December 9, 2022

Medline Industries, Inc.
Dinah Rincones
Sr. Regulatory Affairs Specialist
Three Lakes Drive
Northfield, Illinois 60093

Re: K213054
Trade/Device Name: Medline Sure-Snap Safety Needle, Medline Sure-Snap Safety Syringe
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: Class II
Product Code: FMF, FMI, MEG
Dated: September 17, 2021
Received: September 22, 2021

Dear Dinah Rincones:

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Alan M. Stevens -S3

CAPT Alan M. Stevens
Assistant Director
DHT3C: Division of Drug Delivery and
General Hospital Devices,
and Human Factors
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Office of Product Evaluation and Quality
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)*
K213054

Device Name
Medline Sure-Snap Safety Needle and Medline Sure-Snap Safety Syringe.

Indications for Use *(Describe)*
The Medline Sure-Snap Safety Syringe is intended for use in the aspiration and injection of fluids for medical purposes. After withdrawal of the needle from the body, the attached needle safety shield can be manually activated to cover the needle immediately after use to minimize risk of accidental needle stick.

The Medline Sure-Snap Safety Needle is intended for use with a luer-lock syringe for aspiration and injection of fluids for medical purposes. After withdrawal of the needle from the body, the attached needle safety shield can be manually activated to cover the needle immediately after use to minimize risk of accidental needle stick.

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
[AS REQUIRED BY 21CFR807.92(c)]

Submitter / 510(k) Sponsor
Dinah Rincones
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Phone: 847-949-2687
Email: Drincones@medline.com

Summary Preparation Date
September 17, 2021

Type of 510(k) Submission
Traditional

Device Name / Classification

- **Device Common Name** - Piston Syringe with Safety Hypodermic Single Lumen Needle, Safety Hypodermic Single Lumen Needle
- **Proprietary Name** - Medline Sure-Snap Safety Needle and Medline Sure-Snap Safety Syringe
- **Class** - Class II
- **Review Panel** - General Hospital
- **Regulation Number** - 21 CFR 880.5860
- **Classification Product Code** - FMF (Piston Syringe)
- **Subsequent Product Codes** - FMI (Hypodermic Single Lumen Needle)
  - MEG (Antistick Syringe)

Predicate Device
Primary Predicate Device: Syringe with Safety Needle, Safety Needle (K193526).
Secondary Predicate Device: BD Eclipse Hypodermic Needle (K161170).

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Device Description

The Medline Sure-Snap Safety Needle and Medline Sure-Snap Safety Syringe comprises hypodermic single lumen luer-lock safety needles alone (Identified in this submission as Medline Sure-Snap Safety Needles) and a combination of hypodermic single lumen luer-lock safety needles with luer-lock piston syringes (identified in this submission as Medline Sure-Snap Safety Syringes).

Medline Sure-Snap Safety Needles

The Medline Sure-Snap Safety Needle consists of a permanently attached metal single lumen hypodermic needle that is sharpened at one end and at the other end joined to a female connector (Needle Hub) designed to mate with a male connector (nozzle) of a luer-lock piston syringe. It also comprises a safety shield to minimize risk of accidental needle stick. The safety shield is a mechanism that covers the needlepoint after use and should be activated immediately following the injection. It can be activated by centering the thumb or forefinger on the textured finger pad and pushing the safety cover forward over the needle until you hear or feel it lock. A hard surface can also be used to push-up against. The small hook located on the back wall of the safety sheath locks the needle into place once it is activated; this prevents the needle from being "un-activated."

The Medline Sure-Snap Safety Needles are offered in a variety of gauge sizes (18-30 gauge) and needle lengths (½''- $1^{1/2}$''). The needle hub and the safety needle sheath is color-coded to the appropriate gauge needle per ISO 6009. The Medline Sure-Snap Safety Needle should only be used with luer-lock syringes. This product is single use, provided sterile and will be available in the following design configurations:

