DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

May 19, 2017

Sol-Millennium Medical, Inc.
Mr. James Barley
Regulatory Affairs Director
1735 North Brown Road, Suite 120
Lawrenceville, Georgia 30043

Re: K163073
Trade/Device Name: Sol-Care Safety Blood Collection Needle (with and without Pre-attached Tube Holder)
Regulation Number: 21 CFR 862.1675
Regulation Name: Blood specimen collection device
Regulatory Class: Class II
Product Code: JKA, FPA
Dated: April 10, 2017
Received: April 18, 2017

Dear Mr. James Barley:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Change Control Table, Change History

Change Control Table

Version	Document Author	Document Approver	Date Approved
1.00	Name, Title, Office	Name, Title, Office	MM/DD/YYYY

Complete Change Control Table (all versions) retained in SWIFT Docs.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K163073

Device Name
Sol-Care Safety Blood Collection Needle(with and without Pre-attached Tube Holder)

Indications for Use *(Describe)*
The Sol-Care Safety Blood Collection Needle(with and without Pre-attached Tube Holder) is a single-use, sterile, winged blood collection needle to be used for blood collection or short-term infusion (up to 2 hours) of intravenous fluids. The device is designed with a safety mechanism to help reduce the risk of 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.

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Safety Blood Collection Needle (with and without pre-attached Tube Holder) 510(k)

510(k) Summary

(As required by 21 CFR 807.92(a))

510(k) Number K163073

Date Prepared: April 10, 2017

A. Submitter Information

Sol-Millennium Medical, Inc.
1735 North Brown Road
Suite 120
Lawrenceville, GA 30043
Contact Person: James Barley
Phone Number: 404-973-2200

B. Device Information

Trade/Proprietary Name:	Sol-Care Safety Blood Collection Needle (with and without Pre-attached Tube Holder)
Common name of device:	Winged Collection Set, Small Vein Set
Classification Name:	Blood Specimen Collection Device
Product Code:	JKA, FPA
Regulatory Class:	II
Classification Number:	862.1675
Reason for 510(k):	New device

C. Predicate Device: BD Vacutainer Safety Lok Blood Collection Set

March 3, 1998

Predicate 510(k) #:	K980414
Predicate product code:	JKA

D. Device Description

The Sol-Care Safety Blood Collection Needle Set (Butterfly Needle) is a single-use, sterile, winged blood collection needle that can be used for blood collection and/or the short-term infusion of intravenous fluids. The Butterfly Needle Set is available with a 21, 23 or 25 gauge needle with Butterfly Wings and a Safety Shield with tubing leading to a covered needle assembly and Tube Holder. The product is available with and without the Tube Holder.

The Sol-Care Safety Blood Collection Needle consists of:

- Stainless steel cannula (Intravenous end and Non-patient end of Cannula)
- Wings (Color coded according to needles gauge)
- Tubing
- Female luer adaptor
- Intravenous (IV) needle protector (covers the needle before use)

The optional SOL-M™ Blood Collection Tube Holder and SOL-M™ Blood Culture Holder include a male luer adapter for attachment to the Sol-Care Safety Blood Collection Needle.

The Sol-Care Safety Blood Collection Needle has a sharps injury prevention feature. The Butterfly Wing Assembly consists of a needle assembly and a Safety Shield. After use, the health care professional can pull back on the tubing while holding the butterfly wing and the needle will retract and lock into the Safety Shield. In the activated position the needle cover guards against accidental needlesticks during normal handling and disposal.

The devices are sterilized by Ethylene Oxide Gas. The Safety Blood Collection Needle is supplied in a hard Tray Pack while the Safety Blood Collection Needle with a pre-attached Tube Holder is supplied in a soft Tray Pack. Twenty-Five Safety Blood Collection Needles with a pre-attached Tube Holders are packaged in a chipboard box while fifty Safety Blood Collection Needles are packaged in a chipboard box. Each Tray Pack is labeled with the contents and the appropriate information per the Medical Device Directive and FDA's Quality System Regulation and Labeling requirements, 21CFR Part 801.

E. Statement of Indications for Use

Sol-Care Safety Blood Collection Needle (with and without Pre-attached Tube Holder)

The Sol-Care Safety Blood Collection Needle (with and without Pre-attached Tube Holder) is a single use, sterile, winged blood collection needle to be used for blood collection or short-term infusion (up to 2 hours) of intravenous fluids. The device is designed with a safety mechanism to help reduce the risk of needlestick injury.

F. Comparison of Required Technological Characteristics:

Information was submitted to demonstrate that there are no significant differences in technological characteristics between the Sol-Care Safety Blood Collection Needle and BD Vacutainer Safety Lok Blood Collection Set. The following comparison chart shows that the subject device and the predicate device are substantially equivalent:

SIDE BY SIDE COMPARISON TABLE

Feature	Sol-Care Safety Blood Collection Needle (Subject Device)	BD Vacutainer Safety-Lok Blood Collection Set (Predicate Device)	Same, similar or different
Indication for Use	The Sol-Care Safety Blood Collection Needle (with and without a Pre-attached Tube Holder) is a single use, sterile, winged blood collection needle to be used for blood collection or short-term infusion (up to 2 hours) of intravenous fluids. The device is designed with a safety mechanism to help reduce the risk of needlestick injury.	The Vacutainer Brand Blood Collection Set and Safety-Lok Blood Collection Set is a winged blood collection needle and flexible tubing for venipuncture to collect blood specimen from patients or monitoring blood pressure. The Safety-Lok Blood Collection Set also contains a needle safety shield which minimizes the possibility of a needlesticks if manually activated following blood collection. The Vacutainer Brand Blood Collection Set and Safety-Lok Blood Collection Set is also recommended for use in patients with small veins. The Vacutainer Brand Blood Collection Sets and Safety-Lok Blood is also indicated for the	Similar

		intravenous administration of fluids and may be used for any patient population with consideration given to patient size, appropriateness for the solution being infused and duration of therapy.	
Intended use	Blood Collection and Infusion of Intravenous Solutions for up to 2 hours	Blood Collection and Infusion of Intravenous Solutions for up to 2 hours	Same
Product design/ component materials			
Needle Cap	LDPE (Low Density Polyethylene)	Plastic	Similar
Needle, Butterfly Wings	PVC	PVC	Same
Safety Shield	Polypropylene	Polypropylene	Same
Tubing	PVC	PVC	Same
Female Fitting	ABS	ABS	Same
Male Fitting	White Polypropylene	White Polypropylene	Same
Blood Collection Needle	Stainless Steel (SUS 304)	Stainless Steel (SUS 304)	Same
Needle Cover	Clear LDPE (Low Density Polyethylene)	Plastic	Similar
Needle gauges	21G, 23G and 25G	21G, 23G and 25G	Same
Needle Length	3/4”	3/4”	Same
Needle Bevel	60 degree	60 degree	Same
Tubing length	7” and 12”	12”	Same
Packaging design w/o Holder/ materials	Tray Pack	Tray Pack	Same
Method to retract needle	Pull back on tubing until needle is locked within the Safety Shield	Pull back on tubing until needle is locked within the Safety Shield	Same
Method of sterilization	EO	EO	Same
Shelf life	3 year	3 year	Same

G. Summary and Conclusion of Nonclinical Tests:

The Sol-Care Safety Blood Collection Needle (with and without a pre-attached Tube Holder) met the appropriate requirements contained in the following standards:

1. ISO 8536-4:2010, Infusion Equipment for Medical Use – Part 4: Infusion Sets For Single Use, Gravity Feed and ISO 7864:1993, Sterile Hypodermic Needles for Single Use;
   - PRJ001_096, Butterfly Needle Chemistry Test Protocol and Report
   - PRJ001_062, Butterfly Needle Appearance and Size Test Protocol and Report
   - PRJ001_060, Butterfly Needle Systematic Flow Test Protocol and Report
   - PRJ001_056, Butterfly Needle Systematic Blocking Test Protocol and Report
   - PRJ001_057, Butterfly Needle Protector Drawing Force Test Protocol and Report
   - PRJ001_054, Butterfly Needle Puncture Force Test Protocol and Report
   - PRJ001_053, Butterfly Needle Unlocking Force Test Protocol and Report
   - PRJ001_052, Butterfly Needle Shield Pulling Force Test Protocol and Report
   - PRJ001_049, Butterfly Needle Rubber Sealing Test Protocol and Report

2. 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.
   - Simulated Use Study with Nurse Evaluators

3. ISO 11607-1,-1:2009+A1:2014, Packaging for terminally sterilized medical Devices and ISO 11607-2:2006, Packaging for terminally sterilized medical devices -- Part 2: Validation requirements for forming, sealing and assembly processes.
   - Seal Validation of the Soft Pack
   - Seal Validation of the Hard Pack
   - Simulated Transit Test for the Soft Pack
   - Simulated Transit Test for the Hard Pack
   - Accelerated Aging of the Soft Pack and Product Testing at time 0, years 1, 2 and 3
   - Accelerated Aging of the Hard Pack and Product Testing at time 0, years 1, 2 and 3
   - Low Temperature (-20°C) Product Qualification
   - High Temperature (60°C) Product Qualification

4. ISO 11135-1:2007, Medical Apparatus – Epoxy Ethane Sterilization Confirmation and Routine Control
   - The Sol-Care Safety Blood Collection Device family was adopted into an existing validated sterilization. This adoption complies with AAMI TIR 28: , Product Adoption and Process Equivalency for Ethylene Oxide Sterilization. The cycle was validated according to the requirements of ISO 11135-1: 2014, Medical devices – Validation and Routine Control of Ethylene Oxide Sterilization.

5. ISO 594-2:1998, Conical fittings with 6% (Luer) taper for syringes, needles and certain other medical equipment – Part 2: Lock Fittings
   - PRJ001_059, Butterfly Needle Systematic Leakage Test Protocol and Report

6. ISO 10993-1:2006, Biological evaluation of medical devices Part 1: Evaluation and testing
   - Cytotoxicity,
   - Irritation Test/Intracutaneous Reactivity
   - Sensitization Study,
   - USP and ISO Systemic Toxicity Studies
   - Haemolysis test
   - Thrombosis Testing
   - Complement Activation C3a and SC5b-9 Asay with Sponsor-Supplied Comparison Articie (GLP)
   - ASTM Hemolysis Assay - Direct Contact and Extract Method (GLP)

H. Discussion of Clinical Tests:

None submitted

I. Conclusions Demonstrating Substantial Equivalence through Performance Testing:

The device has been tested and found to meet all product specifications and requirements. Product labeling clearly shows that the device is for single use only. After review of the Risk Analysis, all verification and validation test data and reports, the conclusion of the Design Review Committee was that the Sol-Care Safety Blood Collection Needle (with and without pre-attached Tube Holder) are substantially equivalent to the predicate device.