Shanghai Kindly Enterprise Development Group Co., Ltd
℅ Evan Hu
Official Correspondent
Shanghai Mind-Link Business Consulting Co., Ltd.
Room A08, Floor 14th, No 699, Jiaozhou Road, Jingan District
Shanghai, 200040 Cn

Re: K221416
Trade/Device Name: Sterile Safety Syringes for Single Use
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: Class II
Product Code: MEG, FMF, FMI
Dated: August 05, 2022
Received: August 08, 2022

Dear Evan Hu:

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

Section 4

Indications for Use Statement

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)*
K221416

Device Name
Sterile Safety Syringes for Single Use

Indications for Use *(Describe)*
The Sterile Safety Syringes for Single Use are intended for use in the 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 sticks. The Sterile Safety Syringes for Single Use are single use, disposable devices, 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Section 5

510(K) Summary

I. SUBMITTER:

Shanghai Kindly Enterprise Development Group Co., Ltd.

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Submission Correspondent：Evan Hu

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II. Proposed Device

Name of Device: Sterile Safety Syringes for Single Use

Regulation Number: 21 CFR PART 880.5860

Common Name: Syringe, Antistick

Syringe, Piston

Needle, Hypodermic, Single Lumen

Classification Name: Piston syringe

Regulatory Class: II

Product Code: MEG, FMF, FMI

III. PREDICATE DEVICE

Name of Device: Safety Needles

Sterile Syringe

Sterile Syringe with Safety Needle

Sterile Syringe with Needle

Hypodermic Needle for Single Use

(K183665)

Regulation Number: 21 CFR 880.5860

Common Name: Syringe, Antistick

Syringe, Piston

Needle, Hypodermic, Single Lumen

Classification Name: Piston syringe

Regulatory Class: II

Product Code: MEG, FMF, FMI

IV. DEVICE DESCRIPTION

The proposed device consists of a safety hypodermic needle and a luer slip or luer lock syringe. Models of Sterile Safety Syringes for Single Use shown in Table 11.1 and 11.2 are available in various models according to different syringe volume and needle specifications.

Table 11-1 Models of Sterile Safety Syringes for Single Use (Luer Lock Type)

Syringe volume	Matched needle				
	REF	Needle gauge	Needle length	Needle wall	Bevel
1ml	SRS21012325	23G	25mm	Thin wall	11±2°

	SRS21012525	25G	25mm	Thin wall	11±2°
	SRS21012516	25G	16mm	Thin wall	11±2°
	SRS21012713	27G	13mm	Regular wall	11±2°
2ml	SRS21022325	23G	25mm	Thin wall	11±2°
	SRS21022525	25G	25mm	Thin wall	11±2°
	SRS21022516	25G	16mm	Thin wall	11±2°
	SRS21022713	27G	13mm	Regular wall	11±2°
3ml	SRS21031838	18G	38mm	Thin wall	11±2°
	SRS21032025	20G	25mm	Thin wall	11±2°
	SRS21032038	20G	38mm	Thin wall	11±2°
	SRS21032125	21G	25mm	Thin wall	11±2°
	SRS21032138	21G	38mm	Thin wall	11±2°
	SRS21032225	22G	25mm	Thin wall	11±2°
	SRS21032238	22G	38mm	Thin wall	11±2°
	SRS21032325	23G	25mm	Thin wall	11±2°
	SRS21032338	23G	38mm	Thin wall	11±2°
	SRS21032525	25G	25mm	Thin wall	11±2°
	SRS21032538	25G	38mm	Thin wall	11±2°
5ml	SRS21051838	18G	38mm	Thin wall	11±2°
	SRS21052025	20G	25mm	Thin wall	11±2°
	SRS21052038	20G	38mm	Thin wall	11±2°
	SRS21052125	21G	25mm	Thin wall	11±2°
	SRS21052138	21G	38mm	Thin wall	11±2°
	SRS21052225	22G	25mm	Thin wall	11±2°
	SRS21052238	22G	38mm	Thin wall	11±2°
	SRS21052325	23G	25mm	Thin wall	11±2°

	SRS21052338	23G	38mm	Thin wall	11±2°
	SRS21052525	25G	25mm	Thin wall	11±2°
	SRS21052538	25G	38mm	Thin wall	11±2°
10ml	SRS21102138	21G	38mm	Thin wall	11±2°
	SRS21102238	22G	38mm	Thin wall	11±2°

Table 11-2 Models of Sterile Safety Syringes for Single Use (Luer Slip Type)

Syringe volume	Matched needle				
	REF	Needle gauge	Needle length	Needle wall	Bevel
1ml	SRS22012325	23G	25mm	Thin wall	11±2°
	SRS22012525	25G	25mm	Thin wall	11±2°
	SRS22012516	25G	16mm	Thin wall	11±2°
	SRS22012713	27G	13mm	Regular wall	11±2°
2ml	SRS22022325	23G	25mm	Thin wall	11±2°
	SRS22022525	25G	25mm	Thin wall	11±2°
	SRS22022516	25G	16mm	Thin wall	11±2°
	SRS22022713	27G	13mm	Regular wall	11±2°
3ml	SRS22031838	18G	38mm	Thin wall	11±2°
	SRS22032025	20G	25mm	Thin wall	11±2°
	SRS22032038	20G	38mm	Thin wall	11±2°
	SRS22032125	21G	25mm	Thin wall	11±2°
	SRS22032138	21G	38mm	Thin wall	11±2°
	SRS22032225	22G	25mm	Thin wall	11±2°
	SRS22032238	22G	38mm	Thin wall	11±2°
	SRS22032325	23G	25mm	Thin wall	11±2°