Table 1: Medline Sure-Snap Safety Needle Configurations

Medline Model Number	Description	Needle Gauge	Needle Length	Safety Needle Sheath/Needle Hub Color
SSN100187	NEEDLE,HYPODERM,SAFETY,18GX1.5	18G	1.5in	Pink
SSN100185	NEEDLE,HYPODERM,SAFETY,18GX1	18G	1in	Pink
SSN100195	NEEDLE,HYPODERM,SAFETY,19GX1	19G	1in	Cream
SSN100205	NEEDLE,HYPODERM,SAFETY,20GX1	20G	1in	Yellow
SSN100207	NEEDLE,HYPODERM,SAFETY,20GX1.5	20G	1.5in	Yellow
SSN100215	NEEDLE,HYPODERM,SAFETY,21GX1	21G	1in	Green
SSN100217	NEEDLE,HYPODERM,SAFETY,21GX1.5	21G	1.5in	Green
SSN100225	NEEDLE,HYPODERM,SAFETY,22GX1	22G	1in	Black
SSN100227	NEEDLE,HYPODERM,SAFETY, 22GX1.5	22G	1.5in	Black
SSN100235	NEEDLE,HYPODERM,SAFETY, 23GX1	23G	1in	Blue
SSN100237	NEEDLE,HYPODERM,SAFETY, 23GX1.5	23G	1.5in	Blue
SSN100255	NEEDLE,HYPODERM,SAFETY, 25GX1	25G	1in	Orange
SSN100257	NEEDLE,HYPODERM,SAFETY, 25GX1.5	25G	1.5in	Orange

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Medline Model Number	Description	Needle Gauge	Needle Length	Safety Needle Sheath/Needle Hub Color
SSN100253	NEEDLE,HYPODERM,SAFETY, 25GX5/8	25G	5/8in	Orange
SSN100276	NEEDLE,HYPODERM,SAFETY, 27GX1.25	27G	1.25in	Grey
SSN100273	NEEDLE,HYPODERM,SAFETY, 27GX5/8	27G	5/8in	Grey
SSN100272	NEEDLE,HYPODERM,SAFETY, 27GX0.5	27G	0.5in	Grey
SSN100302	NEEDLE,HYPODERM,SAFETY, 30GX0.5	30G	0.5in	Yellow

Medline Sure-Snap Safety Syringe

The Medline Sure-Snap Safety Syringes are a combination of hypodermic single lumen luer-lock safety needles with luer-lock piston syringes. The Medline Sure-Snap Safety Syringes are sterile, non-pyrogenic, single use devices intended to be used to inject fluids into or withdraw fluids from the body.

The Medline Sure-Snap Safety Syringes will be available in the following design configurations:

Table 2: Medline Sure-Snap Safety Syringe Configurations

Medline Model Number	Description	Needle Gauge	Needle Length	Safety Needle Sheath/Needle Hub Color	Syringe Volume
SSN101235F	SYR W/NDLE,SAFETY,23GX1, 1ML	23G	1in	Blue	1mL
SSN101255F	SYR W/NDLE,SAFETY,25GX1, 1ML	25G	1in	Orange	1mL
SSN101272F	SYR W/NDLE,SAFETY,27GX0.5, 1ML	27G	0.5in	Grey	1mL
SSN103205	SYR W/NDLE,SAFETY,20GX1, 3ML	20G	1in	Yellow	3mL
SSN103207	SYR W/NDLE,SAFETY,20GX1.5, 3ML	20G	1.5in	Yellow	3mL
SSN103217	SYR W/NDLE, SAFETY,21GX1.5, 3ML	21G	1.5in	Green	3mL
SSN103215	SYR W/NDLE,SAFETY,21GX1, 3ML	21G	1in	Green	3mL
SSN103227	SYR W/NDLE,SAFETY,22GX1.5, 3ML	22G	1.5in	Black	3mL
SSN103225	SYR W/NDLE,SAFETY,22GX1, 3ML	22G	1in	Black	3mL
SSN103235	SYR W/NDLE,SAFETY,23GX1, 3ML	23G	1in	Blue	3mL
SSN103255	SYR W/NDLE,SAFETY,25GX1, 3ML	25G	1in	Orange	3mL
SSN103253	SYR W/NDLE,SAFETY,25GX5/8, 3ML	25G	5/8in	Orange	3mL
SSN105217	SYR W/NDLE,SAFETY,21GX1.5, 5ML	21G	1.5in	Green	5mL
SSN110227	SYR W/NDLE,SAFETY,22GX1.5, 10ML	22G	1.5in	Black	10mL
SSN110207	SYR W/NDLE,SAFETY,20GX1.5, 10ML	20G	1.5in	Yellow	10mL
SSN110217	SYR W/NDLE,SAFETY,21GX1.5, 10ML	21G	1.5in	Green	10mL

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Indications for Use

The Medline Sure-Snap Safety Syringe is intended for use in the aspiration and injection of fluids for medical purposes. After withdrawal of the needle from the body, the attached needle safety shield can be manually activated to cover the needle immediately after use to minimize risk of accidental needle stick.

