October 11, 2022

Sol-Millennium Medical Inc.
Ying Zhao
Sr. Manager, Regulatory Affairs
315 Shawnee North Dr. Suite 100
Suwanee, Georgia 30024

Re: K222744
Trade/Device Name: Sol-M Luer Lock Syringe
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: Class II
Product Code: FMF
Dated: September 9, 2022
Received: September 12, 2022

Dear Ying Zhao:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

CAPT Alan M. Stevens
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K222744

Device Name
SOL-M Luer Lock Syringe

Indications for Use *(Describe)*
The Sol-M Luer Lock Syringe is intended for aspiration and injection of medications and fluids into 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.

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510(k) SUMMARY

K222744

Date Prepared	October 7, 2022
Submitter	Sol-Millennium Medical Inc. 315 Shawnee North Dr. Suite 100 Suwanee, GA 30024 Phone: 815-578-2200
Primary Contact Person	Ying Zhao Sol-Millennium Medical Inc. Sr. Manager, Regulatory Affairs Phone: 919-324-2268 Email: yzhao@sol-m.com
Secondary Contact Person	PJ Pasia Sol-Millennium Medical Inc. Director, Regulatory Affairs Phone: 847-363-1264 Email: ppasia@sol-m.com
Device Information	Trade/Device Name: Sol-M™ Luer Lock Syringe Regulatory Number: 21 CFR 880.5860 Regulatory Name: Piston Syringe Regulatory Class: II Product Code: FMF Review Panel: General Hospital
Predicate Device	K101359: Sol-M™ Luer Lock Syringe Manufacturer: Sol-Millennium Medical Inc.

INDICATIONS FOR USE

The Sol-M™ Luer Lock Syringe is intended for aspiration and injection of medications and fluids into the body.

REASON FOR SUBMISSION

The purpose of this submission is to evaluate the suitability of the Sol-M™ Luer Lock Syringe (formerly known as InviroStripe Luer Lock Syringes) cleared under K101359 by Sol-Millennium to be used with power-driven pumps and to add statements on the labeling indicating compatibility with pumps. There is no change to Indications for Use, material, dimensions, design, and packaging compared with the predicate device.

DEVICE DESCRIPTION

The Sol-M™ Luer Lock Syringe is used to aspirate and inject fluid/medication into the body. The syringe is a sterile, single-use, 3-part syringe with luer lock conical connection. The Sol-M™ Luer Lock Syringe consists of the following components:

- Barrel: The lubricated hollow cylinder has gradient markings on it. The tip of the barrel has a luer lock fitting for the user to attach a hypodermic needle or administration line.
- Plunger: The plunger is used to pull back to aspirate fluids or depress to inject fluids.
- Gasket: The gasket maintains the fluid in the barrel between the syringe nozzle and the plunger.

In addition to being used manually, the Sol-M™ Luer Lock Syringe can also work with a power-driven syringe pump, with the luer lock tip connected to the IV administration line to deliver specific volume of fluid/medication.

The syringe is individually blister packaged, and EtO sterilized with SAL of 10^{-6}. The Sol-M™ Luer Lock Syringe is provided in 1, 3, 5, 10, 20, 30, and 60ml volume.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

The design and technological features of the subject device are the same as existing Sol-M™ Luer Lock Syringe. The existing Sol-M™ Luer Lock Syringe is identical to InviroStripe Standard Luer Lock Syringe cleared under K101359 by Inviro Medical, Inc. The brand name changed to Sol-M™ from InviroStripe when Sol-Millennium acquired Inviro Medical, Inc in 2011.

The difference between the subject device and the predicate device is that the subject device is suitable for use with power-driven syringe pumps. These two devices are identical on Indication for Use, material, dimensions, design, and technology. The similarities and differences are illustrated in the table below.

Comparison of Technology and Features

Element of Comparison		Subject Device Sol-M™ Luer Lock Syringe (K222744)	Predicate Device Sol-M™ Luer Lock Syringe (K101359)	Comment
Product Code		FMF	FMF	Same
Syringe Type		Piston, syringe	Piston, syringe	Same
Indication for Use		The Sol-M™ Luer Lock Syringe is intended for aspiration and injection of medications and fluids into the body.	The Sol-M™ Luer Lock Syringe is used to inject medicine or vaccines into, or withdraw fluids from, the body.	Different/See Comment #1
Principle of Operation		Three-piece piston syringe. Plunger is used to fill syringe as well as discharge the fluid for both manual and pump-driven operation.	Three-piece piston syringe. Plunger is used to fill syringe as well as discharge the fluid.	Different/See Comment #2
Specific Drug Use		General use	General use	Same
Tip Type		Luer lock, ISO 80369-7	Luer lock, ISO 80369-7	Same
Nominal Capacity		1, 3, 5, 10, 20, 30, and 60ml	1, 3, 5, 10, 20, 30, and 60ml	Same
Barrel Marking Specs		Graduated scale	Graduated scale	Same
Gradations legibility		Bold Markings	Bold Markings	Same
Device Component	**Barrel**	Polypropylene	Polypropylene	Same
	Plunger	Polypropylene	Polypropylene	Same
	Gasket	IR Rubber	IR Rubber	Same
Lubricant Composition		Silicone oil	Silicone oil	Same
Lubricant Amount/cm²		≤ 0.25 mg/cm²	≤ 0.25 mg/cm²	Same
Barrel transparency		Clear	Clear	Same
Biocompatibility		ISO 10993	ISO 10993	Same
Labeling		Per 21 CFR 801 Include “Suitable for Use with Power-Driven Syringe Pumps” statement	Per 21 CFR 801	Different/See Comment #3
Sterilization Method		EtO	EtO	Same
Sterility Level (SAL)		10^{-6}	10^{-6}	Same
Shelf Life		3 years	5 years	Different/See Comment #4
Manual Use		ISO 7886-1	ISO 7886-1	Same
Critical Dimensions		ISO 7886-2	Not applicable	Different/See Comment #5
Short-term Flow Rate Error		ISO 7886-2	Not applicable	Different/See Comment #6
Pump Forces		ISO 7886-2	Not applicable	Different/See Comment #7
Syringe Compliance		ISO 7886-2	Not applicable	Different/See Comment #8

