October 22, 2024

Sol-Millennium Medical Inc.
% Amy Li, Technology Director
Shanghai Mind-link Consulting Co., Ltd.
Room A08, Floor 14th, No 699, Jiaozhou Rode
Jing'an District, Shanghai, Shanghai 201803, China

Re: K242099
Trade/Device Name: Sol-M™ Slip Tip Syringe without Needle, Sol-M™ Eccentric Tip Syringe without Needle
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: Class II
Product Code: FMF
Dated: June 27, 2024
Received: September 27, 2024

Dear Amy Li:

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)*
K242099

Device Name
Sol-M™ Slip Tip Syringe without Needle
Sol-M™ Eccentric Tip Syringe without Needle

Indications for Use *(Describe)*
The syringe without needle is used to inject fluids into, or withdraw fluids from, the body.

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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K242099 510(k) Summary

1. Date of preparation: October 22, 2024

2. Submitter information
   Address: 311 S Wacker Drive, Suite 4100, Chicago, Illinois, 60606, United States
   Contact person: Manu Kalia, Global QARA Director, +1 847-313-9577, mkalia@solm.com
   Submission correspondent: Amy.li, Technology director, +86 15721449974, amy.li@mind-link.net

3. Subject Device

   Trade name: Sol-M™ Slip Tip Syringe without Needle, Sol-M™ Eccentric Tip Syringe without Needle
   Common name: Piston Syringe
   Regulation: 21 CFR § 880.5860
   Product code: FMF
   Classification: Class II
   Review Pannel: General Hospital

4. Predicate Device
   K221079
   Trade Name: Sterile Hypodermic Syringes for Single Use
   Regulation Number: 21 CFR 880.5860
   Regulation Name: Piston Syringe
   Regulatory Class: Class II
   Product Code: FMF
   Review Panel: General hospital

5. Indication for use statement
   The syringe without needle is used to inject fluids into, or withdraw fluids from, the body

6. Device description
   The Slip Tip and Eccentric Tip Syringe without Needle is a sterile, single-use, standard 3 piece piston. The device is packed individually and EO sterilized with 10^{-6} SAL.

   6.1 The proposed device includes different specifications.

   - 1ml Slip Tip Syringe without Needle
   - 3ml Slip Tip Syringe without Needle
   - 5ml Slip Tip Syringe without Needle
   - 10ml Slip Tip Syringe without Needle
   - 20ml Slip Tip Syringe without Needle
   - 30ml Slip Tip Syringe without Needle
   - 60ml Slip Tip Syringe without Needle
   - 10ml Eccentric Tip Syringe without Needle

- 20ml Eccentric Tip Syringe without Needle
- 60ml Eccentric Tip Syringe without Needle

6.2 Label requirement

- The label shall meet the requirements of 21 CFR Part 801

7. Comparison of technological characteristics with the predicate devices

The subject device has the same intended use, technology, and design; and performance specifications are either identical or substantially equivalent to existing legally marketed predicate devices. The differences between the subject device and predicate devices do not alter suitability of the proposed device for its intended use.

Item	**Proposed Device Slip Tip Syringe without Needle, Eccentric Tip Syringe without Needle**	**Predicate Device Sterile Hypodermic Syringes for Single Use K221079**	**Remark**
Indication for Use	The syringe without needle is used to inject fluids into, or withdraw fluids from, the body.	The Sterile Hypodermic Syringes for Single Use are intended to be used for medical purpose to inject fluid into or withdraw fluid from body.	Same
Prescription or OTC (over the counter)	Prescription use	Prescription use	Same
Configuration	Barrel	Barrel	Same
	Plunger	Plunger	Same
	Piston	Piston	Same
Operation Mode	For manual use only	For manual use only	Same
Single Use	Single Use	Single Use	Same
Syringe performance	Complied with ISO 7886-1	Complied with ISO 7886-1	Same
Luer Connector Performance	Complied with ISO 80369-7	Complied with ISO 80369-7	Same
Volume	Slip tip:1ml, 3ml, 5ml, 10ml, 20ml, 30ml, 60ml Eccentric tip: 10ml, 20ml, 60ml	1ml, 2ml, 3ml, 5ml, 10ml, 20ml, 30ml, 50ml, 60ml, 100ml	Similar. Analysis 1.
Connector Type	Luer slip(Slip tip, Eccentric tip)	Luer slip/Luer lock	Similar. Analysis 2.
Barrel	Polypropylene(PP)	Polypropylene(PP)	Same
Plunger	Polypropylene(PP)	Polypropylene(PP)	Same
Piston	Polyisoprene rubber(IR)	Polyisoprene	Same
Lubricant	Polydimethylsiloxane	Polydimethylsiloxane	Same
Sterilization	EO Sterilized	EO Sterilized	Same
Shelf life	5 years	5 years	Same

Analysis 1:Volume

The subject device has less volume compared with the predicate device, but the predicate device has additional volumes 2ml and 100ml. However, all syringe performance was tested in accordance with ISO 7886-1 and ISO 80369-7. Therefore, this difference in syringe volume will not affect the Substantial Equivalence (SE) between the proposed device and the predicate device.

Analysis 2: Connector Type

The subject device has the same connector type compared with the predicate device, but the predicate device has an additional Luer lock type. However, the Luer connector performance complies with ISO 80369-7. Therefore, this difference in connector type will not affect the Substantial Equivalence (SE) between the proposed device and the predicate device.

8. Non-clinical Performance Testing

Non-clinical tests were conducted to verify that the proposed device meets all design specifications. The test results demonstrated that the proposed device complies with the following standards:

8.1 ISO 7886-1:2017 Sterile hypodermic syringes for single use- Part 1: Syringes for manual use.

8.2 ISO 80369-7:2021 Small-bore connectors for liquids and gases in healthcare application -- Part 7: Connectors for intravascular or hypodermic application

8.3 ISO 80369-20:2015 Small-bore connectors for liquids and gases in healthcare applications - Part 20: Common test methods

8.4 ISO 10993-1:2018 Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process

8.5 ISO 10993-4:2017 Biological evaluation of medical devices — Part 4: Selection of tests for interactions with blood

8.6 ISO 10993-5:2009 Biological evaluation of medical devices Part 5: Tests for in vitro cytotoxicity

8.7 ISO 10993-7:2008 Biological evaluation of medical devices — Part 7: Ethylene oxide sterilization residuals

8.8 ISO 10993-10: 2010 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization

8.9 ISO 10993-11:2017 Biological evaluation of medical devices — Part 11: Tests for systemic toxicity

8.10 USP <788> Particulate Matter for injection

8.11 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

8.12 ASTM F88/F88M-15, Standard Test Method For Seal Strength Of Flexible Barrier Materials

8.13 ASTM F1929-15 Standard Test Method for Detecting Seal Leaks in Porous Medical Package by Dye Penetration

9. Clinical Testing

No clinical study is included in this submission.

10. Conclusion

The differences between the predicate and the subject device do not raise any new or different questions of safety or effectiveness. The subject device is substantially equivalent to the predicate device Sterile Hypodermic Syringes for Single Use (K221079).