Jiangsu Zhiyu Medical Instrument Co, Ltd.
Ellen Guan
Official Correspondent
No 88, Nanyuan Road, Industrial Park
Taixing, Jiangsu 225400
China

Re: K212857
Trade/Device Name: Sterile Syringe for Single Use (with Needle), Sterile Hypodermic Needle for Single Use
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: Class II
Product Code: FMF, FMI
Dated: April 12, 2023
Received: April 12, 2023

Dear Ellen Guan:

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,

Courtney Evans -S

Digitally signed by Courtney Evans -S
Date: 2023.05.09 14:10:13 -04'00'

For 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)*
K212857

Device Name
Sterile Syringe for Single Use (with Needle)
Sterile Hypodermic Needle for Single Use

Indications for Use *(Describe)*
The Sterile Syringe for Single Use (with Needle) is intended to be used for medical purposes to inject fluid into or withdraw fluid from body.
The Sterile Hypodermic Needle for Single Use is 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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K212857
510(K) Summary

[As required by section 807.92(c)]

I. SUBMITTER (OWNER)

Name: Jiangsu Zhiyu Medical Instrument Co., Ltd.

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Phone: +86-0523-82565715, +86-0523-82565758

Contact person: Ellen Guan

Contact email: gxyellen1004@aliyun.com

Date of preparation: May 4, 2023

II. DEVICE IDENTIFICATION

2.1 Trade name: Sterile Syringe for Single Use (with Needle)

Common name: Hypodermic Syringe

Classification name: Piston Syringe

Classification regulation: 21 CFR 880.5860

Product code: FMF

Classification: II

2.2 Trade name: Sterile Hypodermic Needle for Single Use

Common name: Hypodermic Needle

Classification name: Hypodermic Single Lumen Needle

Classification regulation: 21 CFR 880.5570

Product code: FMI

Classification: II

III. PREDICATE DEVICE IDENTIFICATION

3.1 510(k) number: K201284

3.2 Trade name: Sterile Hypodermic Syringe for Single use, with/without needle; luer/luer-lock

Sterile Hypodermic needle for Single use

3.3 Common name: Hypodermic Syringe

Hypodermic Needle

3.4 Classification regulation: 21 CFR 880.5860, 21 CRF 880.5570

3.5 Product code: FMF, FMI

3.6 Classification: II

IV. DEVICE DESCRIPTION

4.1 Overview

The Sterile Hypodermic Syringe is a sterile, single-use, polypropylene syringe that consists of the barrel, plunger, and stopper and is assembled with a hypodermic needle.

The Sterile Hypodermic Needle is a single lumen needle made of austenitic steel, consisting of a protective cap, a needle seat and a needle tube connection.

4.2 Models

Syringe: 1mL, 2mL, 5mL, 10mL, 20mL, 50mL

Needle Gauge	Outer Diameter of Stylet		
	Normal wall	Thin wall	Ultra-thin wall
30G x 1/2”	X	X	—
29G x 1/2"	X	X	—
28G x 1/2”	X	X	—
27G x 1/2”	X	X	—
27G x 5/8”	X	X	—
26G x 1/2"	X	X	—
26G x 5/8”	X	X	—
25G x 5/8”	X	X	—
25G x 3/4”	X	X	—

25G x 1”	X	X	—
24G x 3/4”	X	X	—
24G x 1”	X	X	—
23G x 1”	X	X	X
23G x 5/4”	X	X	X
23G x 3/2”	X	X	X
22G x 1”	X	X	X
22G x 5/4”	X	X	X
22G x 3/2”	X	X	X
21G x 5/4”	X	X	X
21G x 3/2”	X	X	X
20G x 5/4”	X	X	X
20G x 3/2”	X	X	X
19G x 5/4”	X	X	X
19G x 3/2”	X	X	X
18G x 5/4”	X	X	X
18G x 3/2”	X	X	X

1ml, 2ml and 5ml syringe can use the needles:

30G x 1/2”, 29G x 1/2", 28G x 1/2”, 27G x 1/2”, 27G x 5/8”, 26G x 1/2", 26G x 5/8”, 25G x 5/8”, 25G x 3/4”, 25G x 1”, 24G x 3/4”, 24G x 1”, 23G x 1”, 23G x 5/4”, 23G x 3/2”, 22G x 1”, 22G x 5/4”, 22G x 3/2”, 21G x 5/4”, 21G x 3/2”;

