August 10, 2020

Jiangsu Caina Medical Co., Ltd.
% Diana Hong
General Manager
Mid-Link Consulting Co., Ltd
P.O. Box 120-119
Shanghai, 200120 Cn

Re: K192551
Trade/Device Name: 1ml Luer Slip or Luer Lock Syringe, Syringe with permanently attached needle, Safety Syringe with permanently attached needle
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: Class II
Product Code: FMF, MEG
Dated: June 24, 2020
Received: July 13, 2020

Dear Diana Hong:

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,

For CAPT Alan Stevens
Assistant Director
DHT3C: Division of Drug Delivery and
General Hospital Devices,
and Human Factors
OHT3: Office of Gastrorenal, ObGyn,
General Hospital and Urology Devices
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)*
K192551

Device Name
1ml Luer Slip or Luer Lock Syringe
Syringe with permanently attached needle
Safety Syringe with permanently attached needle

Indications for Use *(Describe)*

1ml Luer Slip or Luer Lock Syringe

1ml Luer Slip or Luer Lock Syringe is intended to be connected with the luer slip or luer lock needle and intended for use by health care professionals for general purpose aspiration of fluid from vials, ampoules and liquid injection below the surface of the skin.

Syringe with permanently attached needle

The Syringe with permanently attached needle is intended for use by health care professionals for general purpose aspiration of fluid from vials, ampoules and liquid injection below the surface of the skin.

Safety Syringe with permanently attached needle

The Safety Syringe with permanently attached needle is intended for use by health care professionals for general purpose aspiration of fluid from vials, ampoules and liquid injection below the surface of the skin. The Safety sheath of Syringe is designed to aid in the prevention of needle stick injuries and reduce the potential or syringe reuse.

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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Exhibit #3 510(k) Summary

This 510(k) Summary is being submitted in accordance with requirements of Title 21, CFR Section 807.92.

The assigned 510(k) Number: K192551

1. Date of Preparation: 08/06/2020

2. Sponsor Identification

Jiangsu Caina Medical Co., Ltd.

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Establishment Registration Number: 3005670221

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3. Designated Submission Correspondent

Ms. Diana Hong (Primary Contact Person)
Ms. Jing Cheng (Alternative Contact Person)

Mid-Link Consulting Co., Ltd
P.O. Box 120-119, Shanghai, 200120, China

Tel: +86-21-22815850,
Fax: 360-925-3199
Email: info@mid-link.net

4. Identification of Proposed Device

Trade Name: 1ml Luer Slip or Luer Lock Syringe
Syringe with permanently attached needle
Safety Syringe with permanently attached needle
Common Name: Piston Syringe and antistick syringe

Regulatory Information:
Classification Name: Piston Syringe;
Classification: II;
Product Code: FMF, MEG;
Regulation Number: 21CFR 880.5860
Review Panel: General Hospital;

Indications for Use:
1ml Luer Slip or Luer Lock Syringe
1ml Luer Slip or Luer Lock Syringe is intended to be connected with the luer slip or luer lock needle and intended for use by health care professionals for general purpose aspiration of fluid from vials, ampoules and liquid injection below the surface of the skin.

Syringe with permanently attached needle
The Syringe with permanently attached needle is intended for use by health care professionals for general purpose aspiration of fluid from vials, ampoules and liquid injection below the surface of the skin.

Safety Syringe with permanently attached needle
The Safety Syringe with permanently attached needle is intended for use by health care professionals for general purpose aspiration of fluid from vials, ampoules and liquid injection below the surface of the skin. The Safety sheath of Syringe is designed to aid in the prevention of needle stick injuries and reduce the potential or syringe reuse.

Device Description
The proposed Syringes include 1ml Luer Slip or Luer Lock Syringe, Syringe with permanently attached needle, Safety Syringe with permanently attached needle.

Each of the 1ml Luer Slip or Luer Lock Syringe, Safety Syringe with permanently attached needle. have one kind of product configuration, and the Syringe with permanently attached needle has two kinds of product configurations (Type A and Type B).

The proposed syringes are available in different combination of syringe volumes and/or needle sizes

(refer to Table 1).

