December 3, 2018

Sol-Millennium Medical, Inc.
James Barley
Director of RA
1735 North Brown Road, Suite 120
Lawrenceville, Georgia 30043

Re: K182146
Trade/Device Name: Sol-M Blood Collection Needles, Sol-Care Safety Blood Collection Needles, Sol-Care Safety Blood Collection Needle with Holder, Sol-M Blood Collection Set
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: Class II
Product Code: FMI
Dated: July 18, 2018
Received: August 8, 2018

Dear 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. 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Sarah B. Mollo -S

for 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K182146

Device Name
Sol-M Blood Collection Needle
Sol-Care Safety Blood Collection Needle
Sol-Care Safety Blood Collection Needle with Holder and Sol-M Blood Collecting Set

Indications for Use *(Describe)*
The Sol-M Blood Collection Needle is intended to be used with vacuum blood collection tube for the collection of venous blood.

The Sol-Care Safety Blood Collection Needle is intended to be used with vacuum blood collection tube for the collection of venous blood. The safety shield is intended to aid in the protection against accidental needle stick injury.

The Sol-Care Safety Blood Collection Needle with Holder is intended to be used with vacuum blood collection tube for the collection of venous blood. The safety shield is intended to aid in the protection against accidental needle stick injury.

The Sol-M Blood Collecting Set is intended to be used with vacuum blood collection tube for the collection of venous blood.

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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510(k) Summary (As required by 21 CFR 807.92(a)) **K182146**

Summary of for the Sol-M Blood Collection Needle, Sol-Care Safety Blood Collection Needle and Sol-M Blood Collection Set

Date Prepared: November 30, 2018

A. Applicant and Correspondent

Name:	Sol-Millennium Medical, Inc.
Address:	1735 North Brown Road, Suite 120 Lawrenceville, GA 30043
Contact Person:	James Barley Director of RA
Phone:	(404) 433-3058

Manufacturer

Zhejiang kindly medical devices Co., Ltd.

No.758, 5th Binhai Road, Binhai Industrial Park, Longwan District, 325025 Wenzhou, Zhejiang Province, PRC.

B. Name of Device

- Trade/Proprietary/Model Name: Sol-M Blood Collection Needle
  - Sol-Care Safety Blood Collection Needle
  - Sol-M Blood Collection Set
- Common Name of Devices: Blood Collection Needle
  - Safety Blood Collection Needle
  - Blood Collection Set
- Panel: General Hospital
- Classification Number: 21 CFR 880.5570
- Classification Name: Needle, Hypodermic, Single Lumen
- Regulatory Class: II
- Product Code: FMI

Device to Which New Device is Substantially Equivalent

Device Name:	Blood Collecting Devices
Manufacturer:	Zhejiang Kindly Medical Devices Co., Ltd.
Classification Number:	21 CFR 880.5570
Classification Name:	Needle, Hypodermic, Single Lumen
Regulatory Class:	II
Product Code:	FMI
Reference:	K172763

C. Device Description

The proposed devices are blood collection devices form a channel between patient's vein and the vacuum blood collection tube intended for collection of blood. The proposed devices are divided into several types, the configuration for each type of proposed device are provided as follows

Product name	Ref No.	Patient-End Needle	Non-Patient End Needle	Integrated Needle	Flexible Tube	Needle Holder	Safety Feature	Visible Flashback
Blood Collection Needle – one piece	04-11	X	X	X	N.A.	N.A.	N.A.	N.A.
Blood Collection Needle – Direct	04-13	X	X	X	N.A.	N.A.	N.A.	X
Blood Collection Needle – Multi piece	04-31	X	X	N.A.	N.A.	N.A.	N.A.	X
Safety Blood Collection Needle – Direct	04-12	X	X	X	N.A.	N.A.	X	N.A.
Safety Blood Collection Needle – Multi piece	04-32	X	X	N.A.	N.A.	N.A.	X	X
Safety Blood Collection Needle w/Holder – One piece	04-15	X	X	X	N.A.	X	X	N.A.
Safety Blood Collection Needle w/Holder – Direct	04-34	X	X	N.A.	N.A.	X	X	X

In addition, the proposed devices are divided into several types and available in different specifications as follows:

