August 30, 2022

Sol-Millennium Medical, Inc.
PJ Pasia
Director, Regulatory Affair
315 Shawnee North Drive Suite 100,
Suwanee, Georgia 30024

Re: K213718
Trade/Device Name: SOL-GUARD Safety Pull Button Collection Set
Regulation Number: 21 CFR 862.1675
Regulation Name: Blood Specimen Collection Device
Regulatory Class: Class II
Product Code: JKA, FPA
Dated: August 1, 2022
Received: August 2, 2022

Dear PJ Pasia:

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,

David Wolloscheck, Ph.D.
For Payal Patel
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)*
K213718

Device Name
SOL-GUARD™ Safety Pull-Button Blood Collection Set

Indications for Use *(Describe)*
The SOL-GUARD™ 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 adapter, 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 remain under the direct supervision of a clinician.

The recommended use of the device is to activate the needle safety feature prior to removal 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.

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K213718. 510(k) Summary

Date Prepared: August 30, 2022

A. Submitter Information

Sol-Millennium Medical, Inc.
315 Shawnee North Drive, Suite 100
Suwanee, GA 30024

Contact Person:	PJ Pasia
Phone Number:	847-363-1264

B. Device Information

Trade/Proprietary Name:	SOL-GUARD™ Safety Pull-Button Blood Collection Set
Common name of device:	Tubes, Vials, Systems, Serum Separators, Blood Collection
Product Code:	JKA, FPA
Regulatory Class:	II
Regulation Number:	862.1675
Regulation Name:	Blood Specimen Collection Device
Review Panel	Clinical Chemistry

C. Predicate Device

K153309	BD Vacutainer® UltraTouch™ Push Button Blood Collection Set

D. Device Description

SOL-GUARD™ 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.

The SOL-GUARD™ Safety Pull-Button Blood Collection Set is comprised of 3 different configurations as shown below.

Model Name	Attachments
SOL-GUARD™ Safety Pull-Button Blood Collection Set with Pre-attached Holder	Provided with pre-assembled Luer adapter and Tube holder
SOL-GUARD™ Safety Pull-Button Blood Collection Set with Luer Adapter	Provided with Luer adapter only
SOL-GUARD™ Safety Pull-Button IV Infusion Set	No attachment provided

E. Indications for Use

Characteristic	Subject Device SOL-GUARD™ Safety Pull-Button Blood Collection Set K213718	Predicate Device BD Vacutainer UltraTouch Push Button Blood Collection Set K153309
Indications for Use	The SOL-GUARD™ 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 adapter, 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 remain under the direct supervision of a clinician. The recommended use of the device is to activate the needle safety feature prior to removal the venipuncture site. The retraction of the intravenous (IV) end of the needle aids in the prevention of accidental needlesticks injury.	The BD Vacutainer UltraTouch Push 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 adapter, 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, 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 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.
Prescription Only or Over the Counter	Prescription Only	Prescription Only

There is minor difference to the Indications for Use Statement between the predicate and the subject device. The duration of usage in the Indication for Use statement, “up to 2

hours" versus "short term" is not an actual difference. The predicate device's maximum time for infusion is also up to 2 hours, according to predicate's IFU, except not stated in their Indication for Use statement. Specifying the duration of use provides clarity and does not affect safety or effectiveness or raise different questions of safety and effectiveness.

F. Comparison of Technological Characteristics

Information was submitted to demonstrate that there are no significant differences in technological characteristics between the SOL-GUARD™ Safety Pull-button Blood Collection Set and the BD Vacutainer® UltraTouch Push Button Blood Collection Set. The following comparison chart and discussions show that the subject device and the predicate device are substantially equivalent.

SIDE BY SIDE COMPARISON TABLE

Specification	Subject Device SOL-GUARD Safety Pull-Button Blood Collection Set K213718	Predicate Device BD Vacutainer Ultratech Push Button Blood Collection Set K153309	Comments (Same or Different)
Indicated for infusion	Yes	Yes	Same
Single use	Yes	Yes	Same
Activation of safety mechanism	Pull Button	Push Button	Different /See comment #1
Components:			
Needle Gauge Sizes	21G, 23G, 25G	21G, 23G, 25G	Same
Needle Diameter ID	Thin Wall	Ultra-Thin Wall	Different /See comment #2
Tubing Length	7" and 12"	7" and 12"	Same
Needle Length	0.75"	0.75"	Same
Needle Point	3-bevel	5-bevel	Different /See comment #3
Performance:			
Sterilization Method	Ethylene Oxide	Gamma	Different /See comment #4
Sterility Assurance Level (SAL)	10^{-6}	10^{-6}	Same
Non-pyrogenic	Yes	Yes	Same
Shelf life	3 years	2 years	Different /See comment #5
Materials:			
Needle	Stainless Steel	Stainless Steel	Different /See comment #6
Needle/Hub Glue	Epoxy Glue	UV cure adhesive	
Spring	Stainless Steel	Stainless Steel	

