June 18, 2026

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

Re: K253110
Trade/Device Name: Sol-Glide Safety Needle; Sol-Glide Safety Needle with Syringe
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: Class II
Product Code: FMF, QNQ, FMI
Dated: May 18, 2026
Received: May 18, 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
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)*
K253110

Device Name
Sol-Glide Safety Needle;
Sol-Glide Safety Needle with Syringe

Indications for Use *(Describe)*
The Sol-Glide™ Safety Needle is used in conjunction with a standard syringe. The Sol-Glide™ Safety Needle with Syringe is used to inject fluids into, or withdraw fluids from the body. The safety mechanism encapsulates the needle after use. In the activated position, the protective shield 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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510(k) Summary - K253110

Date Prepared: 06/18/2026

1. SUBMITTER INFORMATION:

Company Name: Sol-Millennium Medical, Inc.
Address: 311 South Wacker Drive, Suite 4100, Chicago. Illinois, USA 60606
Company Person: Mike Xie
Telephone: 847-400-4821
Email:yxie@solm.com

2. DEVICE IDENTIFICATION

Trade Name: Sol-Glide Safety Needle;
Sol-Glide Safety Needle with Syringe
Common Name: Safety Hypodermic Needle, Safety Hypodermic Needle with Syringe
Classification Name: Needle, hypodermic, single lumen
Classification: II
Product Code: FMF
Subsequent Product codes: QNQ, FMI
Regulation Number: 21 CFR 880.5570, 21 CFR 880.5860
Review Panel: General Hospital

3. PREDICATE DEVICES:

Primary Predicate Device : K241821 – Sol-M Luer Lock Syringe with Safety Needle; Luer Lock Syringe with Exchangeable Needle; Luer Lock Syringe with Blunt Fill Needle

Secondary Predicate 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

Third Predicate Device: K012736 – Monoject Safety Needle

4. DEVICE DESCRIPTION:

The SOL-Glide Safety Needle is a sterile, single-use, hypodermic needle with safety feature to be initiated by the end user by activating the sliding arm over the needle after injection completes, that is intended to administer medication in a conjunction with standard syringe. Needle gauge ranging from 18G to 25G, needle length including ⅝", 1" and 1½". The SOL-Glide™ safety needle is sterilized by Ethylene Oxide Gas and supplied sterile in individual blister pack.

The Sol-Glide Safety Needle with Syringe is the same Sol-Glide Safety Needle mentioned above but pre-attached to a Luer Lock or Luer Slip Slip syringe offered in 1ml (standard and low dead space), 3ml, 5ml or 10mL configurations in a sterile individual blister pack.

5. INDICATIONS FOR USE

The Sol-Glide™ Safety Needle is used in conjunction with a standard syringe. The Sol-Glide™ Safety Needle with Syringe is used to inject fluids into, or withdraw fluids from the body. The safety mechanism encapsulates the needle after use. In the activated position, the protective shield guards against accidental needle stick during normal handling and disposal of the used needle/syringe combination.

6. TECHNOLOGICAL COMPARISONS

Table 1. Comparison of Sol-Glide Safety Needle with syringe (needle with Luer lock syringe combination configuration) with the primary predicate

Item	Subject Device Sol-Glide Safety Needle with syringe (needle with Luer lock syringe)	Primary predicate Sol-M Luer Lock Syringe with Safety Needle; Luer Lock Syringe with Exchangeable Needle; Luer Lock Syringe with Blunt Fill Needle	Remark
K number	K253110	K241821	