Comment #1:
The Indication for Use statement is reworded for clarification only, no change to the indication of the device.

Comment #2:
The subject device can be used for both manual injection and injection with infusion pumps, while the predicate device can only be used for manual injection. The difference was evaluated by well-established methods included in the FDA-recognized standard ISO 7886-2:2020 Sterile Hypodermic Syringes for Single Use – Part 2: Syringes for Use with Power-Driven Syringe Pumps. The Sol-M™ Luer Lock Syringe was subjected to design controls and tested to this specific standard to support substantial equivalence. Test methods and acceptance criteria utilized by Sol-Millennium have no changes or deviations from those included in ISO 7886-2. Testing results demonstrated that the subject device is as safe and effective as the predicate device.

Comment #3:
Labeling is updated to add pump compatible statement. As addressed in Comment 2, verification data demonstrated that no safety and effectiveness issues are raised.

Comment #4:
Due to commercialization demand for the subject device, 3-year shelf-life testing per ISO 7886-2 was conducted. The difference does not raise safety and effectiveness questions for its intended purpose.

Comment #5:
Testing per ISO 7886-2 was conducted to demonstrate the satisfaction of dimensional requirements which are critical to the fit of the syringe in a syringe pump and flow accuracy. Using the subject device with pumps does not raise any safety or effectiveness issue.

Comment #6:
Testing per ISO 7886-2 was conducted to demonstrate the maximum permissible flow rate error by subject device met the acceptance criteria. The syringe, when used with pump, can deliver medication or fluid at consistent flow rate. There is no safety and effectiveness questions raised.

Comment #7:
The required pump force to move plunger along barrel was measured and made available to pump manufacturers per ISO 7886-2. This information can be shared between pump and syringe manufacturers to ensure correct software programing by pump manufacturers.

Comment #8:
Testing per ISO 7886-2 was conducted to demonstrate the maximum allowable fluid displaced by the subject device met the acceptance criteria. The syringe, when used with pump, can delivery accurate volume of medication or fluid as be used as manually. There is no safety and effectiveness questions raised.

BIOCOMPATIBILITY

Biocompatibility testing was leveraged from the predicate device submission since there were no change to materials and manufacturing process and no biological concern was introduced.

STERILIZATION

There was no change in the sterilization process or materials involved with the sterilization, and the sterility assurance level remains unchanged.

SHELF LIFE

Shelf-life verification studies were conducted at T=3 under real time conditions to verify that the claimed shelf life of 3 years is supported. There were no failures identified and the test confirmed that the claimed expiration date is supported.

SUMMARY OF NON-CLINICAL TESTS (BENCH TESTING)

The Sol-M™ Luer Lock Syringe had been previously tested in compliance with ISO 7886-1 for demonstrating manual use covered under K101359. To demonstrate that the device is also suitable for use with syringe pumps, Sol-Millennium has performed non-clinical testing according to ISO 7886-2. The performance and design testing conducted serve as the basis for establishing substantial equivalence; the testing included the following.

- ISO 7886-2:2020 Sterile hypodermic syringes for single use - Part 2: Syringes for use with power-driven syringe pumps
- ISO 7886-1:2017 Sterile hypodermic syringes for single use - Part 1: Syringes for manual use

The compatibility with syringe pumps was considered the technical characteristic which could potentially introduce new risks to the subject device. Compliance to ISO 7886-2 Sterile hypodermic syringe for single use – Part 2: Syringes for use with power-driven syringe pumps, serves as the mitigation to the identified safety concerns.

CLINICAL TESTING

Clinical studies were not deemed necessary to support the substantial equivalence decision.

CONCLUSION

Sol-Millennium considers the Sol-M™ Luer Lock Syringe substantially equivalent to the predicate device. The subject device's Indications for Use, dimensional, materials, and technology are unchanged compared to the predicate device cleared under K101359. The potential risks introduced by adding pump compatibility were successfully mitigated by design control activities. The results of the testing demonstrated that the Sol-M™ Luer Lock Syringe

performs as intended and performs as well as the legally marketed predicate devices for the same intended use. Based on the comparison and analysis above, the subject device is determined to be Substantially Equivalent (SE) to the predicate device.