



Food and Drug Administration  
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August 19, 2016

Sol-Millennium Medical, Inc.  
Jim Barley  
Director Of RA/QA  
1735 North Brown Road, Suite 120  
Lawrenceville, Georgia 30043

Re: K162030

Trade/Device Name: 0.5ml Sol-Care™ Retractable Safety Syringes  
Regulation Number: 21 CFR 880.5860  
Regulation Name: Piston Syringe  
Regulatory Class: Class II  
Product Code: MEG  
Dated: July 14, 2016  
Received: July 22, 2016

Dear Jim 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" (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 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,

**Michael J. Ryan -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

## Indications for Use

510(k) Number (if known)

K162030

Device Name

0.5ml Sol-Care™ Retractable Safety Syringes

Indications for Use (Describe)

The 0.5ml Sol-Care™ Retractable Safety Syringe is used to inject fluids into, or withdraw fluids from, the body. In addition, the 0.5ml Sol-Care™ Retractable Safety Syringes is designed to aid in the prevention of needle stick injuries.

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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## Special 510(k) Summary

(As required by 21 CFR 807.92(a))

Date Prepared: August 16, 2016

## A. Submitter Information

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

404-973-2200

Trade Name: 0.5ml Sol-Care™ Retractable Safety Syringes

## B. Device Information

Trade/Proprietary Name: 0.5ml Sol-Care™ Retractable Safety Syringes  
Common name of device: Piston Syringe with Safety Feature  
Regulation Name: Piston Syringe  
Product Code: MEG  
Regulatory Class: II  
Regulation Number: 880.5860  
Reason for 510(k): Special 510(k) Device Modification to add 0.5ml Sol-Care™ Retractable Safety Syringe

C. Predicate Device: 1, 3, 5, 10 and 20ml Sol-Care™ Retractable Safety Syringe

Syringes received marketing clearance on  
September 4, 2009 under 510(k) # K092430.

Predicate product code: MEG

## D. Device Description

The 0.5ml Sol-Care™ Retractable Safety Syringe with Fixed Needle is a sterile, single use, safety syringe with a fixed needle that is used to inject fluids into, or withdraw fluids from, the body. The 0.5ml Sol-Care™ Retractable Safety Syringe with Fixed Needle is also designed to aid in the prevention of needle stick injuries.

The retractable piston 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 – Once the plunger is fully depressed, it engages the needle assembly. As the plunger is retracted, the needle assembly is retracted into the barrel. Once the plunger is fully retracted and locked into place, the plunger is snapped off leaving the needle inside the barrel of the syringe.
3. Stopper – The Stopper maintains the fluid in the barrel between the base of the barrel and Plunger.
4. Cannula – The cannula/needle penetrates the patient’s skin to inject/withdraw fluid from the body.
5. Locking Ring – A plastic insert at the top of the barrel. After the injection, the health care professional retracts the plunger with the needle into the barrel. Once the plunger is fully retracted, the plunger is locked onto position at the bottom of the barrel. This safety mechanism ensures the needle cannot be pushed back
6. Needle Cap – The Cap is used to cover and protect the tip of the cannula/needle from being damaged.
7. O-Ring – The O-Ring minimizes the risk of leakage around the adapter
8. Protective Cap - The Protective Cap prevents pre-engagement of the safety mechanism. Only provided with products packaged in a ten pack.

After use, the health care professional firmly pushes the plunger past the zero line to engage the safety mechanism. Once the safety mechanism is engaged, pulling back the plunger causes the needle to be retracted into the barrel. In this position against the flange, lateral pressure on the plunger results in a controlled fracture of the plunger. Both the syringe and the plunger are discarded into a sharps container.

The 0.5ml Sol-Care™ Retractable Safety Syringe with Fixed Needle are sterilized by Ethylene Oxide and supplied sterile in a blister pack or tray pack. One hundred syringes are packaged in a chipboard box. Each blister pack/tray pack and chipboard box is labeled with the contents and the appropriate information per the FDA’s Quality System Regulation and Labeling requirements.

