July 21, 2022

Shanghai Kindly Enterprise Development Group Co., Ltd
% Ryan Li
RA Manager
Shanghai Mind-link Consulting Co., Ltd.
Room A08, Floor 14th, No 699, Jiaozhou Road, Jingan District
Shanghai, 200040
China

Re: K220183
Trade/Device Name: Sterile Safety Syringe for Single Use (Retractable)
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: Class II
Product Code: MEG
Dated: June 14, 2022
Received: June 21, 2022

Dear Ryan Li:

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,

CAPT Alan M. 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K220183

Device Name
Sterile Safety Syringe for Single Use (Retractable)

Indications for Use *(Describe)*
The Sterile Safety Syringe for Single Use (Retractable) is intended to provide a safe and reliable method of injecting fluids into or withdrawing fluids from the body. The Sterile Safety Syringe for Single Use (Retractable) is designed to aid in the prevention of needle stick injuries and reduce the potential for syringe reuse. The Sterile Safety Syringe for Single Use (Retractable) is a single use, disposable device, provided sterile.

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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I. PREPARATION DATE: 7/20/2022

II. SUBMITTER:

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III. DEVICE

Name of Device: Sterile Safety Syringe for Single Use (Retractable)
Regulation Number: 21 CFR PART 880.5860
Common Name: Syringe, Antistick
Classification Name: Piston syringe
Regulatory Class: II
Product Code: MEG

IV. PREDICATE DEVICE

Name of Device: Retractable Safety Syringe, Retractable Safety Tuberculin Syringe, Retractable Safety Allergy Syringe (Bi)
Regulation Number: 21 CFR 880.5860
Common Name: Syringe, Antistick
Classification Name: Piston syringe
Regulatory Class: II
Product Code: MEG

V. DEVICE DESCRIPTION

The proposed device, Sterile Safety Syringe for Single Use (Retractable), is available in 1ml. The models of syringe and needle are listed in the below table.

Table 5-1 Models of syringe and needle

Syringe volume(ml)	Matched needle			
	Needle gauge (G)	Needle length (mm)	Needle wall	Bevel
1 mL	23G	25	RW	11±2°

	25G	25	RW	11±2°
	26G	13	RW	11±2°
	27G	13	RW	11±2°
	28G	13	RW	11±2°
	29G	13	RW	11±2°
	30G	8, or 13	TW	11±2°
	31G	6, or 8	TW	11±2°

The proposed device consists of seven components:(1) protective cap, (2) needle tube, (3) connecting seat, (4) plunger stopper, (5) sliding sleeve, (6) barrel, (7) plunger.

The proposed devices are sterilized by ethylene oxide to achieve a SAL 10-6 and supplied in sterility maintenance small package which could maintain the sterility of the device during the shelf life of 5 years.

VI. INDICATIONS FOR USE/INTENDED USE

The Sterile Safety Syringe for Single Use (Retractable) is intended to provide a safe and reliable method of injecting fluids into or withdrawing fluids from the body. The Sterile Safety Syringe for Single Use (Retractable) is designed to aid in the prevention of needle stick injuries and reduce the potential for syringe reuse. The Sterile Safety Syringe for Single Use (Retractable) is a single use, disposable device, provided sterile.

VII. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The Sterile Safety Syringe for Single Use (Retractable) is compared with the predicate device, Retractable Safety Syringe, Retractable Safety Tuberculin Syringe, and Retractable Safety Allergy Syringe (K191490). The results are shown below in the Technological Characteristics Comparison Table:

DEVICE	Proposed device Sterile Safety Syringe for Single Use (Retractable)	Predicate device Retractable Safety Syringe, Retractable Safety Tuberculin Syringe, Retractable Safety Allergy Syringe (K191490)	Remark
Indications for Use/Intended use	The Sterile Safety Syringe for Single Use (Retractable) is intended to provide a safe and reliable method of injecting fluids into or withdrawing fluids from	The Retractable Safety Syringe works like a conventional hypodermic syringe except for its ability to retract the contaminated needle inside of the syringe immediately after patient injection. Needle retraction is activated by the syringe user. Because the contaminated needle is automatically	Similar **Note 1**

	the body. The Sterile Safety Syringe for Single Use (Retractable) is designed to aid in the prevention of needle stick injuries and reduce the potential for syringe reuse. The Sterile Safety Syringe for Single Use (Retractable) is a single use, disposable device, provided sterile.	withdrawn into the syringe plunge, the syringe user is protected from accidental needle sticks. These accidental needle sticks would occur between removing the needle from the patient and disposing of the syringe in a sharps disposable container. For general injection use: The function of Retractable Safety Syringe is to provide a safe and reliable method of injecting fluids into or withdrawing fluids from the body. The Retractable Safety Syringe is designed to aid in the prevention of needle stick injuries and reduce the potential or syringe reuse. The syringe contains various capacity, such as 1ml, 2.5ml, 3ml, 5ml and 10ml. For allergy use: The 1ml Retractable Safety Allergy Syringe is intended for the preparation/mixing of allergenic extracts/ prescribed substances, the manual aspiration of fluids, and for the injection of fluids into parts of the body below the surface of the skin. The Retractable Safety Syringe is designed to aid in the prevention of needle stick injuries and reduce the potential or syringe reuse. For Tuberculin use: The 1ml Retractable Safety Tuberculin Syringe is intended for the delivery of Tuberculin. The Retractable Safety Syringe is designed to aid in the prevention of needle stick injuries and reduce the potential or syringe reuse.	
Classification Product Code	MEG	MEG	Same
Prescription Only or Over the Counter	Prescription	Prescription	Same
Regulation No.	21 CFR 880.5860	21 CFR 880.5860	Same
Class	II	II	Same