Classification		Class II	Class II	Same
Product Code and regulation number		FMF, FMI, QNQ 21 CFR 880.5570 21 CFR 880.5860	FMF, FMI, MEG 21 CFR 880.5570 21 CFR 880.5860	Different – Note 1
Indications for use		The Sol-Glide™ Safety Needle is used in conjunction with a standard syringe. The Sol-Glide™ Safety Needle with Syringe is used to inject fluids into, or withdraw fluids from the body. The safety mechanism encapsulates the needle after use. In the activated position, the protective shield guards against accidental needle stick during normal handling and disposal of the used needle/syringe combination.	The Luer Lock Syringe 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.	Different – Note 2
Needle Gauge Range		18G – 25G	18G – 30G	Different – Note 3
Needle Length Range		5/8 inch to 1 ½ inch	5/8 inch to 1 ½ inch	Same
Needle Performance		Complied with ISO 7864, ISO 9626	Complied with ISO 7864, ISO 9626	Same
Syringe Volume Range		1mL, 3mL, 5mL and 10mL	1mL, 3mL, 5mL and 10 mL	Same
Luer Connector Performance		Luer Lock Complied with ISO 80369-7	Luer Lock Complied with ISO 80369-7	Same
Material (Syringe)	Barrel	Polypropylene(PP)	Polypropylene(PP)	Same
	Plunger	Polypropylene(PP)	Polypropylene(PP)	
	Gasket	IR rubber	IR rubber	
	Lubricant	Silicone oil	Silicone oil	
Material (Needle)	Needle hub	Polypropylene(PP)	Polypropylene(PP)	Same
	Needle cap	Polypropylene(PP)	Polypropylene(PP)	
	Needle	Stainless Steel SUS 304	Stainless Steel SUS 304	
	Adhesive	UV Glue	UV Glue	
Biocompatibility		Complied with ISO 10993-1	Complied with ISO 10993-1	Same
Sterilization Method		EO Sterilized	EO Sterilized	Same

Discussion in details:

Note 1: Product Code and regulation number
The subject device includes product codes FMF, FMI and QNQ, whereas the predicate has similar codes of FMF, FMI and MEG. which correspond to the syringe piston component and the hypodermic single lumen needle component, respectively. The absence of MEG from the subject device listing in this comparison does not reflect a difference in intended use, operating principle, or safety performance as the subject device uses only the syringe (FMF) component from this predicate. Additionally, the subject device has QNQ which this predicate does not, however the QNQ refers to a low dead space syringe that will be applicable in the second predicate and does not apply to this primary predicate. Therefore, the difference in product code assignment is administrative/classification-related and does not raise new or different questions of safety or effectiveness when compared to predicate.

Note 2: Indications for use
The subject device and predicate have the similar indications for use. Both describe the functions of a safety needle and syringe combination that when used together can inject and withdraw fluids from the body. Both describe a safety mechanism that guards against accidental needle stick injuries. Although the wording differs slightly between the devices, the functional intent and clinical use are equivalent. Therefore, these differences do not raise new or different questions of safety or effectiveness when compared to predicate.

Note 3: Needle gauge Range
The predicate device has a greater range of gauges than the subject device. The subject device only intends to use a subset of needle gauges within range in combination with the Sol-Glide Safety needle and within the cleared range of the reference device. Therefore, these differences do not raise new or different questions of safety or effectiveness when compared to predicate.

Table 2. Comparison of Sol-Glide Safety Needle with syringe (needle with luer lock and luer slip Low Dead Space syringe combination configuration) with secondary predicate

Item		Proposed Device Sol-Glide Safety Needle with syringe (needle with luer lock and luer slip Low Dead Space syringe)	Secondary predicate device Luer Lock/Slip Tip Syringe (Low Dead Space) without needle or with Exchangeable Needle Luer Lock Syringe (Low Dead Space) with Safety needle	Remark
K number		K253110	K242291	
Classification		Class II	Class II	Same
Product Code and regulation number		FMF, FMI, QNQ 21 CFR 880.5570 21 CFR 880.5860	QNQ 21 CRF 880.5860	Different – Note 1
Indications for use		The Sol-Glide™ Safety Needle is used in conjunction with a standard syringe. The Sol-Glide™ Safety Needle with Syringe is used to inject fluids into, or withdraw fluids from the body. The safety mechanism encapsulates the needle after use. In the activated position, the protective shield guards against accidental needle stick during normal handling and disposal of the used needle/syringe combination.	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.	Different – Note 2
Needle Gauge Range		23G – 25G	23G – 30G	Different – Note 3
Needle Length Range		5/8 inch - 1 inch	1/2 inch to 1 ½ inch	Different – Note 4
Needle Performance		Complied with ISO 7864, ISO 9626	Complied with ISO 7864, ISO 9626	Same
Syringe Volume Range		1mL	1mL	Same
Dead Space Specification		Syringe: Low Dead Space Max: 0.02mL Needle: Dead Space not calculated	Syringe: Low Dead Space Max: 0.02mL Needle: Dead Space not calculated	Same
Luer Connector Performance		Luer lock and Luer Slip Complied with ISO 80369-7	Luer lock and Luer Slip Complied with ISO 80369-7	Same
Syringe performance		Conforming with ISO 7886-1	Conforming with ISO 7886-1	Same
Material (Syringe)	Barrel	Polypropylene(PP)	Polypropylene(PP)	Same
	Plunger	Polypropylene(PP)	Polypropylene(PP)	
	Gasket	IR rubber	IR rubber	
	Lubricant	Silicone oil	Silicone oil	

