May 4, 2023

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

Re: K220713
Trade/Device Name: Sol-Guard Auto-disable Syringe
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: Class II
Product Code: FMF
Dated: April 6, 2023
Received: April 7, 2023

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)*

K220713

Device Name
SOL-GUARD Auto-Disable Syringe

Indications for Use *(Describe)*
The Sol-Guard Auto-Disable Syringe is intended for aspiration and injection of fluids into the body. In addition, the Sol-Guard Auto-Disable Syringe is designed to prevent syringe and needle reuse.

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

In accordance with 21 CFR 807.92(a) the following summary of information is provided:

Date Summary Prepared:	May 5, 2023
Submitter/Applicant:	Sol-Millennium Medical Inc. 315 Shawnee North Dr. Suite 100 Suwanee, GA 30024 Phone: 815-578-2200 Fax: 815-759-2548
Primary Contact Person:	Ying Zhao Sol-Millennium Medical Inc. Sr. Manager, Regulatory Affairs Phone: 847-363-1264 Email: yzhao@sol-m.com
Device Information	Trade/Device Name: Sol-Guard™ Auto-Disable Syringe Regulatory Number: 21 CFR § 880.5860 Regulatory Name: Syringe, Piston Regulatory Class: II Product Code: FMF Review Panel: General Hospital
Predicate Device Information	K153537 Manufacturer: Sol-Millennium Medical Inc. Sol-M Insulin Syringe, Sol-M TB Syringe The predicate device has not been subject to a design-related recall.

Device Description:
The SOL-GUARD Auto-Disable syringe is a sterile, single-use, 3-part hypodermic syringe with an auto-disable feature that is intended to deliver a fixed dose of medicine/vaccine immediately after filling. The SOL-GUARD Auto-Disable syringe has a fixed needle and plunger rod with affixed metal clip which is designed for the prevention of the syringe and needle re-use by automatically activating the clip and locking the plunger after injection. The syringe is individually blister packaged, and EtO sterilized with SAL of 10^{-6}. This syringe is intended for aspiration and injection of fluids.

The auto-disable syringes are configured as follows.

Product Size	Needle Gauge	Needle length
0.3ml	23G	1"
0.3ml	23G	1 1/2"
0.3ml	25G	1''
0.5ml	23G	1"
0.5ml	23G	1 1/2"
0.5ml	25G	1"
0.65ml	26G	3/8"

Indications For Use:
The Sol-Guard™ Auto-Disable Syringe is intended for aspiration and injection of fluids into the body. In addition, the Sol-Guard™ Auto-Disable Syringe is designed to prevent syringe and needle reuse.

Technological Charateristic
The subject device is a standard 3-piece piston syringe with a permanently attached needle and with an auto-disable feature that prevents reuse of the syringe after injection by locking the plunger in place after injection. The syringe consists of a syringe barrel with a permanently attached needle, a plunger rod with an integral metal clip, and a rubber stopper (gasket).

The subject device has a feature that passively activates upon delivering an injection of the nominal fixed dose to prevent subsequent reuse of the syringe and the needle. The passive activation is where the reuse prevention feature does not require an additional step by the user during injection to activate the protection feature.

The reuse prevention is achieved using serrations on the internal wall of the barrel and a metal clip/claw on the plunger that automatically blocks the plunger once depressed so it cannot be retracted again. This is a single-use device.

Comparison of Technological Characteristic
The design and technological features of the Sol-Guard™ Auto-Disable Syringe, which is the subject of this Special 510(k), are the same as Sol-M Insulin Syringe and Sol-M TB Syringe

previously cleared under K153537. The differences between the subject device and the predicate devices are the inclusion of the auto-disable feature that locks the plunger after injection. Table 1 presents a comparison of the devices' technology, features, and materials.

Table 1. Technology and features

Element of Comparision	Proposed Device Sol-Guard™Auto-Disable Syringe	Predicate Device (K153537) Sol-M Insulin Syringe, Sol-M TB Syringe
Product Code	FMF	FMF
Syringe Type	Piston, syringe	Piston, syringe
Indication for use	The Sol-Guard™ Auto-Disable Syringe is intended for aspiration and injection of fluids into the body. In addition, the Sol-Guard™ Auto-Disable Syringe is designed to prevent syringe and needle reuse.	TB Syringe is intended to be used for medical purposes to inject fluids into or withdraw fluids from the body. Insulin Syringe with needle, with the calibration unit of insulin for U-100, is device intended for medical purposes for the manual aspiration of insulin, and for the injection of insulin into parts of the body below the surface of the skin.
Intended Use	The SOL-GUARD™ Auto Disable syringes are used to inject vaccine/medications into the body by physicians, nurses, and other qualified health care professionals. It is designed with safety feature for the prevention of the syringe reuse.	TB Syringe is intended to be used for medical purposes to inject fluids into or withdraw fluids from the body. Insulin Syringe with needle, with the calibration unit of insulin for U-100, is device intended for medical purposes for the manual aspiration of insulin, and for the injection of insulin into parts of the body below the surface of the skin.
Principle of operation	Three-piece piston syringe. Plunger is used to fill syringe as well as discharge the fluid. The Auto-Disable syringe has a fixed needle and plunger rod with affixed metal clip which is designed for the prevention of the syringe and needle re-use by automatically activating the clip and locking the plunger after injection.	Three-piece piston syringe. Plunger is used to fill syringe as well as discharge the fluid. The syringe has a fixed needle.
Specific Drug Use	Vaccine/Medication	Insulin syringes - Insulin TB syringes – General Use (included vaccine/medication)
Length	Assembly length 131mm	Assembly length 131mm
Diameter	I.D. of barrel: 4.7mm	I.D. of barrel: 4.7mm
Tip Type	Fixed Needle	Fixed Needle
Volume	0.3ml, 0.5ml, 0.65ml	Insulin Syringes - 0.3, 0.5, 1ml TB Syringes – 0.5, 1 ml
Needle Length	3/8" to 1 1/2"	5/16" to 1 1/2"
Needle Gauge	23-26 gauge	Insulin- 29-31 gauge TB – 23-27 gauge
Needle Tip Configuration	Hypodermic needle	Hypodermic needle
Barrel Marking Specs	Graduated scale in ml for fixed dose	Insulin: graduated scale in U100 TB: graduated scale in ml
Device Component	Barrel, piston, plunger, needle, needle cover, metal clip	Barrel, piston, plunger, needle, needle cover