10ml syringe can use the needles:

25G x 5/8”, 25G x 3/4”, 25G x 1”, 24G x 3/4”, 24G x 1”, 23G x 1”, 23G x 5/4”, 23G x 3/2”, 22G x 1”, 22G x 5/4”, 22G x 3/2”, 21G x 5/4”, 21G x 3/2”, 20G x 5/4”, 20G x 3/2”, 19G x 5/4”, 19G x 3/2”, 18G x 5/4”, 18G x 3/2”;

20ml and 50ml syringe can use the needles:

21G x 5/4”, 21G x 3/2”, 20G x 5/4”, 20G x 3/2”, 19G x 5/4”, 19G x 3/2”, 18G x 5/4”, 18G x 3/2”.

4.3 Device Characteristics

The device is EO sterilized and for single use only.

4.4 Environment of Use

General hospital

4.5 Operation Principle

The plunger of syringe can be pulled and pushed along inside the barrel, allowing the syringe to take in and expel the fluids through the connector to the patient. For Manual Use Only.

4.6 Materials of Use

Medical polypropylene, Natural rubber or Synthetic rubber, austenitic stainless steel（SUS304）

Contact type: Tissue/bone/dentin

Duration: Limited exposure (less than 24h)

V. INDICATIONS FOR USE

The Sterile Syringe for Single Use (with Needle) is intended to be used for medical purposes to inject fluid into or withdraw fluid from body.

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

VI. COMPARISON WITH THE PREDICATE DEVICE

5.1 Technical Characteristics

Table 1: Hypodermic Syringe

Item	proposed device	Predicate Device	Comparison
Product name	Sterile Syringe for Single Use (with Needle)	Sterile Hypodermic Syringe for Single use, with/without needle; luer/luer-lock	/
Product code	FMF	FMF	similar
Regulation No.	21 CFR 880.5860	21 CFR 880.5860	similar
Class	II	II	similar
Indication for use	The Sterile Hypodermic Syringe for Single Use with/without needle is intended to be used for medical purposes to inject	The Sterile Hypodermic Syringe for Single Use with/without needle is intended to be used for medical purposes to inject fluid into or	similar

	fluid into or withdraw fluid from body.	withdraw fluid from body.	
Configuration	Piston Plunger Barrel	Piston Plunger Barrel	similar
Volume	1mL, 2mL, 5mL, 10mL, 20mL, 50mL	1ml, 3ml, 5ml, 6ml, 10ml, 20ml, 30ml, 35ml, 50ml, 60 ml	Difference 1
Needle size	18G, 19G, 20G, 21G, 22G, 23G, 24G, 25G, 26G, 27G, 28G, 29G, 30G	18G, 19G, 20G, 21G, 22G, 23G, 24G, 25G, 26G, 27G, 28G, 29G, 30G	similar
Needle length	13mm-38mm	4–38 mm	Difference 2
Intended user	Medical professionals and trained care givers	Medical professionals and trained care givers	similar
Environment of use	Hospital	Hospital	similar
Single use	Yes	Yes	similar
Operation mode	For Manual Use Only. The plunger of syringe can be pulled and pushed along inside the barrel, allowing the syringe to take in and expel the fluids through the connector to the	For Manual Use Only. The plunger of syringe can be pulled and pushed along inside the barrel, allowing the syringe to take in and expel the fluids through the connector to the patient.	similar

	patient.		
Label/labeling	Complied with 21 CFR part 801	Complied with 21 CFR part 801	similar
Performance	Complied with ISO 7886-1 ISO 7864 ISO 9626	Complied with ISO 7886-1 ISO 7864 ISO 9626	similar
Biocompatibility	Complied with ISO 10993-4/5/10/11	Complied with ISO 10993-4/5/10/11	similar
Patient contact component and material			
Piston	Isoprene Rubber	Isoprene Rubber	similar
Barrel	PP	PP	similar
Plunger	PP	PP	similar
Needle	PP, SUS304	PP, SUS304	similar
Sterilization			
Sterility condition	EO sterilized	EO sterilized	similar
SAL	10^{-6}	10^{-6}	similar
Endotoxin Limit	20 EU per device	20 EU per device	similar