The Medline Sure-Snap Safety Needle is intended for use with a luer-lock syringe for aspiration and injection of fluids for medical purposes. After withdrawal of the needle from the body, the attached needle safety shield can be manually activated to cover the needle immediately after use to minimize risk of accidental needle stick.

Summary of Technological Characteristics

Refer to Table 3 on the next page.

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Table 3: Comparison of the Proposed Device with the Predicate Device

Device Characteristic	Subject Device	Primary Predicate Device	Secondary Predicate Device	Remarks (Comparison with the Primary Predicate Device)
Product Name	Medline Sure-Snap Safety Needle and Medline Sure-Snap Safety Syringe	Syringe with Safety Needle, Safety Needle	BD Eclipse Hypodermic Needle	N/A
510(k) Reference	K213054	K193526	K161170	N/A
Product Owner	Medline Industries, Inc.	Jiangsu Caina Medical Co., Ltd	Becton, Dickinson and Company	N/A
Product Code	Classification Product Code: • FMF (Piston Syringe) Subsequent Product Codes: • FMI (Hypodermic Single Lumen Needle) • MEG (Antistick Syringe)	Classification Product Code: • FMF (Piston Syringe) Subsequent Product Codes: • FMI (Hypodermic Single Lumen Needle) • MEG (Antistick Syringe)	FMI: Needle, Hypodermic, Single Lumen	**SAME**
Regulation Number	21 CFR 880.5860 21 CFR 880.5570	21 CFR 880.5860 21 CFR 880.5570	21 CFR §880.5570	**SAME**
Device Description	Safety needle alone and a combination of a piston syringe with a safety needle.	Safety needle alone and a combination of a piston syringe with a safety needle.	Safety Needle alone	**SAME**
Indications for Use	**Safety Needle** The Medline Sure-Snap Safety Needle is intended for use with a luer-lock syringe for aspiration and injection of fluids for medical purposes. After withdrawal of the needle from the body, the attached needle safety shield can be manually activated to cover the needle immediately after use to minimize risk of accidental needle stick.	**Safety Needle** The Safety Needle is intended for use with a luer-lock syringe for aspiration and injection of fluids for medical purpose. After withdrawal of the needle from the body, the attached needle safety shield can be manually activated to cover the needle immediately after use to minimize risk of accidental needle stick.	**Safety Needle** The BD Eclipse Hypodermic Needle is used for general-purpose injection and aspiration of fluid from vials, ampoules and parts of the body below the surface of the skin. The BD Eclipse Hypodermic Needle is compatible for use with standard luer-lock syringes. The BD Eclipse Hypodermic Needle contains a mechanism that covers the needlepoint after use. In the activated position the needle cover guards against accidental needle sticks during normal handling and disposal of the used needle/ syringe combination.	**SAME**