Table 1 specification of proposed device

Model	Needle length (mm)	Needle gauge	Needle wall type	Needle bevel	Syringe size/volume
1ml Luer Slip or Luer Lock Syring	NA	NA	NA	NA	1ml
Syringe with permanently attached needle-type B	20, 25	21G	RW, TW	11°±2°, 15°±2°	1ml
	20, 25	23G	RW, TW	11°±2°, 15°±2°	
Syringe with permanently attached needle-type A	8,10,13,16	29G	RW, TW	11°±2°, 15°±2°	0.3ml
	8,10,13,16	30G	RW, TW	11°±2°, 15°±2°	
	8,10,13,16	31G	RW, TW	11°±2°, 15°±2°	
	10, 13, 16	25G	RW, TW	11°±2°, 15°±2°	0.5ml
	10, 13, 16	26G	RW, TW	11°±2°, 15°±2°	
	10, 13, 16	27G	RW, TW	11°±2°, 15°±2°	
	10, 13, 16	28G	RW, TW	11°±2°, 15°±2°	
	8, 10, 13, 16	29G	RW, TW	11°±2°, 15°±2°	
	8, 10, 13, 16	30G	RW, TW	11°±2°, 15°±2°	
	8, 10, 13, 16	31G	RW, TW	11°±2°, 15°±2°	
	10, 13, 16	25G	RW, TW	11°±2°, 15°±2°	1ml
	10, 13, 16	26G	RW, TW	11°±2°, 15°±2°	
	10, 13, 16	27G	RW, TW	11°±2°, 15°±2°	
	10, 13, 16	28G	RW, TW	11°±2°, 15°±2°	
	8, 10, 13, 16	29G	RW, TW	11°±2°, 15°±2°	
	8, 10, 13, 16	30G	RW, TW	11°±2°, 15°±2°	
	8, 10, 13, 16	31G	RW, TW	11°±2°, 15°±2°	
Safety Syringe with permanently attached needle	8,10,13,16	29G	RW, TW	11°±2°, 15°±2°	0.3ml
	8,10,13,16	30G	RW, TW	11°±2°, 15°±2°	
	8,10,13,16	31G	RW, TW	11°±2°, 15°±2°	
	10, 13, 16	25G	RW, TW	11°±2°, 15°±2°	0.5ml
	10, 13, 16	26G	RW, TW	11°±2°, 15°±2°	
	10, 13, 16	27G	RW, TW	11°±2°, 15°±2°	
	10, 13, 16	28G	RW, TW	11°±2°, 15°±2°	
	8, 10, 13, 16	29G	RW, TW	11°±2°, 15°±2°	
	8, 10, 13, 16	30G	RW, TW	11°±2°, 15°±2°	
	8, 10, 13, 16	31G	RW, TW	11°±2°, 15°±2°	

	10, 13, 16	25G	RW, TW	11°±2°, 15°±2°	1ml
	10, 13, 16	26G	RW, TW	11°±2°, 15°±2°	
	10, 13, 16	27G	RW, TW	11°±2°, 15°±2°	
	10, 13, 16	28G	RW, TW	11°±2°, 15°±2°	
	8, 10, 13, 16	29G	RW, TW	11°±2°, 15°±2°	
	8, 10, 13, 16	30G	RW, TW	11°±2°, 15°±2°	
	8, 10, 13, 16	31G	RW, TW	11°±2°, 15°±2°	

The proposed Syringe is sterilized by Ethylene Oxide Gas to achieve a SAL of 10^{-6} and supplied sterility maintenance package which could maintain the sterility of the device during the shelf life of five years.

5. Identification of Predicate Devices

5.1 Predicate device 1

510(k) Number: K170651

Product Name: Sterile Disposable Syringe with Safety Needle
Sterile Disposable Syringe with Needle
Sterile Disposable Syringe (used as predicate device)
Sterile Disposable Safety Needle
Sterile Disposable Needle

Manufacturer: Yangzhou Medline Industry Co., Ltd.

5.2 Predicate device 2

510(k) Number: K132681

Product Name: Sol-Guard Insulin Safety Syringe and Tuberculin Safety Syringe

Manufacturer: Sol-Millennium Medical, Inc.

6. Identification of Reference Devices

510(k) Number: K150758

Product Name: Safelock Disposable Insulin Syringe

Manufacturer: Jiangsu Caina Medical Co., Ltd.

Indication for Use:

Safelock disposable insulin syringe is intended to inject U-100 insulin into the human body and aid in the prevention of accidental needle stick injuries.

