Zhejiang Kindly Medical Device Co., Ltd.
℅ Amy Li
Technical Director
Shanghai Mind-link Business Consulting Co., Ltd.
Room A08, Floor 14th, No 699, Jiaozhou Road, Jingan District
Shanghai, Jingan 201803
China

Re: K233037
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 19, 2023
Received: September 25, 2023

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Juliane C. Lessard -S

Juliane C. Lessard, Ph.D.
Director
DHT3C: Division of Drug Delivery and
General Hospital Devices,
and Human Factors
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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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K233037

Device Name
Sterile Hypodermic Needles For Single Use

Indications for Use *(Describe)*
Sterile Hypodermic Needle 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.

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K233037 510k Summary

1. Date of preparation: December 1, 2023

2. Sponsor Identification

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3. Designated submission correspondent

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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. Predicate devices

(1) 510(K) number: K180417

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

(2) 510(K) number: K223334

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

6. Indication for use statement

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

7. Device description

The proposed device, Sterile Hypodermic Needles For Single Use consists of needle tube, needle hub and hard pack(Butt-end lower protective cap and Upper needle protective cap) or protective cap for needle. The needle tube is made from stainless steel (SUS 304), the needle hub made of Polypropylene material (abb. PP) and the colour complies with ISO 6009.

Sterile Hypodermic Needles for Single Use have two kinds of sterile barrier type, paper-film package type and hard-pack package. Besides the sterile barrier, the materials of middle package and outer package are same. Middle package is made of 350g ivory board and the outer package is made from double-corrugated paper.

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

Additionally, each component is made from properly tested raw materials.

6.1 The proposed device includes different specifications.

Models of Sterile Hypodermic Needles For Single Use shown in Table 19-1 are available in various models according to different needle gauge and different needle length.

Table 19-1 Models of Sterile Hypodermic Needles For Single Use

Nozzle type	Needle Gauge (G)	Wall type	Designated metric size (mm)	ID min (mm)	Needle length (mm)	Bevel		Color of needle hub
						Long Bevel	Short Bevel	
Luer lock	14	RW	2.10	1.500	25, 32, 38, 50	11°±2°	17°±2°	Pale Green
		TW		1.600		11°±2°	17°±2°	
Luer lock	15	RW	1.80	1.300	25, 32, 38, 50	11°±2°	17°±2°	Blue-grey
		TW		1.460		11°±2°	17°±2°	
Luer lock	16	RW	1.60	1.100	25, 32, 38, 50	11°±2°	17°±2°	White
		TW		1.283		11°±2°	17°±2°	
Luer lock	17	RW	1.40	0.950	25, 32, 38, 50	11°±2°	17°±2°	Red-violet
		TW		1.156		11°±2°	17°±2°	
Luer lock	18	RW	1.20	0.790	13, 25, 32, 38, 50	11°±2°	17°±2°	Pink
		TW		0.910		11°±2°	17°±2°	
Luer lock	19	RW	1.10	0.648	25, 32, 38, 50	11°±2°	17°±2°	Cream
		TW		0.750		11°±2°	17°±2°	

Luer lock	20	RW	0.90	0.560	25, 32, 38, 50	11°±2°	/	Yellow
		TW		0.635		11°±2°	/	
Luer lock	21	RW	0.80	0.490	25, 32, 38, 50	11°±2°	/	Deep Green
		TW		0.547		11°±2°	/	
Luer lock	22	RW	0.70	0.390	25, 32, 38, 50	11°±2°	/	Black
		TW		0.440		11°±2°	/	
Luer lock	23	RW	0.60	0.317	8, 25, 38	11°±2°	/	Deep Blue
		TW		0.370		11°±2°	/	
Luer lock	24	RW	0.50	0.280	20, 25	11°±2°	/	Med Purple
Luer lock	25	RW	0.55	0.232	16, 25, 38	11°±2°	/	Orange
		TW		0.292		11°±2°	/	
Luer lock	26	RW	0.50	0.232	9, 13, 16	/	17°±2°	Brown
		TW		0.292		11°±2°	/	
Luer lock	27	RW	0.45	0.184	6, 8, 9, 12, 13, 15, 20	/	17°±2°	Medium gery
		TW		0.241		11°±2°	/	

