December 16, 2022

Zhejiang kindly Medical Devices Co., Ltd.
℅ Amy Li
Technical Director
Shanghai Mind-Link Business Consulting Co., Ltd.
Room A04, 14th Floor, No 699, Jiaozhou Road, Jingan District
Shanghai, 200040
China

Re: K223334
Trade/Device Name: Sterile Hypodermic Needles for Single Use
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: Class II
Product Code: FMI
Dated: September 15, 2022
Received: November 1, 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,

Alan M. Stevens -S3

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)*
K223334

Device Name
Sterile Hypodermic Needles for Single Use.

Indications for Use *(Describe)*
The Sterile Hypodermic Needles for Single Use are intended for use with syringes and injection devices for general purpose fluid injection/aspiration.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

K22334 510k Summary

1. Date of preparation: December 16, 2022

2. Sponsor Identification

Name: Zhejiang Kindly Medical Device Co., Ltd.

Add.: No 758, 5th Binhai Road, Binhai Industrial Park, Longwan, Wenzhou City, Zhejiang Province.

Contact Person: Zhang Qian

Position: Technical Manager

Tel: +86 13858871856

Email: zhangqian@kdlchina.com

3. Designated submission correspondent

Ms. Amy Lee (Primary Contact Person)

Mind-Link Consulting Co., Ltd.

Tel: +86 15721449974

Email: amy.li@mind-link.net

4. Identification of Proposed Device

Trade Name: Sterile Hypodermic Needles For Single Use

Regulation Number: 21 CFR 880.5570

Regulation Name: Hypodermic Single Lumen Needle

Regulatory Class: Class II

Product Code: FMI

Review Panel: General hospital

5. Indication for use statement

The Sterile Hypodermic Needle for Single Use are intended for use with syringes and injection devices for general purpose fluid injection/aspiration.

6. Device description

The proposed device, Sterile Hypodermic Needles For Single Use, consists of a needle tube, needle hub and protective cap. The needle tube is made from stainless steel (SUS 304), the needle hub made of Polypropylene material (abb. PP) and the color complies with ISO 6009.The protective cap is made of PP and does not contact the patient.

The conical fitting of Sterile Hypodermic Needles For Single Use is a luer that can be used with other medical devices which have 6% conical fitting. It is provided sterile with EO sterilization, and the sterilization assurance level (SAL) is 10^{-6}.

Additionally, each component is made from properly tested raw materials. And the Sterile Hypodermic Needles For Single Use are individually packaged in a sterile barrier.

6.1 The proposed device includes different specifications.

Models of Sterile Hypodermic Needles For Single Use shown in Table 5-1 are available in various models according to different needle gauge.

Table 5-1 Models of Sterile Hypodermic Needles For Single Use

Nozzle type	Needle gauge (G)	Needle length (mm)	Wall type	Bevel		Color
				Long Bevel	Short Bevel	
Luer lock	31	20,13, 8, 6, 5, 4	RW	11°±2°	17°±2°	White
			TW	11°±2°	17°±2°	
Luer lock	32	20,13, 8, 6, 5, 4	TW	11°±2°	17°±2°	Deep green
Luer lock	33	13, 8, 6, 5, 4	RW	11°±2°	17°±2°	Black
			TW	11°±2°	17°±2°	
Luer lock	34	13, 8, 6, 5, 4	RW	11°±2°	17°±2°	Orange
			TW	11°±2°	17°±2°	

6.2 Label requirement

The label shall meet the requirements of 21 CFR Part 801.

7. Comparison of technological characteristics with the predicate devices

The Sterile Hypodermic Needles for Single Use have the same intended use, technology, and design; and performance specifications are either identical or substantially equivalent to existing legally marketed predicate devices. The differences between the Sterile Hypodermic Needles for Single Use and predicate devices do not alter suitability of the proposed device for its intended use.