	SRS22032338	23G	38mm	Thin wall	11±2°
	SRS22032525	25G	25mm	Thin wall	11±2°
	SRS22032538	25G	38mm	Thin wall	11±2°
5ml	SRS22051838	18G	38mm	Thin wall	11±2°
	SRS22052025	20G	25mm	Thin wall	11±2°
	SRS22052038	20G	38mm	Thin wall	11±2°
	SRS22052125	21G	25mm	Thin wall	11±2°
	SRS22052138	21G	38mm	Thin wall	11±2°
	SRS22052225	22G	25mm	Thin wall	11±2°
	SRS22052238	22G	38mm	Thin wall	11±2°
	SRS22052325	23G	25mm	Thin wall	11±2°
	SRS22052338	23G	38mm	Thin wall	11±2°
	SRS22052525	25G	25mm	Thin wall	11±2°
	SRS22052538	25G	38mm	Thin wall	11±2°
10ml	SRS22102138	21G	38mm	Thin wall	11±2°
	SRS22102238	22G	38mm	Thin wall	11±2°

V. INDICATIONS FOR USE

The Sterile Safety Syringes for Single Use are intended for use in the 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 sticks. The Sterile Safety Syringes for Single Use are single use, disposable devices, provided sterile.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The Sterile Safety Syringes for Single Use are compared with the predicate device, Safety Needles, Sterile Syringe, Sterile Syringe with Safety Needle, Sterile Syringe with Needle, Hypodermic Needle for Single Use (K183665). The results are shown below in the Technological Characteristics Comparison Table:

Device	**Sterile Safety Syringes for Single Use**	**Safety Needles, Sterile Syringe, Sterile Syringe with Safety Needle, Sterile Syringe with Needle, Hypodermic Needle for Single Use (K183665)**	**Remark**
Indication for Use	The Sterile Safety Syringes for Single Use are intended for use in the 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 sticks. The Sterile Safety Syringes for Single Use are single use, disposable devices, provided sterile.	The sterile syringe with safety needle is intended for use in the 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 sticks.	Same
Classification **Product Code**	MEG, FMF,FMI	MEG, FMF,FMI	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	Barrel	Barrel (Polypropylene)	Same

		Plunger Plunger stopper Needle tube Protective needle hub Protective cap	Plunger (Polypropylene) Stopper (Polyisoprene) Needle cap (Polypropylene) Needle tube (SUS304) Hub with protector (Polypropylene)	
Sterility		EO Sterilized	EO Sterilized	Same
Size	**Volume**	1ml, 2ml, 3ml, 5ml, 10ml	1ml, 3ml, 5ml, 10ml, 20ml, 30ml, 50ml, and 60ml	Different **Note 1**
	Syringe Type	Luer Lock/Luer Slip	Luer Lock/Luer Slip/Luer slip Eccentric	
	Needle Gauge	18G, 20G, 21G, 22G, 23G, 25G, 27G	18G, 20G, 21G, 22G, 23G, 25G, and 26G	
	Needle Length	13mm, 16mm, 25mm, 38mm	1/2"-2"	
Single Use		Yes	Yes	Same
Biocompatibility		No Cytotoxicity	No Cytotoxicity	Same
		No Irritation to Skin	No Irritation to Skin	
		No significant evidence of sensitization	No significant evidence of sensitization	
		No systemic toxicity	No systemic toxicity	
		No Hemolysis	No Hemolysis	
		Non pyrogenic	Non pyrogenic	
Performance Test		Conforms with the requirements of ISO 7864, ISO 9626, ISO 7886, and ISO 80369-7. Needle Safety Feature:Testing conducted per ISO	Conforms with the requirements of ISO 7864, ISO 9626, ISO 7886, and ISO 80369-7. Needle Safety Feature: Testing conducted per ISO 23908:2011.	Same

	23908:2011.	Force to activate safety mode: NMT 10N Force to disengage safety mode: NLT 20N Force to separate safety feature from needle hub: NLT 50N	

Note 1

Analysis: Although there are differences between proposed device and predicate device in terms of syringe type, syringe volume, needle length and needle gauge, corresponding performance tests were conducted on all the specifications including ISO 7886-1, ISO 7864-1 and ISO 9626-1 to prove it meet the specific requirements. Therefore, this difference does not raise different questions of safety and effectiveness.

VII PERFORMANCE DATA

Non-Clinical Performance Test Conclusion

Biocompatibility

The proposed device is external communicating device, blood path indirect, contact duration is limited (≤24hrs). The biocompatibility tests were conducted to verify that the proposed devices are not adverse to human tissue based on the following standards:

- ISO 10993-1 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
- ISO 10993-2:2006 Biological evaluation of medical devices-Part 2: Animal welfare requirements
- 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 10993-11：2017 Biological evaluation of medical devices -- Part 11: Tests for systemic toxicity
- ISO 10993-12:2012 Biological evaluation of medical devices -- Part 12: Sample preparation and reference materials
- ASTM 756-17 Standard Practice for Assessment of Hemolytic Properties of Material

Other non-clinical tests were conducted to verify that the proposed device met all design specifications was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the Sterile Safety Syringe for Single Use (Retractable) complies with the following standards:

- ISO 10993-7:2008 Biological evaluation of medical devices- Part 7: Ethylene Oxide Sterilization Residuals
- USP 43-NF38:2020 <85> Bacterial Endotoxins Test
- USP 43-NF38:2020 <151> Pyrogen Test (USP Rabbit 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
- 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 80369-7:2021 Small-bore connectors for liquids and gases in healthcare applications — Part 7: Connectors for intravascular or hypodermic applications

- 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 Syringes for Single Use 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 and the proposed device do not raise any new or different questions of safety or effectiveness. The proposed device is substantially equivalent to the predicate device with respect to indications for use and technological characteristics.