## E. Statement of Indications for Use

The 0.5ml Sol-Care™ Retractable Safety Syringe is used to inject fluids into, or withdraw fluids from, the body. In addition, the 0.5ml Sol-Care™ Retractable Safety Syringe is designed to aid in the prevention of needle stick injuries.

## F. Comparison of Required Technological Characteristics

Information was submitted to demonstrate that there are no significant differences in technological characteristics between the 0.5ml Sol-Care™ Retractable Safety Syringe with Fixed Needle and the cited predicate device. The following comparison chart shows the subject device and the predicate device are substantially equivalent:

**0.5ml Sol-Care™ Retractable Safety Syringe with Fixed Needle versus 1, 3, 5, 10 and 20ml Sol-Care™ Retractable Safety Syringe**

Side by Side Comparison Table

ELEMENT OF COMPARISON	0.5ml Sol-Care™ Retractable Safety Syringe	1, 3, 5, 10, 20ml Sol-Care™ Retractable Safety Syringe  (Predicate Device – 510(k)# K092430)	Comparison Summary
Intended Use(s)	The 0.5ml Sol-Care™ Retractable Safety Syringe with Fixed Needle is used to inject fluids into, or withdraw fluids from, the body. In addition, the 0.5ml Sol-Care™ Retractable Safety Syringe with Fixed Needle is designed to aid in the prevention of needle stick injuries.	The Sol-Care™ Retractable Safety Syringe is used to inject fluids into, or withdraw fluids from, the body. In addition, the Sol-Care™ Retractable Safety Syringe is designed to aid in the prevention of needle stick injuries.	Identical
Principle of Operation	After use, the plunger is fully retracted into the barrel providing protection against needle sticks, rendering the device unusable.	After use, the plunger is fully retracted into the barrel providing protection against needle sticks, rendering the device unusable.	Identical
Syringe Type	Piston	Piston	Identical

Tip Type	Fixed Needle	Fixed needle and Luer Lock	Similar
Volume	0.5ml	1, 3, 5, 10, and 20 ml	Similar
Barrel Transparency	Clear	Clear	Identical
Biocompatibility	<ul style="list-style-type: none"> <li>• Cytotoxicity</li> <li>• Sensitization Study</li> <li>• Irritation Test/Intracutaneous Reactivity</li> <li>• USP and ISO Systemic Toxicity Studies</li> <li>• Haemolysis test</li> </ul>	<ul style="list-style-type: none"> <li>• Cytotoxicity</li> <li>• Sensitization Study</li> <li>• Irritation Test/Intracutaneous Reactivity</li> <li>• USP and ISO Systemic Toxicity Studies</li> <li>• Haemolysis test</li> </ul>	Identical
Sterilization	ETO	ETO	Identical
Materials	Plunger, Barrel, Cap – Polypropylene  Stopper – Santoprene Thermoplastic Elastomer  Needle – Stainless steel	Plunger, Barrel, Cap – Polypropylene  Stopper – Santoprene Thermoplastic Elastomer  Needle- Stainless steel	Identical
Labeling	Per 21 CFR 801	Per 21 CFR 801	Identical

G. Summary and Conclusion of Nonclinical and Clinical Tests:

The 0.5ml Sol-Care™ Retractable Safety Syringe met the appropriate requirements contained in the following standards:

1. ISO 7886:1993, Sterile Hypodermic Syringes for Single Use
2. ISO 7886-4:2006, Sterile Hypodermic Syringes for Single Use – Syringes with re-use prevention feature
4. ISO 11607-1,-1:2006, Packaging for terminally sterilized medical devices
5. ISO 11135:2007, Medical Apparatus – Epoxy Ethane Sterilization Confirmation and Routine Control
6. ISO 10993-1:2006, Biological evaluation of medical devices Part 1: Evaluation and testing
7. ISO 9626:1991, Stainless Steel needle tubing for the manufacture of medical devices

H. Discussion of Clinical Tests:

None submitted.

I. Conclusions Demonstrating Safety, Effectiveness and Performance:

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 0.5ml Sol-Care™ Retractable Safety Syringe is substantially equivalent to the predicate device.