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	Syringe with Safety Needle The Medline Sure-Snap Safety Syringe is intended for use in the aspiration and injection of fluids for medical purposes. After withdrawal of the needle from the body, the attached needle safety shield can be manually activated to cover the needle immediately after use to minimize risk of accidental needle stick.	**Syringe with Safety Needle** The Syringe with Safety Needle is intended for use in the aspiration and injection of fluids for medical purposes. After withdrawal of the needle from the body, the attached needle safety shield can be manually activated to cover the needle immediately after use to minimize risk of accidental needle stick.	**N/A**	**SAME**
Operating Principle	**Safety Needle** The Medline Sure-Snap Safety Needles are devices that are composed of a hypodermic needle with a one piece hub/adapter and pivoting cover that is connected to the hub. The device consists of a mechanism that covers the needle point after use.	**Safety Needle** The Safety Needles are devices that are composed of a typical hypodermic needle with a one piece hub/adapter and pivoting cover that is connected to the adapter. The device consists of a mechanism that covers the needle point after use.	**Safety Needle** BD Eclipse Hypodermic Needles are devices that are composed of a typical hypodermic needle with a one piece hub/adapter and pivoting cover that is connected to the adapter. The device consists of a mechanism that covers the needle point after use.	**SAME**
	Syringe The Medline Sure-Snap Safety Syringe is a luer-lock piston syringe for manual use with safety needle.	**Syringe** The Syringe with Safety Needle is a luer-lock piston syringe for manual use with safety needle.	**N/A**	**SAME**
Design Features	**Safety Needle** Components: Needle hub, needle tube/cannula, lubricant, safety shield, needle cap. Specifications: • Needle length: 0.5in – 1.5in • Needle Gauge Range: 18G-30G (18G, 19G, 20G, 21G, 22G, 23G, 25G, 27G, 30G). • Bevel: Regular, short, intradermal. • Luer-lock connector. • Needle hub color: per ISO 6009	**Safety Needle** Components: Needle hub, needle tube/cannula, lubricant, Safety shield, needle cap. Specifications: • Needle length: 0.5in – 1.5in • Needle Gauge Range: 16G-31G (16G, 18G, 19G, 20G, 21G, 22G, 23G, 25G, 26G, 27G, 28G, 29G, 30G, 31G) • Luer-lock connector. • Needle hub color: per ISO 6009	**Safety Needle** Components: Needle hub, needle tube/cannula, lubricant, Safety shield, needle cap. Specifications: • Needle length: 0.5in – 1.5in • Needle Gauge: 18G-30G • Bevel: Regular, short, intradermal. • Luer-lock connector. • Needle hub color: per ISO 6009	**SIMILAR** The subject device needle gauge (G) are within the range of the predicate needle G cleared.

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	Syringe Components: Barrel, plunger, gasket. Connector: Luer-Lock. Volume: 1, 3, 5, 10mL.	**Syringe** Components: Barrel, plunger, gasket. Connector: Luer-Lock. Volume: 1, 3, 5, 10, 20, 30, 60mL.	N/A	**SIMILAR** The subject device piston syringe volume is within the range of the predicate device piston syringe volume cleared.
Contact Type and Duration	**Needle** External communicating coming in contact with circulating blood for a contact period for less than 24 hours.	**Needle** External communicating coming in contact with circulating blood for a contact period for less than 24 hours.	**Needle** External communicating coming in contact with circulating blood for a contact period for less than 24 hours.	**SAME**
	Syringe External communicating device coming in contact with blood path indirect for a contact period less than 24hrs.	**Syringe** External communicating device coming in contact with blood path indirect for a contact period less than 24hrs.	N/A	**SAME**
Sterile vs. Non-Sterile	EO Sterilized	EO Sterilized	EO Sterilized	**SAME**
Sterilization/ SAL Level	Per ISO 11135 / SAL 10^{-6}	Per ISO 11135 / SAL 10^{-6}	Per ISO 11135 / SAL 10-6	**SAME**
Disposable vs. Non-Disposable	Disposable	Disposable	Disposable	**SAME**
Single Use vs. Reusable	Single Use	Single Use	Single Use	**SAME**
Non-pyrogenic	Yes	Yes	Yes	**SAME**
Prescription vs. OTC	Rx	Rx	Rx	**SAME**

Discussion of Similarities and Differences

Medline believes that the technological differences between the subject and predicate device do not raise new questions of safety and effectiveness.

Does the New Device Have the Same Intended Use?

Yes, the subject device and predicate device have the same intended use: To be used for aspiration and injection of fluids for medical purpose. After withdrawal of the needle from the body, the attached needle safety shield can be manually activated to cover the needle immediately after use to minimize risk of accidental needle stick.

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Does the New Device Have Technological Characteristics that Raise New Types of Safety and Effectiveness Questions?