The safety shield of the proposed syringes is the same as that of the legally marketed device, Safety Insulin Syringe (Safelock Disposable Insulin Syringe), as cleared in K150758, which is also

manufactured by Jiangsu Caina Medical Co., Ltd

7. 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 following standards:

- ISO 80369-7:2016 Small-bore connectors for liquids and gases in healthcare applications — Part 7: Connectors for intravascular or hypodermic applications.
- ISO 80369-20:2015 Small-bore connectors for liquids and gases in healthcare applications — Part 20: Common test methods.
- ISO 7886-1:2017 Sterile hypodermic syringes for single use- Part 1: Syringes for manual use.
- ISO 9626:2016, Stainless Steel Needle Tubing for the Manufacture of Medical Devices.
- ISO 7864:2016 Sterile hypodermic needles for single use — Requirements and test methods
- ISO 10993-7:2008 Biological Evaluation of Medical Devices - Part 7: Ethylene Oxide Sterilization Residuals.
- USP 41-NF36:2018<85> Bacterial Endotoxin Limit
- ASTM F88/F88M-15, Standard Test Method for Seal Strength of Flexible Barrier Materials. (Sterility)
- ASTM F1929-15 Standard Test Method for Detecting Seal Leaks in Porous Medical Package by Dye Penetration
- ASTM F1886/F1886M-16, Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection
- ISO 23908：2011 Sharps injury protection - Requirements and test methods –Sharps protection features for single-use hypodermic needles, introducers for catheters and needles used for blood sampling.
- Medical Devices with Sharps Injury Prevention Features - Guidance for Industry and FDA Staff

Biocompatibility testing

The contact level of the proposed device is blood path, indirect, and the contact duration is limited contact (<24 hours). The patient-contact components and materials of the 1ml Luer Slip or Luer Lock Syringe, Syringe with permanently attached needle, Safety Syringe with permanently attached needle, are identical to the patient-materials of product components of Safety Insulin Syringe (Safelock Disposable Insulin Syringe), as cleared in K150758, which is also manufactured by Jiangsu Caina Medical Co., Ltd. Therefore, the proposed syringes' biocompatibility can be demonstrated by the reference device (K150758).

8. Clinical Test Conclusion

No clinical study is included in this submission.

9. Substantially Equivalent (SE) Comparison

Table 2 Comparison of differences for 1ml Luer Slip or Luer Lock Syringe

ITEM	Proposed Device	Predicate Device 1 K170651	Reference device K150758	Remark
Product	1ml Luer Slip or Luer Lock Syringe	Sterile Disposable Syringe	Safelock Disposable Insulin Syringe	/
Product code	FMF	FMF	FMF MEG	Same
Regulation No.	21CFR 880.5860	21CFR 880.5860	21CFR 880.5860	Same
Class	II	II	II	Same
Indications for Use	1ml Luer Slip or Luer Lock Syringe is intended to be connected with the luer slip or luer lock needle and intended for use by health care professionals for general purpose aspiration of fluid from vials, ampoules and liquid injection below the surface of the skin.	The Sterile Disposable Syringe is a sterile luer lock or luer slip syringe which is intended to be used with a hypodermic needle for the aspiration and injection of fluids for medical purpose.	Safelock disposable insulin syringe is intended to inject U-100 insulin into the human body and aid in the prevention of accidental needle stick injuries.	Difference 1
Configuration and material	(1) barrel (PP) (2) plunger (PP) (3) piston (Polysoprene)	(1) barrel (PP) (2) plunger (PP) (3) piston (Polysoprene)	(1) Protective end cap (PE) (2) Plunger (PP) (3) Piston (Polysoprene) (4) barrel (PP) (5) needle cap (PE) (6) needle (Stainless steel 304) (7) Protective shield(PE)	Same
Syringe Volume	1ml	1ml, 2ml, 2.5ml, 3ml, 5ml, 10ml, 20ml, 30ml, 50ml, 60ml	0.3ml, 0.5ml, 1ml	Difference 2

Connector Type	Luer Lock/ Luer slip	Luer Lock/ Luer slip	NA	Same
Syringe performance	ISO 7886-1	ISO 7886-1	ISO 7886-1	Same
Biocompatibility	Conforms to the requirements of ISO 10993 series standards.	Conforms to the requirements of ISO 10993 series standards.	Conforms to the requirements of ISO 10993 series standards.	Same
Method	EO Sterilized	EO Sterilized	EO Sterilized	Same
SAL	10^{-6}	10^{-6}	10^{-6}	Same
Endotoxin Limit	20 EU per device	20 EU per device	20 EU per device	Same
Operation Principle	For Manual Use Only, For Single Use Only	For Manual Use Only, For Single Use Only	For Manual Use Only, For Single Use Only	Same
Label/Labeling	Complied with 21 CFR part 801	Complied with 21 CFR part 801	Complied with 21 CFR part 801	Same

Difference 1- Indication for use

The proposed devices have the same operation principle as that of the predicate device. The description of the indication for use of the proposed device and the predicate devices and reference device are different, but they are all used by health care professionals for fluid aspiration and injection. The essential use of the syringe is the same. Therefore, this item is considered substantially equivalent.

