August 25, 2026

Sol-Millennium Medical, Inc.
Mike Xie
VP of QA/RA
311 S Wacker Dr.
Suite 4100
Chicago, Illinois 60606

Re: K252184
Trade/Device Name: SOL-M Luer Lock Syringe with Exchangeable Needle Tray
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: Class II
Product Code: FMF, FMI
Dated: July 20, 2026
Received: August 3, 2026

Dear Mike Xie:

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 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (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 ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

SHRUTI N. MISTRY -S

Shruti Mistry, M.S.
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

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K252184

Please provide the device trade name(s).

SOL-M Luer Lock Syringe with Exchangeable Needle Tray

Please provide your Indications for Use below.

The Luer Lock Syringe with Exchangeable Needle Tray is used to inject fluids into, or withdraw fluids from, the body.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) Summary
(K252184)

1. **Preparation date: August 25, 2026**

2. **Submitter**

Manufacturer: Sol-Millennium Medical Inc.
Address: 311 S. Wacker Dr, Suite 4100 Chicago, IL 60606, United States
Contact person: Mike Xie, VP of QA/RA, +1 847-400-4821, yxie@solm.com

3. **Device**

Trading name: SOL-M Luer Lock Syringe with Exchangeable Needle Tray
Regulation No.: 21 CFR § 880.5860;21 CFR § 880.5570
Classification name: Syringe, Piston; Needle, Hypodermic, Single Lumen
Classification: Class II
Product code: FMF; FMI
Review panel: General Hospital

4. **Predicate device**

510(k) Number: K241821
Trading name: Luer Lock Syringe with Exchangeable Needle
Regulation No.: 21 CFR § 880.5860; 21CFR 880.5570
Classification name: Syringe, Piston, Antistick, Needle, Hypodermic, Single Lumen
Classification: Class II
Product code: FMF; MEG; FMI
Review panel: General Hospital

5. **Device description**

This sterile, single-use 3-piece piston syringe features a detachable pre-attached needle for manual use. The system includes multiple syringes with exchangeable needles in a bulk tray. Each unit consists of a needle cap, tube, hub, barrel, plunger, and Isoprene rubber piston, with polypropylene barrel and plunger components. Available in 3, 5, and 10mL volumes with 20-23G needle options and Luer lock connector. The device is packaged in a thermal-formed plastic tray protected with a Tyvek sterile-barrier material, sterilized with EO gas, and offers a 5-year shelf life.

The device is for medical professionals use only and for prescription use only.

Table 1. Device specifications

3ml Luer Lock Syringe w/Exch Needle Tray 21G*1''
3ml Luer Lock Syringe w/Exch Needle Tray 22G*1''
3ml Luer Lock Syringe w/Exch Needle Tray 23G*1''
5ml Luer Lock Syringe w/Exch Needle Tray 20G*1''
5ml Luer Lock Syringe w/Exch Needle Tray 21G*1''
10ml Luer Lock Syringe w/Exch Needle Tray 20G*1''
10ml Luer Lock Syringe w/Exch Needle Tray 21G*1''

6. Indications for use/Intended use

The Luer Lock Syringe with Exchangeable Needle Tray is used to inject fluids into, or withdraw fluids from, the body.

7. Comparison of technological characters between proposed and predicate devices

Table 2. Characters comparison

Element of Comparison	**Predicate Device** **Luer Lock Syringe** **with exchangeable needle** **(K241821)**	**Subject Device** **SOL-M Luer Lock Syringe with Exchangeable Needle Tray**
Product Code	FMF, FMI	FMF, FMI
Intended Use/ Indications for Use	The Syringe with exchangeable needle is used to inject medicines and vaccines into, or withdraw fluids from, the body.	The Luer Lock Syringe with Exchangeable Needle Tray is used to inject fluids into, or withdraw fluids from, the body.

Element of Comparison	Predicate Device Luer Lock Syringe with exchangeable needle （K241821）	Subject Device SOL-M Luer Lock Syringe with Exchangeable Needle Tray
		Same, Different phrases that convey the same meaning.
Principle of Operation	Manual	Same
Source of Energy	Manual	Same
Needle/Syringe Connection	ISO 80369-7	Same
Needle physical performance	ISO 7864 ISO 9626	Same
Device Specifications	Syringe volume: 1ml,3ml, 5ml, 10ml Needle gauge: 20G, 21G, 22G, 23G, 25G Needle length: 1", 5/8", 11/2"	Syringe volume: 3ml, 5ml and 10ml Needle gauge: 20G,21G, 22G, 23G Needle length: 1" Same, within scope.
Device Configuration	Syringe - Barrel: PP - Plunger: PP - Gasket: IR rubber - Lubricant: silicone oil	Same

Element of Comparison	Predicate Device Luer Lock Syringe with exchangeable needle (K241821)	Subject Device SOL-M Luer Lock Syringe with Exchangeable Needle Tray
	Needle - Needle hub: PP - Needle cap: PP - Needle: SUS 304 - Adhesive: Glue	
Packaging Method	Individual packaging, Tyvek pouch like	Bulk packaging, plastic tray sealed with a Tyvek sterile-barrier material. Different, new packaging types were applied, packaging integrity and sterility testing results verified its effectiveness. So, difference didn't raise any risk, demonstrating the substantial equivalence.
Sterilization	EtO SAL 10^{-6}	Same
Biocompatibility	Meet ISO 10993	Same

8. Non-clinical testing

Non-clinical tests, and sterilization validation were conducted under K241821 with no changes except to the packaging type.

Biocompatibility testing was re-conducted according to the guidance of Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process".

Package integrity testing (including visual inspection, Seal strength, Dye penetration, and Clean peel) had been conducted on simulated transportation treated products. In addition, package testing had been conducted after aging.

Tyvek is used as the sterile barrier material for the package, and the package integrity was tested by the following methods:

- Visual Check: Internal standard
- Clean peel: ISO 11607-1:2019
- Seal strength: ASTM F88/F88-15
- Dye penetration: ASTM F1929-15
- Sterility: USP <71>
- Endotoxin: European Pharmacopoeia 10.2.6.14.
- Simulated transportation: ISTA-3A:2018

Additionally, Bacterial Aerosol Challenge Testing was conducted to validate the suitability of the syringe inside the tray to maintain a sterile barrier after tray opening.

9. Clinical testing

Not applicable for this submission.

10. Conclusion

The differences between the predicate and the proposed device do not raise any new or different questions of safety or effectiveness. The proposed device is substantially equivalent to the predicate device with respect to indications for use and technological characteristics.