No, the proposed device does not have any new technological characteristics that raise any new safety and/or effectiveness questions. Both device comprise hypodermic single lumen luer-lock safety needles alone and a combination of hypodermic single lumen luer-lock safety needles with luer-lock piston syringes. The predicate and subject device are comprised of the same components: Luer-lock piston syringe and luer-lock safety needles comprised of needle hub, needle tube/cannula, lubricant, needle cap, and a needle stick prevention feature, (i.e. safety shield) intended to be manually operated/activated in order to prevent accidental needle sticks. Additionally, both devices have similar dimensions. The subject device and the predicate device are both offered in 0.5in – 1.5in needle length range; and similar needle gauge (G) range. While the subject device is offered in18G-30G needle gauge range, the predicate device is offered in a needle gauge range of 16G-31G. However, the subject device needle gauge range offered is within the predicates' needle gauge range cleared. In addition, both devices are color-coded per ISO 6009.

Does Descriptive or Performance Information Demonstrate Equivalence?

Yes, the similarities between the proposed device and the predicate device include: design features, intended use, function, and performance specifications. The proposed device is subject to the same performance testing as the predicate, which is based on the same FDA-recognized consensus standards applicable to a device of this type. Both devices also include a needle sick prevention feature. Activation of the safety feature on the proposed and predicate device is achieved by centering the thumb or forefinger on the textured finger pad and pushing the safety cover forward over the needle until you hear or feel it lock. A hard surface can also be used to push-up against. The small hook located on the back wall of the safety sheath locks the needle into place once it is activated; this prevents the needle from being "un-activated." As recommended in the FDA guidance document, *Medical Devices with Sharps Injury Prevention Features*, a simulated clinical use study was conducted on the proposed device in order to specifically assess the function of the needle stick prevention feature. Both the predicate and subject device are also intended for prescription-use only and are only intended to be used by trained medical professionals.

Summary of Testing and Supporting Information

Testing was conducted to demonstrate substantial equivalence of Medline Sure-Snap Safety Needle and Medline Sure-Snap Safety Syringe to the predicate device.

A summary of testing is presented below with more information provided in the applicable sections.

Biocompatibility Testing

The biological evaluation for the **Medline Sure-Snap Safety Needle and Medline Sure-Snap Safety Syringe** was conducted in accordance with FDA guidance document, "*Use of International Standard ISO 10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing*" and ISO 10993-1

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Biological Evaluation of the Medical Devices – Part 1: Evaluation of Testing within a Risk Management Process.

The following biocompatibility tests were performed on the luer-lock piston syringe (used in the Medline Sure-Snap Safety Syringe):

Biocompatibility Testing Performed:

- ISO MEM Elution per ISO 10993-5:2009 Biological Evaluation of Medical Devices-Part 5: Tests for in vitro Cytotoxicity.
- ISO Intracutaneous Irritation Test per ISO 10993-10: 2010 Biological Evaluation of Medical Devices-Part 10: Test for Irritation and Skin Sensitization.
- ISO Guinea Pig Maximization Sensitization Test per ISO 10993-10: 2010 Biological Evaluation of Medical Devices-Part 10: Test for Irritation and Skin Sensitization.
- ISO Acute Systemic Injection Test per ISO 10993-11: 2017 Biological Evaluation of Medical Devices Part 11: Tests for Systemic Toxicity.
- ASTM Hemolysis Assay per ISO 10993-4:2017. Biological Evaluation of Medical Devices, Part 4 – Selection of Tests for Interaction with Blood.
- ISO Materials Mediated Rabbit Pyrogen per ISO 10993-11:2017. Biological Evaluation of Medical Devices, Part 11: Tests for Systemic Toxicity.
- Bacterial Endotoxin Testing and Validation.

The following biocompatibility tests were performed on the Medline Sure-Snap Safety Needle:

Biocompatibility Testing Performed:

- ISO MEM Elution per ISO 10993-5:2009 Biological Evaluation of Medical Devices-Part 5: Tests for in vitro Cytotoxicity.
- ISO Intracutaneous Irritation Test per ISO 10993-10: 2010 Biological Evaluation of Medical Devices-Part 10: Test for Irritation and Skin Sensitization.
- ISO Guinea Pig Maximization Sensitization Test per ISO 10993-10: 2010 Biological Evaluation of Medical Devices-Part 10: Test for Irritation and Skin Sensitization.
- ISO Acute Systemic Injection Test per ISO 10993-11: 2017 Biological Evaluation of Medical Devices Part 11: Tests for Systemic Toxicity.
- ASTM Hemolysis Assay per ISO 10993-4:2017. Biological Evaluation of Medical Devices, Part 4 – Selection of Tests for Interaction with Blood.
- ISO Materials Mediated Rabbit Pyrogen per ISO 10993-11:2017. Biological Evaluation of Medical Devices, Part 11: Tests for Systemic Toxicity.
- Bacterial Endotoxin Testing and Validation.

