



Food and Drug Administration
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Silver Spring, MD 20993-0002

June 17, 2016

Sol-Millennium Medical, Inc.
Mr. Jim Barley
Director of Regulatory Affairs
1735 North Brown Road, Suite 100
Lawrenceville, Georgia 30043

Re: K153537

Trade/Device Name: Sol-M Insulin Syringe and Sol-M TB Syringe
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston syringe
Regulatory Class: II
Product Code: FMF
Dated: May 2, 2016
Received: May 10, 2016

Dear Mr. 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 yours,

 Tina Kiang -
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for Erin I. Keith, M.S

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

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

Indications for Use

510(k) Number (if known)
K153537

Device Name

Sol-M TB Syringe

Indications for Use (Describe)

The Sol-M TB Syringe is intended to be used for medical purposes to inject fluids into or withdraw fluids from the body.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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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)
K153537

Device Name

Sol-M Insulin Syringe

Indications for Use (Describe)

The Sol-M Insulin Syringe with needle, with the calibration unit of insulin for U-100, is a device intended for medical purposes for the manual aspiration of insulin, and for the injection of insulin into parts of the body below the surface skin.

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 for 510(k) # K153537

(As required by 21 CFR 807.92(a))

510(k) Summary for the Sol-M Insulin and TB Syringes

Date Prepared: June 16, 2016

A. Submitter Information

Sol-Millennium Medical, Inc.
1735 North Brown Road
Suite 120
Lawrenceville, GA 30043

Contact:

Jim Barley

Phone Number:

404-973-2200

Trade Names:

Sol-M Insulin Syringe

Sol-M TB Syringe

B. Device Information

Trade/Proprietary Name:

Sol-M Insulin and TB Syringe

Common name of device:

Piston syringe

Classification Name:

Piston syringe

Product Code:

80 FMF

Regulatory Class:

II

Classification Number:

880.5860

Reason for 510(k):

New device

C. Predicate Device:

KDL Syringes and Needles

Predicate 510(k) #:

K112057

Predicate product code:

FMF

Reference Devices:

Sol-Guard Insulin and Tuberculin Safety
Syringe 510(k) # K132681

1 ml Fixed Needle, 3 ml Luer Lock, 5 ml
Luer Lock, 10 ml Luer Lock, 20 ml
LuerLock Safety Syringe 510(k) # K092430

Invirostripe Luer Lock Syringes (1, 3, 10,
20, 30 And 60 ml 510(k) #K101359

D. Device Description

The Sol-M Syringe is a sterile, single use, standard 3 piece piston syringe with a fixed needle. The Sol-M 0.3, 0.5 and 1 ml Insulin Syringe will be labeled with a Units Scale calibrated for U-100 Insulin. The 0.5 and 1 ml TB Syringe will be labeled with a mL Scale.

The piston type syringe is a plastic disposable syringe made of the following components:

1. Barrel – The barrel has a scale showing the capacity of the syringe as well as the company brand name with the Do Not Reuse symbol.
2. Plunger – The plunger is used to aspirate fluid into the barrel or push fluid out of the barrel.
3. Stopper – The Stopper maintains the fluid in the barrel between the base of the barrel and Plunger.
4. Cap – The Cap is used to cover and protect the tip of the barrel from being damaged.

Following is a listing of model numbers and product descriptions included in this submission:

Sol-M Insulin Syringes with Fixed Needle

Sol-M 0.3 ml Insulin Syringe with Fixed Needle	
REF/Catalog #	Description
16331518	0.3ml, 31G x 5/16"/10 Pack PE Bag
16330518	0.3ml, 30G x 5/16"/10 Pack PE Bag
16330128	0.3ml, 30G x 1/2"/10 Pack PE Bag
16329128	0.3ml, 29G x 1/2"/10 Pack PE Bag
Sol-M 0.3 ml Insulin Syringe with Fixed Needle	
REF/Catalog #	Description
16330516	0.3ml, 30G x 5/16"/1 ea. Blister Pack
1633012	0.3ml, 30G x 1/2"/ 1 ea. Blister Pack
1632912	0.3ml, 29G x 1/2"/ 1 ea. Blister Pack
Sol-M 0.5 ml Insulin Syringes with Fixed Needle	
REF/Catalog #	Description
16531518	0.5ml, 31G x 5/16"/10 Pack PE Bag
16530518	0.5ml, 30G x 5/16"/10 Pack PE Bag
16530128	0.5ml, 30G x 1/2"/10 Pack PE Bag
16529128	0.5ml, 29G x 1/2"/10 Pack PE Bag
16130516	0.5ml, 30G x 5/16"/1 ea. Blister Pack
1613012	0.5ml, 30G x 1/2"/ 1 ea. Blister Pack
1612912	0.5ml, 29G x 1/2"/ 1 ea. Blister Pack

Sol-M 1 ml Insulin Syringes with Fixed Needle	
REF/Catalog #	Description
16131518	1ml, 31G x 5/16"/10 Pack PE Bag
16130518	1ml, 30G x 5/16"/10 Pack PE Bag
16130128	1ml, 30G x 1/2"/10 Pack PE Bag
16129128	1ml, 29G x 1/2"/10 Pack PE Bag
16530516	1.0ml, 30G x 5/16"/1 ea. Blister Pack
1653012	1.0ml, 30G x 1/2"/ 1 ea. Blister Pack
1652912	1.0ml, 29G x 1/2"/ 1 ea. Blister Pack

