April 30, 2025

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

Re: K250907
Trade/Device Name: Sol-Guard ™ XtraThin Safety Pull-Button Blood Collection Set
Regulation Number: 21 CFR 862.1675
Regulation Name: Blood Specimen Collection Device
Regulatory Class: Class II
Product Code: JKA, FPA
Dated: March 21, 2025
Received: March 26, 2025

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 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,

Porsche Bennett

Porsche Bennett
For David Wolloscheck, Ph.D.
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)*
K250907

Device Name
Sol-Guard TM XtraThin Safety Pull-Button Blood Collection Set

Indications for Use *(Describe)*
The Sol- GuardTM XtraThin Wall Safety Pull button blood collection set is a sterile, multi-sample, single-use fixed winged blood collection set intended for venipuncture to obtain blood specimens from patients. When used without the male Luer adaptor, the device allows the clinician to obtain blood sampling to the female hub with a syringe, if necessary or can be used for short-term (up to 2 hours), single infusions with consideration given to patient size and appropriateness for the solution being infused. The device is not to be left in place and should remain under the direct supervision of a clinician.
The recommended use of the device is to activate the needle safety feature prior to removal from the venipuncture site. The retraction of the intravenous (IV) end of the needle aids in the prevention of accidental needlestick injury.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

K250907- 510(k) Summary

1. **SUBMITTER INFORMATION:**
   Company Name: Sol-Millennium Medical, Inc.
   Address: 311 South Wacker Drive, Suite 4100, Chicago. Illinois, USA 60606
   Contact Person: Mr. Mike Xie (Vice President of QARA)
   Telephone: 847-400-4821
   Email: yxie@solm.com

2. **DATE PREPARED:** April 30, 2025

3. **DEVICE IDENTIFICATION**
   Trade Name: Sol-Guard™ XtraThin Safety Pull-Button Blood Collection Set
   - Note: XtraThin is a Sol-Millennium trade name.

   Common Name: Tubes, Vials, Systems, Serum Separators, Blood Collection
   Classification Name: Blood Specimen Collection Device
   Classification: II
   Product Code: JKA, FPA
   Regulation Number: 21 CFR 862.1675

4. **PREDICATE DEVICE:**
   510(k) Number: K213718
   Trade Name: Sol-Guard™ Safety Pull-Button Collection Set

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Sol-Millennium Medical Inc.
311 S. Wacker, Suite 4100,
Chicago, IL 60606

5. DEVICE DESCRIPTION:

Sol-Guard™ XtraThin Safety Pull-Button Blood Collection Set is a single-use, sterile, winged blood collection needle that can be used for blood collection and/or the short-term (up to 2 hours) infusion of intravenous fluids. The device is offered with butterfly needle set which has either 21-, 23- or 25-gauge needle with integral butterfly wings, offered in two different flexible tubing lengths of 178mm and 305mm, and a safety tube with tubing leading to a female luer connector. The female luer connector is optionally attached to a luer adapter, or luer adapter plus a tube holder.

The device is designed with spring retractable needle technology that allows needle retraction after use to prevent needle stick injury and blood exposure. When the Button on the body of the butterfly is pulled back, the spring is released, and the needle is retracted into the clear plastic safety tube. In the activated position, the needle is completely enclosed within the clear plastic safety tube which guards against accidental needlesticks during normal handling and disposal.

Table 1. Device Models:

Model Names
Sol-Guard™ XtraThin Safety Pull-Button Blood Collection Set with Pre-attached Holder
Sol-Guard™ XtraThin Safety Pull-Button Blood Collection Set with Luer Adaptor
Sol-Guard ™ XtraThin Safety Pull-Button IV Infusion Set

6. PURPOSE OF SPECIAL 510(k):

The purpose of this Special 510(k) submission is to expand the needle range to include the XtraThin Wall needle type. The intended use of the modified device remains consistent with that of the predicate device.

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7. INDICATIONS FOR USE:

The Sol- Guard™ XtraThin Wall Safety Pull button blood collection set is a sterile, multi-sample, single-use fixed winged blood collection set intended for venipuncture to obtain blood specimens from patients. When used without the male Luer adaptor, the device allows the clinician to obtain blood sampling to the female hub with a syringe, if necessary or can be used for short-term (up to 2 hours), single infusions with consideration given to patient size and appropriateness for the solution being infused. The device is not to be left in place and should remain under the direct supervision of a clinician.

The recommended use of the device is to activate the needle safety feature prior to removal from the venipuncture site. The retraction of the intravenous (IV) end of the needle aids in the prevention of accidental needlestick injury.

8. INTENDED USERS:

Licensed Healthcare Professionals (HCP)

9. TECHNOLOGICAL CHARACTERISTICS COMPARISON

The predicate product utilizes a needle with a thin wall design, while the subject product is equipped with an "XtraThin Wall" needle, featuring a increased inner diameter without any corresponding increase in the outer diameter.