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Performance Testing (Bench)

Non-clinical verification of the Medline Sure-Snap Safety Needle and Medline Sure-Snap Safety Syringe has been conducted to evaluate the safety, performance and functionality of the proposed device.

Functional Performance Testing

The performance testing for the **luer lock piston syringe** (used in the Medline Sure-Snap Safety Syringe) has been conducted in accordance with following standards:

- ISO 7886-1 Second edition 2017-05 Sterile hypodermic syringes for single use - Part 1: Syringes for manual use.
- ISO 80369-7:2016 Small-bore connectors for liquids and gases in healthcare applications - Part 7: Connectors for intravascular or hypodermic applications

The performance testing for the **Medline Sure-Snap Safety Needles** has been performed in accordance with following standards:

- ISO 7864 Fourth edition 2016-08-01 Sterile hypodermic needles for single use - Requirements and test methods.
- ISO 9626 Second edition 2016-08-01 Stainless steel needle tubing for the manufacture of medical devices - Requirements and test methods.
- ISO 23908 First edition 2011-06-11 Sharps injury protection - Requirements and test methods - Sharps protection features for single-use hypodermic needles, introducers for catheters and needles used for blood sampling.
- ISO 80369-7:2016 Small-bore connectors for liquids and gases in healthcare applications - Part 7: Connectors for intravascular or hypodermic applications.

Usability Testing

A human factors study to evaluate the usability of the subject device was additionally conducted. Specifically, a simulated clinical use test was done to assess the usability and function of the needle stick prevention feature as recommended in the FDA guidance document, *Medical Devices with Sharps Injury Prevention Features.* Participating healthcare professionals assessed the function of the safety needle with a pass/fail criteria and provided feedback on the perceived functionality of the proposed device. Of the 1,000 safety needles tested (500 per safety needle type), there were no failures.

Chemical Safety Testing

- Phthalates testing to support the device is not made with DEHP.
- Particulate Matter Testing in accordance with USP <788> Particulate Matter in Injections.
- Limulus Amebocyte Lysate (LAL) Bacterial Endotoxin Testing in accordance with USP <85> Bacterial Endotoxin Testing.

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Performance Testing (Animal)

This section does not apply. No animal testing was performed.

Performance Testing (Clinical)

This section does not apply. No clinical testing was performed.

Sterilization and Shelf Life

The Medline Sure-Snap Safety Needle and Medline Sure-Snap Safety Syringe is terminally sterilized by Ethylene Oxide (EO) and its sterilization validation has been conducted in accordance with ISO 11135:2014 *Sterilization of Health Care Products – Ethylene Oxide – Requirements for Development, Validation, and Routine Control of a Sterilization Process for Medical Devices* to ensure the EO achieves a Sterility Assurance Level (SAL) of 10^{-6}. The proposed device was also evaluated for EO and Ethylene Chlorohydrin (ECH) residuals in accordance with ISO 10993-7:2008 *Biological Evaluation of Medical Devices – Part 7: Ethylene Oxide Sterilization Residuals*.

Additionally, in accordance with ASTM F1980-16, *Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices*, aging studies have been conducted to ensure the functionality and sterility of the proposed device are successfully maintained throughout the duration of its shelf life.

Conclusion

In accordance with 21 CFR Part 807, and based on the information provided in this premarket notification, Medline Industries, LP. concludes that the Medline Sure-Snap Safety Needle and Medline Sure-Snap Safety Syringe is as safe and as effective for its intended use as the predicate devices: Syringe with Safety Needle, Safety Needle (K193526) and BD Eclipse Hypodermic Needle (K161170).