luer Lock Syringe (Low Dead Space) w/o Needle, SOL-M Slip Tip Syringe (Low Dead Space) w/o needle, SOL-M Luer Lock Syringe (Low Dead Space) w/Exchangeable Needle, SOL-CARE Luer Lock Syringe (Low Dead Space) w/Safety Needle, SOL-M Slip Tip Syringe (Low Dead Space) w/Exchangeable Needle
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: Class II
Product Code: QNQ
Dated: October 22, 2024
Received: October 22, 2024

Dear Tanya Wang:

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

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)*
K242291

Device Name
SOL-M Luer Lock Syringe (Low Dead Space) w/o Needle, SOL-M Slip Tip Syringe (Low Dead Space) w/o needle, SOL-M Luer Lock Syringe (Low Dead Space) w/Exchangeable Needle, SOL-CARE Luer Lock Syringe (Low Dead Space) w/Safety Needle, SOL-M Slip Tip Syringe (Low Dead Space) w/Exchangeable Needle

Indications for Use *(Describe)*
The Luer Lock/Slip Tip Syringe (Low Dead Space) without needle is to inject fluids into, or withdraw fluids from, the body.

The Luer Lock/Slip Tip Syringe (Low Dead Space) with exchangeable needle is used to inject fluids into, or withdraw fluids from, the body.

The Luer Lock Syringe (Low Dead Space) with Safety needle is used to inject fluids into, or withdraw fluids from, the body. The safety mechanism covers the needle after use. In the activated position, the protective arm guards against accidental needle stick during normal handling and disposal of the used needle/syringe combination.

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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K242291 510(k) Summary

1. **Preparation date: November 20, 2024**

2. **Submitter**
   Manufacturer: Sol-Millennium Medical Inc.
   Address: 311 S Wacker Drive Suite 4100
   Contact person: Manu Kalia, +1 847-313-9577, mkalia@sol-m.com
   Submission correspondent: Tanya Wang, +86-15216694647, tanya.wang@mind-link.net

3. **Device**
   Trading name: SOL-M Luer Lock Syringe (Low Dead Space) w/o Needle
   SOL-M Slip Tip Syringe (Low Dead Space) w/o needle
   SOL-M Luer Lock Syringe (Low Dead Space) w/Exchangeable Needle
   SOL-CARE Luer Lock Syringe (Low Dead Space) w/Safety Needle
   SOL-M Slip Tip Syringe (Low Dead Space) w/Exchangeable Needle

   Common name: Luer Lock Syringe (Low Dead Space) with Safety Needle
   Luer Lock Syringe (Low Dead Space) with Exchangeable Needle
   Slip Tip Syringe (Low Dead Space) with Exchangeable Needle
   Luer Lock Syringe (Low Dead Space) without Needle
   Slip Tip Syringe (Low Dead Space) without needle

   Regulation No.: 21 CFR 880.5860
   Regulation name: Piston Syringe
   Classification: Class II
   Product code: QNQ

4. **Predicate device**
   K232943, Hypodermic Needle-Pro® EDGE™ Safety Device with Low Dead Space Syringe

5. **Device description**
   The Luer Lock and Slip Tip syringe (Low Dead Space) without Needle is a sterile, single-use, standard 3-piece piston hypodermic syringe.

   The Luer lock and Slip Tip syringe (Low Dead Space) with exchangeable needle is a sterile, single-use, standard 3-piece piston syringe with a detachable pre-attached needle.

   The Luer Lock Syringe (Low Dead Space) with Safety Needle is a Low Dead Space syringe in combination with a safety needle. The safety needle contains a mechanism that covers the needle point after use. In the activated position, the needle cover guards against accidental needle stick during normal handling and disposal of the used needle/syringe combination.

6. **Indications for use**
   The Luer Lock/Slip Tip Syringe (Low Dead Space) without needle is to inject fluids into, or withdraw fluids from, the body.

The Luer Lock/Slip Tip Syringe (Low Dead Space) with exchangeable needle is used to inject fluids into, or withdraw fluids from, the body.

The Luer Lock Syringe (Low Dead Space) with Safety needle is used to inject fluids into, or withdraw fluids from, the body. The safety mechanism covers the needle after use. In the activated position, the protective arm guards against accidental needle stick during normal handling and disposal of the used needle/syringe combination.