Material (Needle)	Needle hub	Polypropylene(PP)	Polypropylene(PP)	Same
	Needle cap	Polypropylene(PP)	Polypropylene(PP)	
	Needle	Stainless Steel SUS 304	Stainless Steel SUS 304	
	Adhesive	UV Glue	UV Glue	
Biocompatibility		Complied with ISO 10993-1	Complied with ISO 10993-1	Same
Sterilization Method		EO Sterilized	EO Sterilized	Same

Discussion in details:

Note 1: Product Code and regulation number
This predicate device is used only for the syringe component of the clearance. Both subject device and this predicate device are combinations of needles pre-attached to syringes however the needle component is different between the subject device and predicate device while the syringe is the same. The predicate device is QNQ which is encompassed in the subject device's list of product codes and regulation. The intent of this predicate device is to be included with the subject device so the subject device including the needle's product codes (FMI) in addition to the syringe's (QNQ) does not raise new or different questions of safety or effectiveness when compared to predicate. Additionally, the subject device's FMF product code corresponds to other non low dead space syringes that are bundled with the needle and accounted for in the primary predicate.

Note 2: Indications for use
The subject device and predicate device have similar indications for use. Both describe the functions of a safety needle and syringe combination that when used together can inject and withdraw fluids from the body. Both describe a safety mechanism that guards against accidental needle stick injuries. Although the wording differs slightly between the devices, the functional intent and clinical use are equivalent. Therefore, these differences do not raise new or different questions of safety or effectiveness when compared to predicate.

Note 3: Needle Gauge Range
The predicate device has a greater range of gauges than the subject device. The subject device only intends to use a subset of needle gauges within range in combination with the Sol-Glide Safety needle and within the cleared range of the reference device. Therefore, these differences do not raise new or different questions of safety or effectiveness when compared to predicate.

Note 4: Needle Length Range
The predicate device has a greater range of needle length than the subject device. The subject device only intends to use a subset of needle lengths within range in combination with the Sol-Glide Safety needle and within the cleared range of the reference device. Therefore, these differences do not raise new or different questions of safety or effectiveness when compared to predicate.

Table 3. Substantial equivalent comparison of Sol-Glide Safety Needle (needle only) to the third predicate.

Item	**Subject Device Sol-Glide Safety Needle**	**Third Predicate device Monoject Safety Needle**	**Remark**
K number	K253110	K012736	
Classification	Class II	Class II	Same
Product Code and regulation number	FMI	FMI	Same
Regulation Number	21 CFR 880.5570	21 CFR 880.5570	Same
Indications for use	The Sol-Glide™ Safety Needle is used in conjunction with a standard syringe. The Sol-Glide™ Safety Needle with Syringe is used to inject fluids into, or withdraw fluids from the body. The safety mechanism encapsulates the needle after use. In the activated position, the protective shield guards against accidental needle stick during normal handling and disposal of the used	The primary function of the device is to inject fluids into, or withdraw fluids from, parts of the body below the surface of the skin. The needle stick prevention feature of the device helps prevent accidental needle sticks by shielding the needle after use.	Different - Note 1

