Zhejiang Kindly Medical Devices Co. Ltd
% Alice Huang
RA Manager
Shanghai Mind-link Business Consulting Co., Ltd.
Room 8208, Second Floor, No 1399, Jiangyue Road,
Minhang District
Shanghai, 201114
China

Re: K213183
Trade/Device Name: Safety Insulin Pen Needles
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: Class II
Product Code: FMI
Dated: September 14, 2022
Received: September 15, 2022

Dear Alice Huang:

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K213183

Device Name

Safety Insulin Pen Needles

Indications for Use *(Describe)*

Safety Insulin Pen Needle is intended to be used with Insulin Pen for hypodermic injection of insulin and medicinal fluids.

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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K213183 510(K) Summary

I. SUBMITTER:

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Summary prepared：10/14/2022

II. DEVICE

Name of Device: Safety Insulin Pen Needles
Regulation Number: 21 CFR 880.5570
Common Name: Hypodermic single lumen needle
Classification Panel: General Hospital
Regulatory Class: II
Product Code: FMI

III. PREDICATE DEVICE

Primary predicate device: K181447 Safety insulin needle for single use

IV. DEVICE DESCRIPTION

The proposed device, Safety Insulin Pen Needle is intended to be used with Insulin Pen for hypodermic injection of insulin and medicinal fluids. It consists of needle tube, needle hub, spring, needle hub sheath, safety protective sheath, positioning ring, outer protective cap and sealing paper. The needle hub is clear, and the positioning ring and sealing paper contains colorants for the different gauge sizes.

The Safety insulin needle for single use is offered in various gauge sized and length.

The proposed device is available in EO sterilized to achieve a Sterility Assurance Level (SAL) of 10^{-6}.

Table 1 Specification of Safety Insulin Pen Needle

Gauge（G）	Specifications Diameter x Length（mm）	Out Diameter（mm）	Inner Diameter（mm）	Point Type	Wall Type	Color of positioning ring
28G	0.36×4	0.349-0.370	≥0.190	LB	TW	Blue-green
28G	0.36×5	0.349-0.370	≥0.190	LB	TW	Blue-green
28G	0.36×6	0.349-0.370	≥0.190	LB	TW	Blue-green
28G	0.36×8	0.349-0.370	≥0.190	LB	TW	Blue-green
28G	0.36×12	0.349-0.370	≥0.190	LB	TW	Blue-green
29G	0.33×4	0.324-0.351	0.133-0.189	LB	RW	Red
29G	0.33×5	0.324-0.351	0.133-0.189	LB	RW	Red
29G	0.33×6	0.324-0.351	0.133-0.189	LB	RW	Red
29G	0.33×8	0.324-0.351	0.133-0.189	LB	RW	Red
29G	0.33×12	0.324-0.351	0.133-0.189	LB	RW	Red
30G	0.30×4	0.298-0.320	0.165-0.189	LB	TW	Yellow
30G	0.30×5	0.298-0.320	0.165-0.189	LB	TW	Yellow
30G	0.30×6	0.298-0.320	0.165-0.189	LB	TW	Yellow
30G	0.30×8	0.298-0.320	0.165-0.189	LB	TW	Yellow
31G	0.25×4	0.254-0.267	0.125-0.145	LB	TW	White
31G	0.25×5	0.254-0.267	0.125-0.145	LB	TW	White
31G	0.25×6	0.254-0.267	0.125-0.145	LB	TW	White
31G	0.25×8	0.254-0.267	0.125-0.145	LB	TW	White
32G	0.23×4	0.229-0.241	0.105-0.124	LB	TW	Deep green
32G	0.23×5	0.229-0.241	0.105-0.124	LB	TW	Deep green
32G	0.23×6	0.229-0.241	0.105-0.124	LB	TW	Deep green

33G	0.20×4	0.203-0.216	0.105-0.124	LB	TW	Black
33G	0.20×5	0.203-0.216	0.105-0.124	LB	TW	Black
33G	0.20×6	0.203-0.216	0.105-0.124	LB	TW	Black
34G	0.18×4	0.178-0.191	0.091-0.104	LB	TW	Orange
34G	0.18×5	0.178-0.191	0.091-0.104	LB	TW	Orange
34G	0.18×6	0.178-0.191	0.091-0.104	LB	TW	Orange

V. INDICATIONS FOR USE

Safety Insulin Pen Needle is intended to be used with Insulin Pen for hypodermic injection of insulin and medicinal fluids.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Safety Insulin Pen Needle is intended to be used with Insulin Pen for hypodermic injection of insulin and medicinal fluids. Additionally, the Safety Insulin Pen Needle is similar to the Safety Insulin Needle For Single Use (K181447) in regard to insertion, design, size ranges, and material.

