July 11, 2022

Shanghai Kindly Enterprise Development Group Co., Ltd.
℅ Amy Li
Technical Director
Shanghai Mind-link Consulting Co., Ltd.
Room A08, Floor 14th, No 699, Jiaozhou Road, Jingan District
Shanghai, 200040
China

Re: K220185
Trade/Device Name: Sterile Safety Insulin Syringes for Single Use
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: Class II
Product Code: MEG, FMF, FMI
Dated: June 10, 2022
Received: June 13, 2022

Dear Amy 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)*
K220185

Device Name
Sterile Safety Insulin Syringes For Single Use

Indications for Use *(Describe)*
The Sterile Safety Insulin Syringes For Single Use are a sterile, single-use, disposable and non-reusable, manual retractable safety insulin syringe intended for injection of U40 or U100 insulin into the body, the sliding sleeve helps protect against needle puncture once activated.

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

The assigned 510(k) Number: K220185

1. Date of preparation: July 8, 2022

2. Sponsor Identification

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3. Designated submission correspondent

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4. Identification of Proposed Device

Trade Name: Sterile safety insulin syringes for single use
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston syringe
Regulatory Class: Class II
Product Code: MEG, FMF, FMI
Regulation Number: 21 CFR 880.5860
Review Panel: General hospital

5. Indication for use statement

The Sterile Safety Insulin Syringes for single use are a sterile, single-use, disposable and non-reusable, manual retractable safety insulin syringe intended for injection of U40 or U100 insulin into the body, the sliding sleeve helps protect against needle puncture once activated.

6. Device description

KDL Sterile safety insulin syringes have a sliding sleeve which is designed to shield the injection needle to protect the user from needle puncture and the sliding sleeve helps protect against needle puncture once activated. The sliding sleeve can be activated manually.

Models of Sterile safety insulin syringes for single use shown in Table 1-1 are available in various models according to different insulin concentration and syringe volume.

Table 1-1 Models of Sterile safety insulin syringes for single use

Syringe volume(ml)	Insulin concentration	Needle gauge(G)	Needle length(mm)	Needle wall type	Bevel
0.5ml	U40	27G	13	RW	11°±2°
		28G	13	RW	11°±2°
		29G	13	RW	11°±2°
		30G	8、13	TW	11°±2°
		31G	6、8	TW	11°±2°
	U100	27G	13	RW	11°±2°
		28G	13	RW	11°±2°
		29G	13	RW	11°±2°
		30G	8、13	TW	11°±2°
		31G	6、8	TW	11°±2°
1ml	U40	27G	13	RW	11°±2°
		28G	13	RW	11°±2°
		29G	13	RW	11°±2°
		30G	8、13	TW	11°±2°
		31G	6、8	TW	11°±2°
	U100	27G	13	RW	11°±2°
		28G	13	RW	11°±2°
		29G	13	RW	11°±2°
		30G	8、13	TW	11°±2°
		31G	6、8	TW	11°±2°

7. Identification of predicate device

510(k) Number: K191639
Product name: TK Insulin Syringe with/without Safety Retractable Device

8. 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 8537: 2016 Third edition, Sterile single-use syringes, with or without needle, for insulin.
- ISO 7864:2016 Fourth edition, Sterile hypodermic needles for single use-Requirements and test method.
- ISO 9626:2016 Second edition 2016-08-01 Stainless steel needle tubing for manufacture of medical device-Requirements and test method.
- ISO 23908:2011 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.
- Guidance for Industry and FDA Staff: Medical Devices with Sharps Injury Prevention Features
- ISO 10993-1:2018 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: Tests for in vitro cytotoxicity
- ISO 10993-7:2008 Biological evaluation of medical devices — Part 7: Ethylene oxide sterilization residuals
- ISO 10993-10: 2010 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
- ISO 10993-11:2017 Biological evaluation of medical devices — Part 11: Tests for systemic toxicity
- USP <788>: Particulate Matter for injection

9. Clinical test conclusion

No clinical study is included in this submission.

10. Substantially Equivalent(SE) comparison

Table 1-2 Comparison of Technology Characteristics

Items	Proposed device	Predicate device K191639	Comment
Produce name	Sterile safety insulin syringes for single use	TK Insulin Syringe with/without Safety Retractable Device	Same
Product code	MEG, FMF,FMI	MEG, FMF	Same
Regulation number	21 CFR 880.5860	21 CFR 880.5860	Same
Class	Class II	Class II	Same
Intended use	The Sterile Safety Insulin Syringes for Single Use are sterile, single-use, disposable,	The TK Insulin Syringe with Safety Retractable Device is a sterile, single-use,	Different. Please refer to