		needle/syringe combination.		
Configuration		Needle cap, needle tube, needle hub with safety arm	Needle cap, needle tube, needle hub with safety arm	Same
Safety feature		Active, manual	Active, manual	Same
Shielding Function		Protective shield covers needle after use to reduce accidental needlestick injury	Protective shield covers needle after use to reduce accidental needlestick injury	Same
Operation Mode		For manual use only	For manual use only	Same
Sterilized		Yes	Yes	Same
Single use		Single use	Single use	Same
Needle	size	18G, 19G, 20G, 21G, 22G, 23G, 25G	18G, 19G, 20G, 21G, 22G, 23G, 25G.	Same
	Length	5/8'', 1'', 1 ½''	5/8", 1", 1 1/2"	
Cannula wall		Thin Wall	Thin Wall	Same
Needle Performance		Complied with ISO 7864, ISO 9626	Complied with ISO 7864, ISO 9626	Same
Luer Connector Performance		Complied with ISO 80369-7	Complied with ISO 80369-7	Same
Materials	Needle cap	Polypropylene	Information not available in public record	Different - Note 2
	Needle hub	Polypropylene	Information not available in public record	
	Needle tube	Stainless Steel SUS 304	Information not available in public record	
	Lubricants	Silicone oil	Information not available in public record	
	Adhesive	UV adhesive	Information not available in public record	
Biocompatibility		Complied with ISO 10993-1	Complied with ISO 10993-1	Same
Sterilization Method		EO Sterilized	Radiation Sterilized	Different - Note 3

Discussion in details:

Note 1: Indications for use
The subject device and predicate device have the same intended use and similar operating principles. Both devices are intended for the injection and withdrawal of fluids and incorporate manually activated safety mechanisms designed to reduce accidental needlestick injuries after use. Although the wording differs slightly between the devices, the functional intent and clinical use are equivalent. Therefore, these differences do not raise new or different questions of safety or effectiveness when compared to predicate.

Note 2: Materials
The specific material composition for the predicate device (K012736) is not fully available in the public 510(k) summary or other public records. The proposed device utilizes standard medical-grade materials commonly used in hypodermic safety needle devices, including polypropylene, stainless steel, silicone oil lubricant, and a UV-cured medical-grade adhesive. All patient-contacting and externally communicating components of the proposed device have been evaluated for biocompatibility in accordance with ISO 10993 standards and demonstrated to be safe for the intended use. The adhesive is fully encapsulated within the device and does not directly contact the patient. Therefore, any differences in material specification do not raise new questions of safety or effectiveness when compared to predicate.

Note 3: Sterilization method
The predicate device is sterilized using radiation sterilization, while the proposed device is sterilized using ethylene oxide (EO). Both radiation and EO are FDA-recognized, validated terminal sterilization methods widely used for single-use medical devices. The EO sterilization process for the proposed device has been validated in accordance with ISO 11135 and demonstrates a Sterility Assurance Level (SAL) of 10^{-6}, equivalent to the predicate device. Therefore, the difference in sterilization method does not raise new questions of safety or effectiveness when compared to predicate.

7. **Non clinical tests**

Document Reference	Title
ISO 23908:2024	Sharps injury protection - Requirements and test methods - Sharps protection features for single-use hypodermic needles, introducers for catheters and needles used for blood sampling
ISO 9626:2016-08-01	Stainless steel needle tubing for the manufacture of medical devices - Requirements and test methods
ISO 80369-7:2021-05	Small-bore connectors for liquids and gases in healthcare applications - Part 7: Connectors for intravascular or hypodermic applications
ISO 11607-1:2019	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
ASTM F88/F88M-21	Standard Test Method for Seal Strength of Flexible Barrier Materials
ASTM F1929-15	Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration
ISO 10993-1: 2018	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
ISTA 3A 2018	Packaged-Products for Parcel Delivery System Shipment 70 kg (150 lb) or Less
ISO 7886-1: 2017	Sterile hypodermic syringes for single use - Part 1: Syringes for manual use
ISO 7864: 2016-08-01	Sterile hypodermic needles for single use - Requirements and test methods
USP 788	Particulate matter in injections
USP 151	Pyrogenicity test
USP 85	Bacterial Endotoxin

8. **Clinical test**

This submission does not contain clinical tests.

Conclusion

The Sol-Glide™ Safety Needle and Sol-Glide™ Safety Needle with Syringe are substantially equivalent to the predicate devices K241821, K242291, and K012736 with respect to intended use and technological characteristics. The subject device incorporates syringes previously cleared under K241821 (standard syringe configurations) and K242291 (Low Dead Space syringe configuration) and these components are unchanged from their legally marketed predicate devices with respect to design, materials, intended use, and performance specifications. The subject device meets the relevant ISO, ASTM and USP standards which demonstrate that any differences between subject device and predicates do not raise new or different questions of safety or effectiveness when compared to the predicate. Therefore, the Sol-Glide™ Safety Needle and Sol-Glide™ Safety Needle with Syringe are substantially equivalent to the predicate devices K241821, K242291, and K012736.