Device Name	Ref No.	Needle Gauge	Needle Length
Blood Collection Needle	04-11	18G-23G	1", 1-1/4", 1-1/2"
	04-13	18G-23G	1", 1-1/4", 1-1/2"
	04-31	19G, 25G	5/8", ¾",1", 1-1/4", 1-1/2", 1-3/4", 2"
Safety Blood Collection Needle	04-12	18G-23G	1", 1-1/4", 1-1/2"
	04-32	19G, 25G	5/8", ¾",1", 1-1/4", 1-1/2", 1-3/4", 2"
Safety Blood Collection Needle with Holder	04-15	18G-23G	1", 1-1/4", 1-1/2"
	04-34	19G, 25G	5/8", ¾",1", 1-1/4", 1-1/2", 1-3/4", 2"
Blood Collection Set	04-21	19G, 25G	5/8", ¾",1"
Safety Blood Collection Set	04-22	19G, 25G	5/8", ¾",1"
Blood Collection Set with Holder	04-23	19G, 25G	5/8", ¾",1"
Safety Blood Collecting Set with Holder	04-24	19G, 25G	5/8", ¾",1"

D. Statement of Indications for Use

- The Sol-M Blood Collection Needle is intended to be used with vacuum blood collection tube for the collection of venous blood.
- The Sol-Care Safety Blood Collection Needle is intended to be used with vacuum blood collection tube for the collection of venous blood. The safety shield is intended to aid in the protection against accidental needle stick injury.
- The Sol-Care Safety Blood Collection Needle with Holder is intended to be used with vacuum blood collection tube for the collection of venous blood. The safety shield is intended to aid in the protection against accidental needle stick injury.
- The Sol-M Blood Collecting Set is intended to be used with vacuum blood collection tube for the collection of venous

E. Non-Clinical Test Conclusion

Non clinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the applicable sections of the following standards:

- ISO 9626:2016 Stainless steel needle tubing for the manufacture of medical devices;
  - Sample needles from Safety blood collection Sets with a Holder were tested as follows per the requirements of ISO 9626: Material verification, surface finish and visual appearance, cleanliness, limits for acidity and alkalinity, size designation, dimensional inspection, stiffness, resistance to breakage and resistance to corrosion.
- ISO 7864:2016 Sterile hypodermic needles for single use - Requirements and test methods
  - Sample needles from Safety blood collection Sets with a Holder were tested as follows per the requirements of ISO7864: Cleanliness, limits for acidity and alkalinity, limits for extractable metals, tubular needle designation, color coding, conical fitting, color of hub, needle cap, tolerance on length, freedom from defects, lubricant, needle point, bond between hub and needle tube and patency of lumen.
- ISO 10993-7:2008 Biological evaluation of medical devices- Part 7: Ethylene oxide sterilization residuals;
  - EO and ECH Residuals Resting of sterilized product
- ASTM F 88/F88M-09 Standard test method for seal strength of flexible barrier materials;
  - Seal Peel Testing of package seals
- ASTM F1140/F1140M-13 Standard test methods for internal pressurization failure resistance of unrestrained packages;
  - Burst and Creep Testing of package
- USP38-NF33 <85> Bacterial Endotoxins Test.
  - Bacterial Endotoxin Testing of device
- ISO 10993-1:2009 Biological evaluation of medical devices- Part 1: Evaluation and testing within a risk management process.
  - Risk management report
- ISO 10993-5:2009 Biological evaluation of medical devices-Part 5: Tests for In Vitro Cytotoxicity
  - Biocompatibility – In Vitro Cytotoxicity Test

- ISO 10993-10:2010 Biological evaluation of medical devices- Part 10: Test for irritation and delayed-type hypersensitivity
  - Intracutaneous reactivity test and Skin Sensitization test
- ISO 10993-11:2006 Biological evaluation of medical devices- Part 11: Tests for systemic toxicity
  - Acute systemic toxicity test
  - Pyrogen test
- ASTM F 756-13 Standard practice for assessment of hemolytic properties of materials
  - Testing for Hemolytic properties of devices
- Guidance for Industry and FDA Staff, Medical Devices with Sharps Injury Prevention Features Document Issued on: August 9, 2005
  - A Simulated Use Study was conducted per the requirements of the FDA's Guidance for Industry and FDA Staff Medical Devices with Sharps Injury Prevention Features, Document Issued on: August 9, 2005

F. Brief discussion of clinical tests submitted, referenced, or relied on in the premarket notification submission for a determination of substantial equivalence.