Luer lock	28	RW	0.40	0.133	6, 8, 12, 15	/	17°±2°	Blue-green
		TW		0.190		11°±2°	/	
Luer lock	29	RW	0.36	0.133	6, 8, 12, 15	11°±2°	17°±2°	Red
		TW		0.190		11°±2°	17°±2°	
Luer lock	30	RW	0.30	0.133	6, 8, 9, 12, 13, 15	11°±2°	17°±2°	Yellow
		TW		0.165		11°±2°	17°±2°	
Luer lock	31	RW	0.25	0.114	20,13, 8, 6, 5, 4	11°±2°	17°±2°	White
		TW		0.125		11°±2°	17°±2°	
Luer lock	32	TW	0.23	0.105	20,13, 8, 6, 5, 4	11°±2°	17°±2°	Deep green
Luer lock	33	RW	0.20	0.089	13, 8, 6, 5, 4	11°±2°	17°±2°	Black
		TW		0.105		11°±2°	17°±2°	
Luer lock	34	RW	0.18	0.064	13, 8, 6, 5, 4	11°±2°	17°±2°	Orange
		TW		0.091		11°±2°	17°±2°	

8. 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 19-2 Comparison of Technology Characteristics

Component	Proposed device		Predicate device K180417		Predicate device K223334		Comment
Indication for use	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.		The Sterile Hypodermic Needles for single use are intended for use with syringes and injection devices for general purpose fluid injection/aspiration.		Same
Product code	FMI		FMI		FMI		Same
Regulation number	21 CFR 880.5570		21 CFR 880.5570		21 CFR 880.5570		Same
Class	II		II		II		Same
Principle of operation	For manual use only		For manual use only		For manual use only		Same
Intended user	Medical professionals and trained care givers		Medical professionals and trained care givers		Medical professionals and trained care givers		Same
Environment of use	Hospitals and clinics		Hospital and clinics		Hospital and clinics		Same
Needle gauge	14G, 15G, 16G, 17G, 18G, 19G, 20G, 21G, 22G, 23G, 24G, 25G, 26G, 27G, 28G, 29G, 30G, 31G, 32G, 33G, 34G		14G, 15G, 16G, 17G, 18G, 19G, 20G, 21G, 22G, 23G, 24G, 25G, 26G, 27G, 28G, 29G, 30G		31G, 32G, 33G, 34G		Different. Analysis 1.
Length	4-50mm.		/		4mm, 5mm, 6mm, 8mm, 13mm, 20mm,		Different. Analysis 2.
Type of wall	Normal wall or thin wall.		Normal wall or thin wall.		Normal wall or thin wall.		Same
Blade angle	Short bevel and long bevel.		Short bevel and long bevel.		Short bevel and long bevel.		Same
Main structure and materials	Needle hub	Polypropylene	Needle hub	Polypropylene	Needle hub	Polypropylene	Same
	Needle tube	Stainless steel	Needle tube	Stainless steel	Needle tube	Stainless steel	Same
	Protective cap Hard pack (Butt-end	Polypropylene	Protective cap	Polypropylene	Protective cap	Polypropylene	Different. Analysis 3.

	lower protective cap, upper needle protective cap)						
Needle hub color	Color-coded per ISO 6009.		Color-coded per ISO 6009.		Color-coded per ISO 6009.		Same
Single use	Yes		Yes		Yes		Yes
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		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		Same
Sterilization	EO		EO		EO		Same
SAL	10^{-6}		10^{-6}		10^{-6}		Same
Pyrogen	Non-pyrogenic		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		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		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		Different. Analysis 4.

	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	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	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	
Labeling	Meets the requirements of 21 CFR Part 801.	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(31-34) compared with predicate device(K180417), so add the secondary predicate(223334) to cover the smaller 31G-34G sizes. However, the all needle gauge(14G-34G) has been registered in FDA. And the proposed needles were tested in accordance with ISO 7864 and ISO 9626 and all test results meet the acceptance criteria per the standards. Therefore, 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 compared with two predicate devices, but the needles were tested in accordance with ISO 7864 and ISO 9626 including the needle length, outer diameter and inner diameter, and all test results meet the acceptance criteria per the standards. Therefore, this difference does not raise new or different questions of safety or effectiveness.

SE Analysis 3: Main Structure

The proposed device and predicate device were both have protective cap to prevent needle sharpness, but the proposed device have another cap which is butt-end lower protective and assembled with upper needle protective cap sealing with a sticker as the sterile barrier to keep product sterility. Howeve, the main structure still same as predicate device. Therefore, this different is not considered to affect the Substantially Equivalency (SE) between the proposed and predicate devices.

SE Analysis 4: Biocompatibility

The proposed device and the two predicate devices all were 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.

9. 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

10. Clinical Testing

No clinical study is included in this submission.

11. 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 (K180417, K223334) with respect to the indications for use, materials, design, and technological characteristics.