Difference 2- Syringe volume

The Syringe volume for proposed devices are different from the predicate devices 1. However, this difference is just in dimension. Different volume devices will be selected by physician per patient's condition. This difference does not affect intended use. In addition, differences in syringe volume between the predicate and subject device were addressed through ISO 7886-1:2017 performance testing. Therefore, this difference does not affect substantially equivalence on safety and effectiveness.

Table 3 Comparison of differences for Syringe with permanently attached needle

ITEM	Proposed Device	Predicate Device 2 K132681	Reference device K150758	Remark
Product	Syringe with permanently attached needle	Sol-Guard Insulin Safety Syringe and Tuberculin Safety Syringe	Safelock Disposable Insulin Syringe	/
Product code	FMF	MEG	FMF MEG	Difference 3
Regulation No.	21CFR 880.5860	21CFR 880.5860	21CFR 880.5860	Same
Class	II	II	II	Same
Indications for Use	The Syringe with permanently attached needle is intended for use by health care professionals for general purpose aspiration of fluid from vials, ampoules and liquid injection below the surface of the skin.	<u>For TB Use</u> The Sol-Guard Tuberculin (TB) Safety Syringe is intended for the delivery of Tuberculin. The Sol-Guard TB Safety Syringe Safety Sleeve covers the needle when activated. In the activated position, the Safety Shield guards against accidental needle stick. <u>For Insulin Use</u> The Sol-Guard Insulin Safety Syringe is intended for the delivery of **U-1 00** insulin. The Sal-Guard Insulin Safety Syringe Safety Sleeve covens the needle when activated. In the activated position, the Safety Shield guards against accidental needle stick.	Safelock disposable insulin syringe is intended to inject U-100 insulin into the human body and aid in the prevention of accidental needle stick injuries.	Difference 4
Configuratio	<u>Syringe with permanently</u>	(1) needle cap	1) Protective end cap	Difference

n and material	attached needle-type A (1) needle cap (PP or PE) (2) needle (Stainless Steel 304) (3) piston (Polysoprene) (4) plunger (PP) (5) barrel (PP) (6) end cap (PP or PE) Syringe with permanently attached needle-type B (1) needle cap (PP or PE) (2) needle (Stainless Steel 304) (3) piston (Polysoprene) (4) plunger (PP or ABS) (5) barrel (PP)	(2) needle (3) piston (4) plunger (5) barrel (6) end cap (7) safety mechanism The material of predicate device is not exposured in the predicate device's 510(k) summary, so the materials of predicate device is unknown	(PE) (2) Plunger (PP) (3) Piston (Polysoprene) (4) barrel (PP) (5) needle cap (PE) (6) needle (Stainless steel 304) (7) Protective shield (PE)	5
Syringe Volume	0.3ml, 0.5ml, 1ml	0.3ml, 0.5ml, 1ml	0.3ml, 0.5ml, 1ml	Same
Needle Gauge	21G, 23G, 25G, 26G, 27G, 28G, 29G, 30G, 31G	25G, 27G, 28G, 29G, 30G, 31G	28G, 29G, 30G	Difference 6
Needle Length	8mm, 10mm, 13mm, 16mm, 20mm, 25mm	8mm, 13mm, 16mm, 25mm	8mm, 10mm, 13mm, 16mm	
Needle wall type	RW, TW	Unknown	RW	
Needle bevel	11°±2°, 15°±2°	15 degree regular point	12°±2°	
Needle performance	ISO 9626 ISO 7864	ISO 9626 ISO 7864	ISO 9626 ISO 7864	Same
Syringe performance	ISO 7886-1	ISO 7886-1	ISO 7886-1	Same
Biocompatibility	Conforms to the requirements of ISO 10993 series standards.	Conforms to the requirements of ISO 10993 series standards.	Conforms to the requirements of ISO 10993 series standards.	Same
Method	EO Sterilized	EO Sterilized	EO Sterilized	Same
SAL	10^{-6}	10^{-6}	10^{-6}	Same
Endotoxin Limit	20 EU per device	20 EU per device	20 EU per device	Same
Operation Principle	For Manual Use Only, For Single Use Only	For Manual Use Only, For Single Use Only	For Manual Use Only, For Single Use Only	Same