Configuration	Plunger stopper Plunger Barrel (graduated) Safety feature	Piston Plunger Barrel (graduated) Safety feature	Same
Sterility	EO Sterilized	EO Sterilized	Same
Environment of use	Hospital	Hospital	Same
Safety feature principle	Sliding sleeve activation	Spring retraction	Different **Note 2**
Volume	1ml	Retractable Safety Syringe: 1ml, 2.5mL, 3mL, 5mL, 10mL Retractable Safety Tuberculin Syringe/ Retractable Safety Allergy Syringe: 1mL	Different **Note 3**
Needle gauge	23G,25G,26G,27G,28G, 29G, 30G and 31G	24G, 25G, 26G, 27G, 28G, 29G, 30G and 31G	Different **Note 4**
Needle length	6mm, 8mm, 13mm, and 25mm	8mm,10mm,13mm,16mm, 20mm, 25mm	Different **Note 4**
Needle wall	Regular wall, Thin wall	Regular wall	Different **Note 4**
Bevel	11±2°	11±2°	Same
Single use	Yes	Yes	Same
Operation mode	For Manual Use Only, For Single Use only	For Manual Use Only, For Single Use only	Same
Materials	Barrel/Plunger/Sliding sleeve: Polypropylene Plunger stopper: Polyisoprene Connecting seat: Polycarbonate Protective cap: Polyethylene Needle tube: Stainless steel Lubricant: Silicone oil	Plunger/Barrel/Needle cap/Plunger lid/ Barrel barb: PP Piston: Polyisoprene, Sealing plug: TPE+PP, Needle tube/Spring: Stainless Steel, Hub: MABS Lubricant: Polydimethylsiloxane	Different **Note 5**

Discussion in details:

Note 1: In terms of the difference between proposed device and predicate device, the predicate device is a buddled submission device that contains Retractable Safety Syringe, Retractable Safety

Tuberculin Syringe and Retractable Safety Allergy Syringe, and each device have different indications for use.
The proposed device is the same as the Retractable Safety Syringe that is included in the predicate device. Overall, they both have the same indications for use/intended use, that inject fluid into or withdraw fluid from the body and aid in prevention of needle stick injures and reuse of the syringe. As a result, this difference will not affect the subject device's safety and effectiveness.

Note 2: The structures of safety features of the proposed and the predicate device are different. The proposed device uses a plastic sleeve that pulls forward to cover the needle after use. The predicate device uses a needle retraction structure that the needle is encapsulated into the barrel after use. Although they use a different mechanical structure, they are both intended to prevent the needle stick injury during use and prevent harm to end-user. The safety feature of the proposed device has been validated to verify the prevention function. As a result, this difference will not affect the subject device's safety and effectiveness.

Note 3: The predicate device has a wider range of models (1ml, 2.5mL, 3mL, 5mL, 10mL) than the proposed device (1mL). Meanwhile, the performance of all models of the proposed device is tested by following ISO 7886-1, to demonstrate the substantial equivalence.

Note 4: Although the needle gauge, needle length and needle wall type is different from the predicate device, the 7864-1 needle test report of the proposed device could demonstrate it is as safe and effective as the predicate device.

Note 5: Although the materials of the proposed device are slightly different from the predicate device, the biocompatibility test reports of the proposed device could demonstrate it is as safe and effective as the predicate device.

VII PERFORMANCE DATA

Biocompatibility

The proposed device is external communicating device, blood path indirect, contact duration is limited (≤24hrs). The following testing was conducted: ISO 10993-1 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process

- ISO 10993-4:2017 Biological evaluation of medical devices -- Part 4: Selection of tests for interactions with blood
- ISO 10993-5:2009 Biological evaluation of medical devices- Part 5: Test for in vitro cytotoxicity
- ISO 10993-10:20101Biological evaluation of medical devices- Part 10: Test for irritation

and delayed-type hypersensitivity

- ISO 10993-11 Biological evaluation of medical devices -- Part 11: Tests for systemic toxicity
- USP 43-NF38:2020 <151> Pyrogen Test (USP Rabbit Test)

Particulate matter testing was conducted in accordance with USP <788> Particulate Matter in Injection and met the USP acceptance criteria.

Sterility, Shipping and Shelf-Life

- ISO 10993-7:2008 Biological evaluation of medical devices- Part 7: Ethylene Oxide Sterilization Residuals
- USP 43-NF38:2020 <85> Bacterial Endotoxins Test
- ASTM F88/F88M-15, Standard Test Method For Seal Strength Of Flexible Barrier Materials
- ASTM F1929-15 Standard Test Method for Detecting Seal Leaks in Porous Medical Package by Dye Penetration
- ASTM F1980 - 16 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
- Shelf life of 5 years

Performance Testing

- ISO 7864:2016 Sterile hypodermic needles for single use-requirements and test method
- ISO 7886-1:2017 Sterile hypodermic syringe for single use- Part 1: Syringes for manual use
- ISO 9626:2016 Stainless steel needle tubing for the manufacture of the medical devices-requirements and test method
- 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

In addition, a simulated clinical use study was conducted on the subject device, Sterile Safety Syringe for Single Use (Retractable) to evaluate the effect of safety feature per FDA Guidance "Medical Devices with Sharps Injury Prevention Features" issued on August 9, 2005. The test results demonstrated that the subject device complies with the requirements.

Clinical Test Conclusion

No clinical study is included in this submission.

VIII. CONCLUSION

The differences between the predicate device and the subject device do not raise any new or different questions of safety or effectiveness. The Sterile Safety Syringe for Single Use (Retractable) is substantially equivalent to the Retractable Safety Syringe with respect to the indications for use and technological characteristics.