Item	**Proposed Device** **Safety Insulin Pen Needle**	**Predicate Device** **Safety insulin needle for single use**	**Remark**
K number	K213183	K181447	
Classification	Class II	Class II	Same
Product Code	FMI	FMI	Same
Common name	Hypodermic single lumen needle	Hypodermic single lumen needle	Same
Intended use	Safety Insulin Pen Needle is intended to be used with Insulin Pen for hypodermic injection of insulin and medicinal fluids.	The Safety insulin needle for single use is intended for use with pen injector devices for the subcutaneous injection of insulin.	Similar Note 1
Indications for use	Safety Insulin Pen Needle is intended to be used with Insulin Pen for hypodermic injection of insulin and	The Safety insulin needle for single use is intended for use with pen injector devices for the	Similar Note 1

	medicinal fluids.		subcutaneous injection of insulin.		
Configuration	needle tube, needle hub, spring, needle hub sheath, safety protective sheath, positioning ring, outer protective cap and sealing paper		needle tube, hub, safety protective cover, self-destruction seat, spring, hub sheath, safety seat and sealed paper.		Different Note 2
Needle Gauge	28G, 29G, 30G, 31G, 32G, 33G, 34G		29G, 30G, 31G, 32G, 33G, 34G		Different Note 3
Needle Length	4mm, 5mm, 6mm, 8mm,12mm		4mm, 5mm, 6mm, 8mm		Different Note 3
Wall type	Regular walled Thin-walled		Thin-walled Extra-thin-walled		Different Note 4
Patient-contact Material	Needle tube	SUS 304	Needle tube	SUS 304	Different Note 5
	Needle hub	PP	Hub	PP	
	Safety protective sheath	ABS	Safety protective cap	MABS	
Design	Compared with traditional insulin pen needle, this product is designed with a safety feature that could help avoid accidental needle stick injury between patients and healthcare professionals.		Compared with traditional insulin pen needle, this product is designed with a safety feature that could help avoid accidental needle stick injury between patients and healthcare professionals.		Same
Single Use	Single use		Single use		Same
Performance testing	Comply with ISO 7864, ISO 9626 and ISO 11608-2		Comply with ISO 7864, ISO 9626 and ISO 11608-2		Same
Biocompatibility	Biocompatible		Biocompatible		Same
Sterility Condition	10^{-6}		10^{-6}		Same

Discussion in details:

Note 1: Intended Use and **Indications for use**

Safety insulin pen needle and safety insulin needle for single use have similar intended use and indications for use, which are intended to be used with Insulin Pen for hypodermic injection of insulin and medicinal fluids. This device is EO sterilized and intended for single use.

Note 2: Configuration

The components name of proposed device are different to that of the predicate, however, the components share the same configuration and function. Therefore, this difference in name will not affect the Substantial Equivalence (SE) between the proposed and predicate device.

Note 3: Needle gauge and Needle length

The needle gauge and needle length of proposed device is more than that of predicate devices. This difference in needle size will not affect the performance of the needle. In addition, all the needle size of proposed device has been tested. The test results comply with ISO 7864 and ISO 9626 standards requirements. Therefore, this difference will not affect the Substantially Equivalency (SE) between the proposed and predicate device.

Note 4: Wall type

The wall thickness of the proposed device is different than the predicate device. The needles including both wall thickness (i.e., Regular walled and Thin-walled) of proposed device have been tested and the test results comply with ISO 7864 and ISO 9626 standards requirements. Therefore, this difference will not affect the Substantial Equivalence (SE) between the proposed and predicate device.

Note 5: Patient-contact Material

Although the material of proposed and the predicate device is different, the patient-contact material of the proposed device material conforms to the ISO 10993 series of standards. Therefore, this difference will not affect the Substantial Equivalence (SE) between the proposed and predicate device.

VII. PERFORMANCE DATA

Non-Clinical Performance Data

To verify that the Safety Insulin Pen Needle is as safe and effective as the predicate device, representative samples of Safety Insulin Pen Needle were underwent a series of tests including bench testing (needle performance testing), and biocompatibility testing (cytotoxicity, sensitization, irritation, systemic toxicity, pyrogen, subchronic toxicity and Particulate Matter).

The test results demonstrated that the proposed device complies with the following standards:

- ISO 7864:2016, Sterile hypodermic needles for single use.

- ISO 9626:2016, Stainless steel needle tubing for the manufacture of medical devices.
- ISO 11608-2 Second edition 2012-04-01, Needle-based injection systems for medical use - Requirements and test methods - Part 2: Needles
- ISO 10993-5: 2009(R), Biological evaluation of medical devices -- Part 5: Tests for In Vitro cytotoxicity.
- ISO 10993-10:2010, Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
- ISO 10993-7:2008 Biological Evaluation of Medical Devices-Part 7: Ethylene Oxide Sterilization Residuals.
- ASTM F88/F88M-15 Standard Test Method for Seal Strength of Flexible Barrier Materials.
- ASTM F1140/F1140M-13 Standard Test Methods for Internal Pressurization Failure Resistance of Unrestrained Packages
- USP <85> Bacterial Endotoxins Test
- ISO 10993-11:2017 Biological evaluation of medical devices — Part 11: Tests for systemic toxicity
- USP <788> Particulate Matter Test

Clinical Performance Data

No data from human clinical studies have been included to support the substantial equivalence of the proposed device, Safety Insulin Pen Needle, as clinical studies are not required for this medical device.

VIII. CONCLUSION

The same intended use, the similarity in overall technological characteristics, and performance data result in that Safety Insulin Pen Needle are substantially equivalent to legally marketed device, Safety insulin needle for single use.