Element of Comparision	Proposed Device Sol-Guard™Auto-Disable Syringe	Predicate Device (K153537) Sol-M Insulin Syringe, Sol-M TB Syringe
Graduation Legibility	Bold Markings	Bold Markings
Needle Cover/Cap Dimensions	Needle cover length from 25mm to 49mm based on nominal needle length	Needle cover length from 25mm to 49mm based on nominal needle length
Needle Cover/Cap Color	Clear (transparent, not colored)	Insulin: Orange according to ISO 8537 TB: according to ISO 6009 except 25G that needle cover is not colored
Lubricant Composition	Dow Corning Medical Silicone 360	Dow Corning Medical Silicone 360
Lubricant Amount/cm2	≤ 0.25 mg/cm^2	≤ 0.25 mg/cm^2
Barrel transparency	Clear	Clear
Delivery Accuracy	Per Auto-disabled syringes for fixed-dose immunization - ISO 7886-3:2020 Hypodermic Syringes - Per ISO 7886-1: 2016	Insulin Syringes– Per ISO 8537:2016 Hypodermic Syringes - Per ISO 7886-1: 2016
Needle Cover/Cap Strength	Internal requirement: force to remove the needle cover below 15N	Internal requirement: force to remove the needle cover below 15N
Hub/Needle bond Strength	Per ISO 7864	Per ISO 7864
Biocompatibility	Per ISO 10993-1	ISO 10993-1
Barrel	Polypropylene	Polypropylene
Plunger	Polypropylene and SS 304 stainless (metal clip)	Polypropylene
Gasket/Stopper	IR rubber	IR rubber
Needle	SS 304	SS 304
Needle Cover/Cap	Polypropylene	Polypropylene
Labeling	Per 21 CFR 801	Per 21 CFR 801
Sterilization Method	EtO	EtO
Sterility Level (SAL)	10^{-6}	10^{-6}
Shelf Life	5 years	5 years

Performance Testing Summary:
Performance testing was conducted to support the addition of the auto-disable feature of the syringe. The Sol-Guard™ Auto-Disable Syringe has been subjected to Design Controls and tested to appropriate device specific standards to support substantial equivalence, and validation to standards necessary to demonstrate the functionality of the device.

Biocompatibility Testing
Biocompatibility testing was leveraged from the predicate device submission since there was no change in the patient direct or in-direct contact components and no biological concern is introduced.

Sterilization
There was no change in the sterilization process or materials involved with the sterilization, and the sterility assurance level remains unchanged. The Microbiology Product Adoption was done in accordance with ISO 11135:2014 Sterilization of health care products – Ethylene oxide – Requirements for development, validation and routine control of a sterilization process for medical devices and AAMI TIR28:2016 Product adoption and process equivalence for ethylene oxide sterilization.

Shelf Life:
Shelf-life verification studies were conducted at T=5 under accelerated aging conditions to verify that the claimed shelf life of 5years 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)
Sol-Millennium has conducted non-clinical testing according to the FDA consensus standards. The performance and design testing conducted serve as the basis for establishing substantial equivalence, the testing included the following.

- ISO 7886-3:2020 Sterile hypodermic syringes for single use - Part 3: Auto-disabled syringes for fixed-dose immunization
- ISO 7886-1:2017 Sterile hypodermic syringes for single use - Part 1: Syringes for manual use

The compatibility of the metal clip of the syringe to the plunger that provides the auto-disable feature for the subject device was considered the technological characteristic which introduced the greatest potential risk of the subject device. Potential functional performance risks include risk on the ability of the plunger to travel within the barrel, scale mark legibility, ability to maintain shelf-life, resulting in a delay in therapy, and inaccurate medication delivery. Compliance to ISO 7886-3 Sterile hypodermic syringes for single use - Part 3: Auto-disabled syringes for fixed-dose immunization, in conjunction with ISO7886-1, serves as the mitigations to the identified safety concerns. The non-clinical testing included assessments related to device material biocompatibility, where it was deemed the metal clip does contact fluid or skin during its intended use.

Results of non-clinical testing both validated the modifications made and served to mitigate the identified risks such that the subject device met requirements for its intended use demonstrating substantial equivalence to its predicate device.

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

Conclusion:
Sol-Millennium considers the Sol-Guard™ Auto-Disable Syringe to be substantially equivalent to the predicate device. The subject device's intended use, indications for use, technology, and principles of operation are unchanged compared to the predicate device cleared under K153537. The addition of an auto-disable feature to prevent syringe and needle reuse does not change the effectiveness of the device and it does not represent a change in user tasks or interactions. The potential risks introduced by adding auto-disable feature were successfully mitigated by design control activities. The subject device is as safe and effective as the predicate device. Based on the comparison and analysis above, the subject device is determined to be Substantially Equivalent (SE) to the predicate devices.