	non-reusable and manually retractable safety insulin syringes intended for injection of insulin into the body. The sliding sleeve helps protect against needle puncture once activated	disposable and non-reusable, manual retractable safety insulin syringe intended for injection of U-100 insulin into the body, while reducing the risk of sharps injuries and the potential for insulin syringe reuse. The TK Insulin Syringe is a sterile, single-use, disposable and non-reusable, insulin syringe intended for injection of U-100 insulin into the body.	Analysis 1.
Principle of Operation	Normal.	Normal.	Same
Syringe Capacity	1ml Needle 27Gx1/2” 1ml Needle 28Gx1/2” 1ml Needle 29Gx1/2” 1ml Needle 30Gx1/2” 1ml Needle 30Gx5/16” 1ml Needle 31Gx5/16” 1ml Needle 31Gx15/64” 0.5ml Needle 27Gx1/2” 0.5ml Needle 28Gx1/2” 0.5ml Needle 29Gx1/2” 0.5ml Needle 30Gx1/2” 0.5ml Needle 30Gx5/16” 0.5ml Needle 31Gx5/16” 0.5ml Needle 31Gx15/64”	TK Insulin Syringe: 0.3cc/ml Needle 27G ×1/” 0.3cc/ml Needle 28G ×1/2” 0.3cc/ml Needle 29G ×1/2” 0.3cc/ml Needle 30G ×1/2” 0.3cc/ml Needle 31G ×3/8” 0.5cc/ml Needle 27G ×1/2” 0.5cc/ml Needle 28G ×1/2” 0.5cc/ml Needle 29G ×1/2” 0.5cc/ml Needle 30G ×1/2” 0.5cc/ml Needle 31G ×3/8” 1cc/ml Needle 27G ×1/2” 1cc/ml Needle 28G ×1/2” 1cc/ml Needle 29G ×1/2” 1cc/ml Needle 30G ×1/2” 1cc/ml Needle 31G ×3/8” TK Insulin Syringe with Safety Retractable Device: 0.5cc/ml Needle 27G ×1/2” 0.5cc/ml Needle 28G ×1/2” 0.5cc/ml Needle 29G ×1/2” 0.5cc/ml Needle 30G ×1/2” 0.5cc/ml Needle 31G ×3/8” 1cc/ml Needle 27G ×1/2” 1cc/ml Needle 28G ×1/2” 1cc/ml Needle 29G ×1/2”	Different. Please refer to Analysis 2.

		1cc/ml Needle 30G ×1/2” 1cc/ml Needle 31G ×3/8”	
Nozzle Type	N.A	N.A	Same
Lubricant for Barrel	Silicone oil	Silicone oil	Same
Barrel Transparency	Transparency and clear	Transparency and clear	Same
Gradations Legibility	Legible	Legible	Same
Materials Barrel Plunger Piston Lubricant for Barrel Needle hub Needle tube Sliding sleeve	 PP PP Rubber DC 360 PP Stainless PP	 PP PP Rubber HC-SS36 PP Stainless PP	Different. Please refer to Analysis 3.
Needle gauge and needle length	Varies sizes	Various sizes	Same
Lubricant for needle	Silicone oil	Silicone	Same
Sterile safety insulin syringes for single use: sharps injury prevention features	Manual Retractable Conforms to ISO 23908.	Manual Retractable Conforms to ISO 23908.	Same
Performances	Conforms to ISO 8537, ISO 7864 and ISO 9626.	Conforms to ISO 8537 and ISO 7864.	Same
Biocompatibility	Complies with: ISO 10993-1: Evaluation and Testing; Part 4: Selection of tests for interactions with blood; Part 5: Tests for in vitro cytotoxicity; Part 7: Ethylene oxide sterilization residuals; Part 10: Tests for irritation and delayed-type hypersensitivity; Part 11: Tests for systemic toxicity, tests for Bacterial endotoxins, Tests for Pyrogenicity And Conforms to USP <788>: Particulate Matter for injection	Conforms to ISO10993 (Part1: Evaluation and testing, Part 4: Selection of tests for interactions with blood, Part 5: Tests for in vitro cytotoxicity, Part 7: Ethylene oxide sterilization residuals, Part 10: Tests for irritation and delayed-type hypersensitivity, Part 11: Tests for systemic toxicity, tests for Bacterial endotoxins, Tests for Pyrogenicity) Conforms to USP <788>: Particulate Matter for injection	Same
Labeling	Meet the requirements of 21 CFR Part 801	Meet the requirements of 21 CFR Part 801	Same

SE Analysis 1: Indication for use

The proposed device and the predicate device have the same indication, that is, for insulin injection. The proposed device has another syringe type for U-40 insulin injection. However, the differences between U-40 insulin syringes and U-100 insulin syringes do not raise any new questions of safety and effectiveness. The difference between U-40 insulin syringe and U-100 insulin syringe is the insulin concentration delivery. The U-40 insulin syringe has red protective cap for color marking in accordance with ISO 8537 to distinguish the insulin concentration. In addition, the tolerance on graduated capacity has been validated in accordance with ISO 8537 Annex H. Therefore, this difference does not affect the Substantially Equivalency (SE) between the proposed and predicate devices.

SE Analysis 2: Syringe Capacity

The Syringe Capacity of the proposed device is covered by the predicate device.

The difference is that the proposed device doesn't include a 0.3ml syringe. This difference does not to affect the Substantially Equivalency (SE) between the proposed and predicate devices.

SE Analysis 3: Materials

The material of the lubricant is different between the proposed device and predicate device. The biocompatibility test of proposed device has been conducted to demonstrate that the proposed device met the biocompatibility requirements. The difference does not raise new questions of safety and effectiveness.

11. Conclusion

The conclusion drawn from the nonclinical tests demonstrates that the subject device, Sterile Safety Insulin Syringes for Single Use are substantially equivalent to the legally marketed predicate device TK Insulin Syringe with/without Safety Retractable Device(K191639).