7. Comparison of technological characters between subject and predicate device

Characters	**Subject device** (K242291) Luer Lock/Slip Tip Syringe (Low Dead Space) without needle or with Exchangeable Needle Luer Lock Syringe (Low Dead Space) with Safety needle	**Predicate device** (K232943) Hypodermic Needle-Pro® EDGE™ Safety Device with Low Dead Space Syringe	Remark
Regulation No.	21 CFR 880. 5860	21 CFR 880.5860	Same
Class	II	II	Same
Indications for use	The Luer Lock/Slip Tip Syringe (Low Dead Space) without needle is to inject fluids into, or withdraw fluids from, the body. The Luer Lock/Slip Tip Syringe (Low Dead Space) with exchangeable needle is used to inject fluids into, or withdraw fluids from, the body. The Luer Lock Syringe (Low Dead Space) with Safety needle is used to inject fluids into, or withdraw fluids from, the body. The safety mechanism covers the needle after use. In the activated position, the protective arm guards against accidental needle stick during normal handling and disposal of the used needle/syringe combination.	The device is intended for use to inject fluids or withdraw fluids from the body. The needle protection device covers the needle after use to help prevent needle sticks.	Different #1
Syringe configuration and material	(1) Plunger stopper (IR rubber) (2) Plunger (PP) (3) Barrel (PP) (4) Lubricant (Silicone)	(1) Plunger stopper (IR rubber) (2) Plunger (PP) (3) Barrel (PP) (4) Lubricant (Silicone)	Same
Needle material (for devices containing needles)	SUS 304	SUS 304	Same
Syringe volume	1 mL	1 mL, 3 mL	Different #2

Luer lock	Luer lock or Luer slip (Slip Tip)	Luer lock or Luer slip (Slip Tip)	Same
Luer compliance	ISO 80369-7	ISO 80369-7	Same
Needle gauge and length	23G, 25G, 27G, 30G 1/2", 5/8", 1", 1 1/2"	23G, 25G 5/8", 1", 1 1/2"	Different #3
Sharps prevention function	Active safety feature for configurations with Safety Needle No safety features in configurations without Safety Needle	Active safety feature	Different #4
Needle performance	Conforming with ISO 9626 and ISO 7864	Conforming with ISO 9626 and ISO 7864	Same
Syringe performance	Conforming with ISO 7886-1	Conforming with ISO 7886-1	Same
Dead space specification	Syringe: Low Dead Space Max: 0.02mL Needle: Dead Space not calculated	Syringe: Low Dead Space Max: 0.015mL Needle: Unknown	Different #5
Sterility method	EO Sterilization	EO Sterilization	Same
Biocompatibility	Conforms with ISO 10993-1	Conforms with ISO 10993-1	Same
Shelf Life	5 years	Unknown	N/A

Substantial equivalence analysis

Different #1

Both the subject device and the predicate device are used to inject fluids or withdraw fluids from the body. The safety mechanism is present in configurations of the subject device that is packaged with a Safety Needle. The safety mechanism for said devices conforms with ISO 23908:2011. This difference does not have an impact on the performance of the subject device.

Different #2 Different #3

The syringe volume, needle gauge, and length of the subject device are different from the predicate device. The performance tests of the subject device have been performed per ISO 7864 and ISO 9626. Therefore, this difference in configuration will not affect the Substantial Equivalence (SE) between the subject and predicate device.

Different #4

The safety mechanism is available in certain configuration in the subject device. For devices containing Safety Needles, the safety mechanism of the subject device and predicate device conform to ISO 23908. This does not impact the substantial equivalence between the subject device Low Dead Space syringe and predicate device.

Different #5

Although the Low Dead Space maximum limits are different, both limits of the subject and predicate devices are significantly below the ISO 7886-1 maximum dead space of 0.07mL for a 1 mL syringe. The subject device's dead space specification (0.02mL maximum) is similar to other previously cleared low dead space syringe's dead space volume specifications. This difference does not impact the substantial equivalence between the subject device Low Dead Space syringe and predicate device.

8. Non-clinical testing

Performance Testing

The subject device was tested and demonstrated to be in conformance with the following FDA-recognized standards. The performance testing results met the requirements of the following standards demonstrating the device's substantial equivalence.

- ISO 7886-1:2017: Sterile hypodermic syringes for single use-Part 1: Syringes for manual use
- ISO 9626:2016 Stainless steel needle tubing for the manufacture of medical devices-Requirements and test methods
- ISO 7864:2016 Sterile hypodermic needles for single use-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
- ISO 23908: 2011 Sharps injury protection-Requirements and test methods-Sharps protection features for single-use hypodermic needles, introducers for catheters and needle used for blood sampling.

Biocompatibility Testing

The subject device was tested in compliance with ISO 10993-1, as the Externally Communicating Device, Blood Path Indirect, Limited Contact (<24 hours).

Sterility and Shelf life

The sterilization process has been conducted to confirm the subject device reached 10^{-6} sterility assurance level and the performance of the products and packaging in line with expectations after sterilization requirements per ISO 11135:2014.

The shelf-life validation study was conducted under the real-time aging condition to determine the subject devices maintain a complete sterile state within the five-year labeling period.

Package Integrity

Package integrity testing under simulated shipping conditions was conducted to satisfy the requirements in ISTA 3A. All packaging was deemed acceptable for the protection of the product and sterility maintenance.

Sterile barrier testing was conducted in compliance with the following FDA-recognized consensus standards.

- Package integrity ASTM F1886/F1886M-16
- Peeling force ASTM F88/F88M-21
- Dye penetration ASTM F1929-2015
- Clean peel ISO 11607-1:2019

9. Clinical testing

Not applicable for this submission**.**

10. Conclusion

The differences between the subject device and the predicate device do not raise any new or different questions of safety or effectiveness. The subject device is substantially equivalent to the predicate device Hypodermic Needle-Pro® EDGE™ Safety Device with Low Dead Space Syringe (K232943).