Label/Labeling	Complied with 21 CFR part 801	Complied with 21 CFR part 801	Complied with 21 CFR part 801	Same

Difference 3- Product code

The proposed devices are a syringe with permanently attached needle, so the corresponding product codes is FMF. The predicate devices 2 are a safety syringe with needle and its product code is MEG. Both proposed device and predicate device are all used by health care professionals for fluid aspiration and injection. The syringe without safety feature is widely used in the clinical. Therefore, the difference on product code and regulation number will not raise new questions on safety and effectiveness of the proposed device.

Difference 4-Indication for use

The proposed devices have the same operation principle as that of the predicate device 2. The description of the indication for use of the proposed device and the predicate devices and reference device are different, but they are all used by health care professionals for fluid aspiration and injection. The syringe without safety feature is widely used in the clinical. Therefore, this item is considered substantially equivalent.

Difference 5- Configuration and materials

The configurations of Syringe with permanently attached needle is similar as the configuration of predicate device 2, the difference is that Syringe with permanently attached needle has no safety mechanism, but the syringe without safety feature is widely used in the clinical. Whether there is a safety mechanism or not will not affect the indication for use of the equipment itself. This difference does not raise new questions about safety and effectiveness.

Although the materials of predicate devices 2 are unknown. The proposed syringes' biocompatibility can be demonstrated by the reference device (K150758). Therefore, the differences on configuration and materials do not raise new questions about safety and effectiveness.

Difference 6- Needle gauge, length, wall type and bevel

The needle gauge and length for proposed devices is different from the predicate devices 2. However, this difference is just in dimension. Different size and length device will be selected by physician per patient's condition. This difference does not affect intended use, differences in needle length and gauge between the predicate and subject device were addressed through ISO 7864:2016 and ISO 9626:2016 performance testing.

The needle wall type for predicate device is unknown. However, the performance test for proposed device has been conducted and the test result conform with requirements of ISO 7864:2016 and ISO 9626:2016 standards.

The needle bevel for proposed devices are different from the predicate device 2. However, this difference is just in dimension. Different needle bevel will be selected by physician per patient's condition. This difference does not affect intended use. In addition, differences in needle bevel between

the predicate and subject device were addressed through ISO 7864:2016 and ISO 9626:2016 performance testing. Therefore, the differences on needle length, gauge, wall type and bevel does not affect substantially equivalence on safety and effectiveness.

Table 4 Comparison of differences for Safety Syringe with permanently attached needle

ITEM	Proposed Device	Predicate Device 2 K132681	Reference device K150758	Remark
Product	Safety Syringe with permanently attached needle	Sol-Guard Insulin Safety Syringe and Tuberculin Safety Syringe	Safelock Disposable Insulin Syringe	/
Product code	MEG	MEG	FMF MEG	Same
Regulation No.	21CFR 880.5860	21CFR 880.5860	21CFR 880.5860	Same
Class	II	II	II	Same
Indications for Use	The Safety Syringe with permanently attached needle is intended for use by health care professionals for general purpose aspiration of fluid from vials, ampoules and liquid injection below the surface of the skin. The Safety sheath of Syringe is designed to aid in the prevention of needle stick injuries and reduce the potential or syringe reuse.	<u>For TB Use</u> The Sol-Guard Tuberculin (TB) Safety Syringe is intended for the delivery of Tuberculin. The Sol-Guard TB Safety Syringe Safety Sleeve covers the needle when activated. In the activated position, the Safety Shield guards against accidental needle stick. <u>For Insulin Use</u> The Sol-Guard Insulin Safety Syringe is intended for the delivery of U-100 insulin. The Sal-Guard Insulin Safety Syringe Safety Sleeve covens the needle when activated. In the activated position, the Safety Shield guards against accidental needle stick.	Safelock disposable insulin syringe is intended to inject U-100 insulin into the human body and aid in the prevention of accidental needle stick injuries.	Difference 7