Not applicable.

G. Substantially Equivalent (SE) Comparison

Comparison of Technology for Substantial Equivalence

ITEM	Predicate Device K172763	Proposed Devices	Remark
Class	II	II	Same
Intended use	The Blood Collecting Needle is intended to be used with vacuum blood collection tube for the collection of venous blood. The Safety Blood Collecting Needle is intended to be used with vacuum blood collection tube for the collection of venous blood. The safety shield is intended to aid in the protection against accidental needle stick injury. The Blood Collecting Set with Holder is intended to be used with vacuum blood collection tube for the collection of venous blood	The Sol-M Blood Collection Needle is intended to be used with vacuum blood collection tube for the collection of venous blood. The Sol-Care Safety Blood Collection Needle is intended to be used with vacuum blood collection tube for the collection of venous blood. The safety shield is intended to aid in the protection against accidental needle stick injury. The Sol-Care Safety Blood Collection Needle with Holder is intended to be used with vacuum blood collection tube for the collection of venous blood. The safety shield is intended to aid in the protection against accidental needle stick injury. The Sol-M Blood Collecting Set is intended to be used with vacuum blood collection tube for the collection of venous	Same

Sol-Millennium Medical

ITEM	Predicate Device K172763	Proposed Devices	Remark
Configuration	Patient-end Needle Protective Cover of Patient-end Needle Patient-end Needle Hub Non-patient end Needle Hub Non-patient end Needle Rubber Sleeve Protective Cover of Non-patient end Needle Double Wing Flexible Tube Conical Fitting Connector Conical Fitting Needle Holder	Patient-end Needle Protective Cover of Patient-end Needle Patient-end Needle Hub Non-patient end Needle Hub Non-patient end Needle Rubber Sleeve Protective Cover of Non-patient end Needle Double Wing Flexible Tube Conical Fitting Connector Conical fitting Needle Holder Safety Shield	Same
ITEM	Predicate Device K172763	Proposed Devices	Remark
Operational mode	Manual	Manual	Same
Specifications	18G, 19G, 20G, 21G, 22G, 23G, 25G 5/8", ¾",1", 1-1/4", 1-1/2", 1-3/4", 2"	18G, 19G, 20G, 21G, 22G, 23G, 25G 5/8", ¾",1", 1-1/4", 1-1/2", 1-3/4", 2"	Same
Safety mechanism	The safety shield is intended to prevent needle sticks.	The safety shield is intended to prevent needle sticks.	Same
Labeling	Conforms to Part 801	Conforms to Part 801	Same
Single use	Yes	Yes	Same

ITEM	Predicate Device K172763	Proposed Devices	Remark
Patient-contact material			
Needle Tube	Stainless Steel	Stainless Steel	Same
Lubricant	Silicone Oil	Silicone Oil	
Adhesive	Epoxy Resin	Epoxy Resin	
Biocompatibility			
In Vitro Cytotoxicity	Conform with ISO 10993	Conform with ISO 10993	Same
Skin Sensitization			
Intracutaneous Reactivity			
Acute Systemic Toxicity			
Hemolytic Properties			
Sterilization			
Method	EO sterilized	EO sterilized	Same
SAL	10^{-6}	10^{-6}	
Endotoxin Limit	20 EU per device	20 EU per device	

The proposed devices, Blood Collecting Needle, Safety Blood Collecting Needle, Blood Collecting Needle with Holder, Safety Blood Collecting Needle with Holder are the same to the predicate device K172763 in device design, Indications for use, manufacturing materials and processes, sterilization, method of operation and technological characteristics. Therefore, the proposed devices can be determined substantially equivalence to predicate devices.

H. Substantially Equivalent (SE) Conclusion

Based on the comparison and analysis above, the proposed devices are determined to be Substantially Equivalent (SE) to the predicate devices.