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Table 2. Comparison between Predicate Device and the subject device:

Elements of Comparison	**Subject Device** Sol-Guard™ XtraThin Safety Pull-Button Blood Collection Set	**Predicate Device** Sol-Guard™ Safety Pull-Button Collection Set: K213718	**Evaluation**
Intended use	○ Sol-Guard ™ XtraThin Safety Pull-Button Blood Collection Set with Pre-attached Holder is intended for venipuncture to obtain blood specimens from patients. ○ Sol-Guard ™ XtraThin Safety Pull-Button Blood Collection Set with Luer Adapter is intended for venipuncture to obtain blood specimens from patients and/or short-term (up to 2 hours) infusion of intravenous fluids without use of pre-attached luer adapter ○ Sol-Guard ™ XtraThin Safety Pull-Button IV Infusion Set is intended for delivery of short-term	○ Sol-Guard™ Safety Pull-Button Blood Collection Set with Pre-attached Holder is intended for venipuncture to obtain blood specimens from patients. ○ Sol-Guard ™ Safety Pull-Button Blood Collection Set with Luer Adapter is intended for venipuncture to obtain blood specimens from patients and/or short-term (up to 2 hours) infusion of intravenous fluids without use of pre-attached luer adapter ○ Sol-Guard ™ Safety Pull-Button IV Infusion Set is intended for	**Same**

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	(up to 2 hours) infusion of intravenous fluids. The device can also be used for blood collection procedures in connection with luer adapter that is available in standalone version.	delivery of short-term (up to 2 hours) infusion of intravenous fluids. The device can also be used for blood collection procedures in connection with luer adapter that is available in standalone version.	
Product Code	JKA, FPA	JKA, FPA	**Same**
Regulation Number	21 CFR 862.1675	21 CFR 862.1675	**Same**
Class definition	US FDA Class II	US FDA Class II	**Same**
Classification Name	Blood Specimen Collection Device	Blood Specimen Collection Device	**Same**
Patient Population	Adults and Pediatrics	Adults and Pediatrics	**Same**
Prescription or OTC	Prescription Only	Prescription Only	**Same**
Number of Uses	Single-Use	Single-Ue	**Same**
Activation of Safety Mehanism	Pull Button	Pull Button	**Same**
Needle Gauge Sizes	21G, 23G, and 25G	21G, 23G and 25G	**Same**
Needle Diameter OD	No Change	No Change	**Same**
Needle Diameter ID	XtraThin Wall	Thin Wall	**Different** Design verification testing conducted demonstrates that the change in inner diameter of the needle does not raise new or different questions of safety and effectiveness when compared to the cleared predicate device.
Tubing Length	XtraThin Wall	Thin Wall	**Same**

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Needle Point	3 Bevel	3 Bevel	**Same**
Needle	Stainless Steel 304	Stainless Steel 304	**Same**
Needle/Hub Glue	Epoxy Glue	Epoxy Glue	**Same**
Spring	Stainless Steel	Stainless Steel	**Same**
Needle Hub	Low Density Polyethylene	Low Density Polyethylene	**Same**
Sliding Button	Polycarbonate	Polycarbonate	**Same**
Needle Protector	Low Density Polyethylene	Low Density Polyethylene	**Same**
Wings	Polyvinyl Chloride	Polyvinyl Chloride	
Housing (A & B)	Polycarbonate	Polycarbonate	**Same**
Tubing	Polyvinyl Chloride	Polyvinyl Chloride	**Same**
Female Luer Lock	Polyvinyl Chloride	Polyvinyl Chloride	**Same**
Luer Adaptor	Luer Adapter Hub: Polypropylene Needle Cap: Low Density Polyethylene Needle: Stainless Steel Rubber Sleeve: Polyisoprene Rubber	Luer Adapter Hub: Polypropylene Needle Cap: Low Density Polyethylene Needle: Stainless Steel Rubber Sleeve: Polyisoprene Rubber	**Same**
Holder	Polypropylene	Polypropylene	**Same**
Sterile	Yes	Yes	**Same**
Sterilization Method	Ethylene Oxide (EO)	Ethylene Oxide (EO)	**Same**
Shelf Life	3 years	3 years	**Same**

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10. NON-CLINICAL TESTING

Table 3. Tests and Performance Specifications for Subject Device

Test Attribute	Standard
1. Needle Size, Stiffness and resistance to breakage	ISO 9626:2016
2. Patency of Lumen	ISO 7864:2016
3. Biological evaluation[1]	ISO 10993-1:2019
4. Sterility	ISO 11135:2014/Amd 1:2018
5. Accelerated aging	ASTM F1980-21
6. Leak Testing for infusion equipment	ISO 8536-4:2019
7. Color coding for identification	ISO 6009:2016
8. Sharp Injury Protection	ISO 23908:2011
9. Connectors for intravascular or hypodermic applications	ISO 80369-7:2021
10. Common Test methods for small-bore connectors for liquids and gases in healthcare applications	ISO 80369-20:2015

Biocompatibility

In accordance with ISO 10993-1, the needle is classified as: Externally Communicating Device, Blood Path Indirect, Limited Contact (<24 hours). The following testing were conducted:

- Cytotoxicity
- Sensitization
- Intracutaneous Reactivity
- Pyrogenicity
- Acute systemic toxicity
- Hemocompatibility

Bench and performance testing of the Sol-Guard™ XtraThin Safety Pull-Button Blood Collection Set were conducted to thoroughly verify and validate the results of our design control activities for the subject device. Comprehensive reviews were conducted on all technological characteristics (Table 3). The testing outcomes demonstrate that the Sol-Guard™ XtraThin Safety Pull-Button Blood Collection Set performs at a level fully equivalent to that of the predicate device.

11. CONCLUSION

The Sol-Guard™ XtraThin Safety Pull-Button Blood Collection Set is substantially equivalent to the predicate device in terms of intended use, principles of operation, technology, design, materials, and performance. The primary difference lies in the inner wall thickness of the needle, which has been shown not to raise new or different questions of safety and effectiveness when compared to the predicate device. The device meets the relevant ISO and ASTM standards, and the increased inner diameter of the needle is not expected to introduce new risks. Design verification testing confirms that the Sol-Guard™ XtraThin Safety Pull-Button Blood Collection Set performs as intended, supporting its substantial equivalence to the predicate device, K213718.