Configuration and material	(1) needle cap (PP or PE) (2) needle (Stainless Steel 304) (3) safety mechanism (PC) (4) piston (Polysoprene) (5) safety mechanism (PP) (6) plunger (PP) (7) barrel (PP)	(1) needle cap (2) needle (3) piston (4) plunger (5) barrel (6) end cap (7) safety mechanism The material of predicate device is not exposured in the predicate device's 510(k) summary, so the materials of predicate device is unknown	(1) Protective end cap (PE) (2) Plunger (PP) (3) Piston (Polysoprene) (4) barrel (PP) (5) needle cap (PE) (6) needle (Stainless steel 304) (7) Protective shield (PE)	Difference 8
Syringe Volume	0.3ml, 0.5ml, 1ml	0.3ml, 0.5ml, 1ml	0.3ml, 0.5ml, 1ml	Same
Needle Gauge	21G, 23G, 25G, 26G, 27G, 28G, 29G, 30G, 31G	25G, 27G, 28G, 29G, 30G 31G	28G, 29G, 30G	Difference 9
Needle Length	8mm, 10mm, 13mm, 16mm, 20mm, 25mm	8mm, 13mm, 16mm, 25mm	8mm, 10mm, 13mm, 16mm	
Needle wall type	RW, TW	Unknown	RW	
Needle bevel	11°±2°, 15°±2°	15 degree regular point	12°±2°	
Needle performance	ISO 9626 ISO 7864	ISO 9626 ISO 7864	ISO 9626 ISO 7864	Same
Syringe performance	ISO 7886-1	ISO 7886-1	ISO 7886-1	Same
Safety feature performance specifications	i. The torque to lock shall be less than 10N·cm ii. The force to destroy forward shall not be less than 30N iii. The force to destroy backward shall not be less than 60N iv. The torque to unscrewing shall	Unknown	Unknown	Difference10

	be greater than 20N·cm			
Biocompatibility	Conforms to the requirements of ISO 10993 series standards.	Conforms to the requirements of ISO 10993 series standards.	Conforms to the requirements of ISO 10993 series standards.	Same
Method	EO Sterilized	EO Sterilized	EO Sterilized	Same
SAL	10^{-6}	10^{-6}	10^{-6}	Same
Endotoxin Limit	20 EU per device	20 EU per device	20 EU per device	Same
Operation Principle	For Manual Use Only, For Single Use Only	For Manual Use Only, For Single Use Only	For Manual Use Only, For Single Use Only	Same
Label/Labeling	Complied with 21 CFR part 801	Complied with 21 CFR part 801	Complied with 21 CFR part 801	Same

Difference 7-Indication for use

The proposed devices have the same operation principle as that of the predicate device 2. The description of the indication for use of the proposed device and the predicate devices and reference device are different, but they are all used by health care professionals for fluid aspiration and injection. The essential use of the syringe is the same. Therefore, this item is considered substantially equivalent.

Difference 8- Configuration and materials

The configurations of Syringe with permanently attached needle is similar as the combinations of the configuration of predicate device 2, the difference is that Safety Syringe with permanently attached needle has no end cap, but there are many products on the market without end cap. This difference does not raise new questions about safety and effectiveness. Whether there is an end cap or not will not affect the indication for use of the equipment itself. This difference does not raise new questions about safety and effectiveness.

The predicate devices 2 material of configurations are unknown. Although the materials of predicate devices 2 are unknown. The proposed syringes' biocompatibility can be demonstrated by the reference device (K150758). Therefore, the differences on configuration and materials do not raise new questions about safety and effectiveness.

Difference 9- Needle gauge, length, wall type and bevel

The needle gauge and length for proposed devices is different from the predicate devices 2. However, this difference is just in dimension. Different size and length device will be selected by physician per patient's condition. This difference does not affect intended use, differences in needle length and gauge between the predicate and subject device were addressed through ISO 7864:2016 and ISO 9626:2016 performance testing.

The needle wall type for predicate device is unknown. However, the performance test for proposed device has been conducted and the test result conform with requirements of ISO 7864:2016 and ISO 9626:2016 standards.

The needle bevel for proposed devices are different from the predicate device 2. However, this difference is just in dimension. Different needle bevel will be selected by physician per patient's condition. This difference does not affect intended use. In addition, differences in needle bevel between the predicate and subject device were addressed through ISO 7864:2016 and ISO 9626:2016 performance testing. Therefore, the differences on needle length, gauge, wall type and bevel does not affect substantially equivalence on safety and effectiveness.

Difference 10- Safety feature performance specifications

The Safety feature performance specifications for predicate device is unknown. However, the safety feature performance test for proposed device has been evaluated and the test result conforms to requirements of ISO 23908:2011 standards. Therefore, the differences on configuration and materials does not affect substantially equivalence.

10. 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.