Specification	Subject Device SOL-GUARD Safety Pull-Button Blood Collection Set K213718	Predicate Device BD Vacutainer Ultratech Push Button Blood Collection Set K153309	Comments (Same or Different)
Needle Hub	Low Density Polyethylene	Polypropylene	
Sliding Button	Polycarbonate	Polypropylene	
Needle Protector	Low Density Polyethylene	Polyethylene	
Wings	Polyvinyl Chloride	Polyolefin	
Housing A	Polycarbonate	Polypropylene	
Housing B	Polycarbonate	Acrylic	
Tubing	Polyvinyl Chloride	Polyvinyl Chloride	
Female Luer Lock Connector	Polyvinyl Chloride	Acrylonitrile-butadiene-styrene	
Luer Adapter	Luer Adapter Hub: Polypropylene Needle Cap: Low Density Polyethylene Needle: Stainless Steel Rubber Sleeve: Polyisoprene Rubber	Luer Adapter hub: Polypropylene Needle Cap: Polypropylene Needle: Stainless Steel Rubber Sleeve: Synthetic Isoprene Rubber	
Holder	Polypropylene	unknown	

Discussions of Differences in Technological Characteristics

Comment 1: Activation of safety mechanism

For the subject device, to activate the safety mechanism, the button on the body of the butterfly is pulled back, while the predicate device requires to push the button. Both (pull and push) actions allow the release of the internal spring that withdraws the needle from the patient's arm into the safety tube of the blood collection device. Both bench testing (Forces for Activation, Simulated "in-Vein" Needle Retraction, Simulated Jammed Retraction, and Safety Shield Unlocking Resistance) and Simulated Usability Study demonstrated that the "Pull" motion can activate the safety mechanism and provide the same protection for needlestick injury as the predicate device. This difference does not affect safety or effectiveness or raise different questions of safety and effectiveness.

Comment 2: Needle Diameter Wall

Although the predicate has an Ultra-Thin wall, its original version was a thin-walled needle covered under K030573 (predicate of BD Vacutainer UltraTouch Push Button Blood Collection Set). The difference in needle wall thickness does not raise any questions of safety and effectiveness.

Comment 3: Needle Point
Although the predicate has a 5-bevel needle point, its original version was a 3-bevel needle point covered under K030573 (predicate of BD Vacutainer UltraTouch Push Button Blood Collection Set). The difference in bevel type does not raise any questions of safety and effectiveness.

Comment 4: Sterilization Method
The sterilization validation per ISO 11135 shows that the subject device can reach the same sterilization assurance level as predicate device and there is no impact to safety and effectiveness caused by using Ethylene Oxide sterilization.

Comment 5: Shelf life
The real time and accelerated shelf-life testing per ASTM F1980-16 were conducted on subject device, demonstrating no safety and effectiveness were impacted by the prolonged shelf life.

Comment 6: Materials
The biocompatibility per ISO 10993 and performance testing showed that differences in materials of construction do not raise any questions of safety or effectiveness.

G. Performance Testing

The SOL-GUARD Safety Pull-Button Blood Collection Set described in this summary were tested and demonstrated to be in conformance with the following FDA recognized standards:

- ISO 7864:2016: Sterile hypodermic needles for single use – Requirements and test methods
- ISO 6009:2016: Hypodermic needles for single use – Colour coding for identification
- ISO 8536-4:2019: Infusion equipment for medical use – Part 4: Infusion sets for single use, gravity feed
- ISO 9626:2016: Stainless steel needle tubing for the manufacture of medical devices – Requirements and test methods
- ISO 80369-7:2021: Small-bore connectors for liquids and gases in healthcare applications – Part 7: Connectors for intravascular or hypodermic applications
- ISO 80369-20:2015: Small-bore connectors for liquids and gases in healthcare applications – Part 20: Common test methods
- ISO 20696:2018: Sterile urethral catheters for single use
- ISO 23908:2011: Sharps injury protection – Requirements and test methods – Sharps protection features for single-use hypodermic needles, introducers for catheters and needles used for blood sampling

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

Particulate Matter
Particulate matter testing was conducted in accordance with USP <788> Particulate Matter in Injections and met the USP acceptance criteria.

Sterility, Pyrogen, Shelf-life, Bacterial Endotoxin, and Shipping
The subject device is intended to be sterilized with Ethylene Oxide procedures validated per ISO 11135. The subject device met applicable acceptance criteria for EO and ECH residuals per ISO 10993-7 and pyrogenicity per USP <151>. The following additional tests were conducted:

- Sterile Barrier Packaging testing (Peeling force per ASTM F88/F88M, Clean Peel per ISO 11607-1, and ASTM F1929 for Dye Penetration Test).
- 3-year shelf-life test per ASTM F1980-16 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices.
- Bacterial Endotoxin testing per European pharmacopoeia 10.2.6.14.
- Simulated Shipping per ISTA 3A Packaged-Product for Parcel Delivery System Shipments 70kg (150lb) or Less.

In addition, bacterial endotoxin testing is conducted on every lot during manufacturing to meet pyrogen limit specification 20EU/device.

H. Conclusion

The differences between the subject and the predicate devices do not raise any new or different questions of safety and effectiveness. Based on the information provided in this submission, the subject devices, have been determined to be substantially equivalent to the predicate device, BD Vacutainer® UltraTouch™ Push Button Blood Collection Set.