Sol-M TB Syringes with Fixed Needle

Sol-M 0.5 ml TB Syringes with Fixed Needle	
REF/Catalog #	Description
180527	0.5ml, 27G x 1/2"/1 each Blister Pack
180526IDB	0.5ml, 26G x 3/8" IDB/1 each Blister Pack
180527T	0.5ml, 27G x 1/2"/25 each Tray Pack
180527IDB	0.5ml, 27G x 3/8"/25 Tray Pack
Sol-M 1 ml TB Syringes with Fixed Needle	
REF/Catalog #	Description
181027	1ml, 27G x 1/2"/1 ea. Blister Pack
181026IDB	1ml, 26G x 3/8"IDB /1 ea. Blister Pack
181026T	1ml, 26G x 1/2"/25 each Tray Pack
181126IDB	1ml, 26G x 1/2"IDB/25 each Tray Pack
181026IDB	1ml, 26G x 3/8"IDB/25 each Tray Pack
181027T	1ml, 27G x 1/2"/25 each Tray Pack
181127IDB	1ml, 27G x 1/2"IDB/25 each Tray Pack
181027IDB	1ml, 27G x 3/8"IDB/25 each Tray Pack
181023T	1ml, 23G x 1/2"/25 ea. Blister Pack

The Sol-M Syringes are sterilized by Ethylene Oxide Gas and supplied sterile in blister pack, tray pack or 10 pack.

E. Statement of Indications for Use

Sol-M Insulin Syringes

The Sol-M Insulin Syringe with needle, with the calibration unit of insulin for **U-100**, is a device intended for medical purposes for the manual aspiration of insulin, and for the injection of insulin into parts of the body below the surface skin.

Sol-M TB Syringe

The Sol-M TB Syringe is intended to be used for medical purposes to inject fluids into or withdraw fluids from the body.

F. Comparison of Required Technological Characteristics:

Information was submitted to demonstrate that there are no significant differences in technological characteristics between the Sol-M Insulin and KDL Insulin Syringes and the Sol-M TB and KDL Hypodermic Syringes. The following comparison chart shows that the subject device and the predicate device are substantially equivalent:

Sol-M Insulin and TB Syringe versus the KDL Syringes and Needle

SIDE BY SIDE COMPARISON TABLE

ELEMENT OF COMPARISON	Sol-M Insulin and TB Syringe	KDL Syringes and Needle
Syringe type	Piston	Piston
Indications for Use	<p><u>Insulin</u></p> <p>The Sol-M Insulin Syringe with needle, with the calibration unit of insulin for U-100, is a device intended for medical purposes for the manual aspiration of insulin, and for the injection of insulin into parts of the body below the surface skin.</p>	<p><u>Insulin</u></p> <p>The sterile Insulin Syringe for single use with needle is a device intended for medical purposes for the manual aspiration of insulin, and for the injection into parts of the body below the surface skin</p>

Indications for Use	<u>General Use</u> The Sol-M TB Syringe is intended to be used for medical purposes to inject fluids into or withdraw fluids from the body.	<u>General Use</u> The Hypodermic Syringes are intended to be used for medical purposes to inject fluids into or withdraw fluids from the body.
Principle of Operation	Three piece piston syringe. Plunger is used to fill syringe as well as discharge the fluid.	Three piece piston syringe. Plunger is used to fill syringe as well as discharge the fluid.
Specific Drug Use	Sol-M Insulin syringes - Insulin Sol-M TB syringes - General Use	KDL Insulin syringes - Insulin KDL Hypodermic syringes - General Use
Tip Type	Fixed Needle	Fixed Needle
Volume	Insulin Syringes - 0.3, 0.5 and 1ml TB Syringes – 0.5 and 1 ml	Insulin Syringes - 0.3, 0.5 and 1ml Hypodermic Syringes – 0.5 and 1 ml
Gradations Legibility	Bold markings	Bold markings
Lubricant Composition	Dow Corning Medical Silicone 360	Dow Corning Medical Silicone 360
Lubricant amount/cm ²	1ml-0.078mg/cm ²	1 ml – 0.078 Mg/cm ²
Barrel Transparency	Clear	Clear
Delivery Accuracy	Insulin Syringes– Per ISO 8537:2007	Insulin Syringes– Per ISO 8537:2007

	Hypodermic Syringes - Per ISO 7886-1:1993	Hypodermic Syringes - Per ISO 7886-1:1993
Hub/Needle Bond Strength	Per ISO 7886	Per ISO 7886
Biocompatibility	Per ISO 10993-1	Per ISO 10993-1
Materials	Barrel, Plunger and Cap – Polypropylene	Barrel, Plunger and Cap – Polypropylene
	Gasket – Santoprene	Gasket - Santoprene
Labeling	Per 21 CFR 801	Per 21 CFR 801

G. Summary and Conclusion of Nonclinical and Clinical Tests:

Bench tests were conducted to verify that the proposed devices met all design specifications and were Substantially Equivalent (SE) to the predicate devices. The test results demonstrated that the proposed devices comply with the following standards:

Sol-M TB Syringes

- ISO 7886-1:1993 Sterile Hypodermic syringes for single use – Part 1: Syringes for manual use;
- ISO 9626:1991 Stainless steel needle tubing for the manufacture of medical devices/Amendment:2001

Sol-M Insulin Syringes

- ISO 8537:2007 Sterile single use syringes, with and without needles, for insulin;
- ISO 9626:1991 Stainless steel needle tubing for the manufacture of medical devices/Amendment:2001

H. Discussion of Clinical Tests:

None submitted

I. Substantially Equivalent Conclusion:

The proposed device, Sol-M TB Syringes (various sizes), has been determined to be substantially equivalent to the predicate device, Sterile Hypodermic Syringe for single use, with needle, (various sizes), 510(k) # K112057.

The proposed device, Sol-M Insulin Syringes (various sizes), is determined to be substantially equivalent (**SE**) to the predicate device, Sterile Insulin Syringe for single use with needle, 510(k) # K112057.