Table 5-2 Comparison of Technology Characteristics

Component	Proposed device	Predicate device K211214	Comment
Indication for use	The Sterile Hypodermic Needles for single use are intended for use with syringes and injection devices for general purpose fluid injection/aspiration.	The Sterile Hypodermic Needles for Single Use are intended to be used with a luer lock or luer slip syringe and injection devices for general purpose fluid injection/aspiration.	Same
Product code	FMI	FMI	Same
Regulation number	21 CFR 880.5570	21 CFR 880.5570	Same
Class	II	II	Same
Principle of operation	For manual use only	For manual use only	Same
Intended user	Medical professionals and trained care givers	Medical professionals and trained care givers	Same
Environment of use	Hospitals and clinics	Hospital and clinics	Same
Needle gauge	31G, 32G, 33G, 34G	30G, 27G, 26G, 25G, 24G, 23G, 22G, 21G, 20G, 19G, 18G	Different. *Analysis 1.*
Length	20mm, 13mm, 8mm, 6mm,	1/2" 、5/8"、1"、1 1/4"、1	Differe

	5mm, 4mm		1/2"		nt. *Analysis 2.*
Type of wall	Normal wall or thin wall.		Normal wall or thin wall.		Same
Blade angle	Short bevel and long bevel.		Short bevel and long bevel.		Same
Main structure and materials	Needle hub	Polypropylene	Needle hub	Polypropylene	Same
	Needle tube	Stainless steel	Needle tube	Stainless steel	Same
	Protective cap	Polypropylene	Protective cap	Polypropylene	Same
Needle hub color	Color-coded per ISO 6009.		Color-coded per ISO 6009.		Same
Single use	Yes		Yes		Same
Performance specifications	Comply with: ISO 7864 Sterile hypodermic needles for single use - Requirements and test methods; ISO 9626:2016 Stainless steel needle tubing for the manufacture of medical devices -Requirements and test methods; ISO 80369-7:2021 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		Complies with ISO 7864:2016 Sterile hypodermic needles for single use - Requirements and test methods, ISO 9626:2016 Stainless steel needle tubing for the manufacture of medical devices -Requirements and test methods, ISO 80369-7:2021 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		Same
Sterilization	EO		EO		Same

SAL	10^{-6}	10^{-6}	Same
Pyrogen	Non-pyrogenic	Non-pyrogenic	Same
Biocompatibility	The biocompatibility evaluation for the subject device was conducted in accordance with the International Standard ISO 10993-1 "Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process," as recognized by FDA and the "Use of International Standard ISO 10993-1 "Biological evaluation of medical devices- Part 1: Evaluation and testing within a risk management process", June 16, 2016. The Sterile Hypodermic Needle for Single Use of testing included following: Cytotoxicity; Skin sensitization; Hemolysis; Intracutaneous reactivity; Acute systemic toxicity; Pyrogenicity. The evaluation of the above testing items meets the requirements And Conforms to USP <788>: Particulate Matter for injection	The biocompatibility evaluation for the subject device was conducted in accordance with the International Standard ISO 10993-1 "Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process," as recognized by FDA and the "Use of International Standard ISO 10993-1 "Biological evaluation of medical devices- Part 1: Evaluation and testing within a risk management process", June 16, 2016. The syringe of testing included the following tests: Cytotoxicity; Skin sensitization; Hemolysis; Intracutaneous reactivity; Acute systemic toxicity; Pyrogenicity. The evaluation of the above testing items meets the requirements	Different. analysis 3.
Labeling	Meets the requirements of 21 CFR Part 801.	Meets the requirements of 21 CFR Part 801.	Same

SE Analysis 1: Needle gauge

The subject device has additional needle gauge sizes (31G, 32G, 33G, 34G) compared with predicate device. This difference does not raise new or different questions of safety or effectiveness.

SE Analysis 2: Needle length

The subject device has different needle lengths as compared to the predicate device. This difference does not raise new or different questions of safety or effectiveness.

SE Analysis 3: Biocompatibility

The proposed device and the predicate device were both tested per the ISO 10993-series. The proposed device also tested particulates per USP <788>. Particulate testing per USP <788> is required to ensure the safe clinical application. Therefore, this difference is not considered to affect the Substantially Equivalency (SE) between the proposed and predicate devices.

8. Non-clinical Performance Testing

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 7864:2016 Sterile hypodermic needles for single use — Requirements and test methods
- ISO 9626:2016 Hypodermic needles for single use - Colour coding for identification
- ISO 80369-7:2021 Small-bore connectors for liquids and gases in healthcare application -- Part 7: Connectors for intravascular or hypodermic application
- ISO 80369-20:2015 Small-bore connectors for liquids and gases in healthcare applications - Part 20: Common test methods
- 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
- 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

9. Clinical Testing

No clinical study is included in this submission.

10. Conclusion

The differences between the predicate and the subject device do not raise any new or different questions of safety or effectiveness. The Sterile Hypodermic Needles for Single Use is substantially equivalent to the Sterile Hypodermic Needles for Single Use (K211214) with respect to the indications for use, materials, design, and technological characteristics.