

510(k) Summary

K101560

Submitter Information

Medline Industries, Inc.
One Medline Place
Mundelein, IL 60060
Contact Person: Matt Clausen
Phone Number: 847-643-4785
Date: March 15, 2011

MAR 25 2011

Device Information

Classification Name: Syringe, Antistick
Proprietary Name: Medline Retractable Safety Syringe
Common Name: Piston or Safety Syringe

Predicate Information

Predicate Name: Inviro Snap Safety Syringe / InviroSnap Safety Syringe
Predicate 510(k) #: K032780 / K092430
Predicate Product Code: MEG

Device Description

The Medline Retractable Safety Syringe is a retractable type piston syringe, designed to aid in the prevention of needle stick injuries. This single-use, disposable syringe consists of the following components:

1. Barrel - The barrel has a scale showing the capacity of the syringe. In addition, the tip of the barrel has a luer lock fitting for the user to attach a needle.
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 in place, the plunger is snapped off leaving the needle in the barrel of the syringe.
3. O-Ring - The O-ring minimizes the risk of leakage around the adapter.
4. Gasket - The gasket maintains the fluid in the barrel between the adapter and plunger.
5. Luer Lock or Needle Holder - The luer lock facilitates passage of the fluid, while holding the needle in place.
6. Hub Holder - Engages the plunger after the injection.
7. 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 into position at the top of the barrel. This safety mechanism makes sure the needle cannot be pushed back out the tip of the barrel.

8. Needle – Pre-attached single lumen stainless steel needle which penetrates the patient's skin to inject/withdraw fluid.

(1ml syringe only)

9. Short Cap – Protective cover for the needle tip. Removed upon use. (1ml syringe only)

10. Big Cap - Protective cover for the plunger. (1ml syringe only)

The Medline Retractable Safety Syringe functions in a manner similar to standard syringes for fluid injection/withdrawal. After use, the health care professional fully depresses the plunger to engage the luer assembly. Once the luer assembly is engaged, pulling back the plunger causes the adapter and the attached needle to be withdrawn into the safety of the barrel. This retraction into the barrel of the syringe can be visually confirmed. In this position against the flange, single-handed lateral pressure on the plunger results in a controlled fracture of the plunger. Once this safety mechanism has been activated, the syringe is permanently disabled and the needle is completely secured within the barrel. Both the syringe and plunger are discarded in a Sharp's container.

Indications For Use Statement

The intended use of this device is to inject fluids into, or withdraw fluids from, the body. In addition, this retractable safety syringe is designed to aid in the prevention of needle stick injuries and reduce the potential for syringe reuse.

Comparison of Required Technological Characteristics

Information was submitted to demonstrate that there are no significant differences in technological characteristics between Medline's Retractable Safety Syringe and the cited predicate devices.

Summary and Conclusion of Testing

Testing consisted of compliance to the applicable sections of the following testing

- ISO 7886-1:1993
- ISO 7886-4:2006
- ISO 9626
- ISO 594
- ISO 10993

Conclusion

In accordance with 21 CFR Part 807, and based on the information provided in this premarket notification, Medline Industries, Inc. concludes that Medline's Retractable Safety Syringe is safe, effective and substantially equivalent as described herein.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room - WO66-G609
Silver Spring, MD 20993-0002

Mr. Matt Clausen
Regulatory Affairs
Medline Industries, Incorporated
One Medline Place
Mundelein, Illinois 60060

MAR 25 2011

Re: K101560
Trade/Device Name: Medline Retractable Safety Syringe
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: II
Product Code: MEG
Dated: March 7, 2011
Received: March 8, 2011

Dear Mr. Clausen:

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.

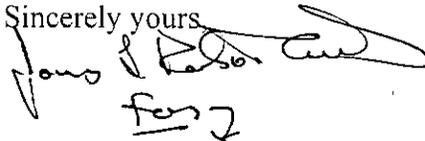
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 Small Manufacturers, International and Consumer Assistance 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



Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

K 101560

Device Name:

Medline Retractable Safety Syringe

Indications For Use:

The Medline Retractable Safety Syringe is used to inject fluids into, or withdraw fluids from, the body. In addition, this safety syringe is designed to aid in the prevention of needle stick injuries and reduce the potential for syringe reuse.

Prescription Use X
(Part 21 CFR 801 Subpart D)

OR

Over-the-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Robert C. Chyng 3/25/11
(Division Sign-Off)

Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: _____

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