Table 2: Hypodermic Needle

Item	proposed device	Predicate Device	Comparison
Product Name	Sterile Hypodermic Needle for Single Use	Sterile Hypodermic needle for Single use	similar
Product code	FMI	FMI	similar
Regulation No.	21 CFR 880.5570	21 CFR 880.5570	similar
Class	II	II	similar
Indication for use	The Sterile Hypodermic Needle for Single Use is intended for use with	The Sterile Hypodermic Needle for single use is intended for use with	similar

	syringes and injection devices for general purpose fluid injection/aspiration.	syringes and injection devices for general purpose fluid injection/aspiration.	
Configuration	Protective cap Needle Adhesives Needle hub	Protective cap Needle Adhesives Needle hub	similar
Intended user	Medical professionals and trained care givers	Medical professionals and trained care givers	similar
Environment of use	Hospital	Hospital	similar
Single use	Yes	Yes	similar
Operation mode	For Manual Use Only For Single Use only	For Manual Use Only For Single Use only	similar
Label/labeling	Complied with 21 CFR part 801	Complied with 21 CFR part 801	similar
Performance	Complied with: ISO 7864 ISO 9626	Complied with: ISO 7864 ISO 9626	similar
Biocompatibility	Complied with ISO 10993-4/5/10/11	Complied with ISO 10993-4/5/10/11	similar
Needle size	18G, 19G, 20G, 21G, 22G, 23G, 24G, 25G, 26G, 27G, 28G, 29G, 30G	18G, 19G, 20G, 21G, 22G, 23G, 24G, 25G, 26G, 27G, 28G, 29G, 30G	similar
Needle length	13mm-38mm	4mm-38mm	Difference 1
Patient contact component and material			
Protective cap	PP	PP	similar
Adhesive	Epoxy resin	Epoxy resin	similar

Needle Hub	PP	PP	similar
Needle	SUS304	SUS304	similar
Sterilization			
Sterility condition	EO sterilized	EO sterilized	similar
SAL	10^{-6}	10^{-6}	similar
Endotoxin Limit	20 EU per device	20 EU per device	similar

Substantial Equivalence Discussion

- Hypodermic Syringe discussion: There are 2 differences between the proposed device and the predicated device related to the volume and needle length.

Difference 1: The proposed device includes 2ml volume syringes which the predicate device doesn't have. But this difference have no adverse effect on clinical safety and performance as the size is within the range of 1mL to 10mL syringes cleared under the predicate. Additionally, the proposed device has been tested according to the standard ISO 7886-1. The requirements of the standard are met.

Difference 2: The needle lengths of the proposed device range from 13mm to 38mm, which is covered by the predicated device's (4mm - 38mm). The needles meet the requirements of the ISO 9626 and ISO 7864 standards.

- Hypodermic Needle discussion: There is one difference between the proposed device and the predicated device related to the needle length. The needle lengths of the proposed device range from 13mm to 38mm, which is covered by the predicated device's (4mm - 38mm). The needle meets the requirements of ISO 9626 and ISO 7864 standards.

5.2 Performance Testing

The Hypodermic Syringe and Hypodermic Needle described in this summary were tested and demonstrated to be in conformance with the following FDA recognized standards:

- ISO 9626:2016: Stainless steel needle tubing for the manufacture of medical devices - Requirements and test methods

- ISO 7886-1:2017 Sterile hypodermic syringes for single use - Part 1: Syringes for manual use
- ISO 7864:2016 Fourth Edition: Sterile hypodermic needles for single use — Requirements and test methods
- 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 10993-10:2010 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 in Injections
- ISO 10993-7:2008 Biological evaluation of medical devices — Part 7: Ethylene oxide sterilization residuals
- ISO 10993-12:2012 Biological evaluation of medical devices — Part 12: Sample preparation and reference materials
- ISO 11135:2014 Sterilization of health-care products — Ethylene oxide — Requirements for the development, validation and routine control of a sterilization process for medical devices
- ISO 11607-2:2019 Packaging for terminally sterilized medical devices — Part 2: Validation

The device is considered in the category of "External Communicating Devices" and are accepted to be in contact for a period less than 24 hours with "Tissue/Bone". Thus, cytotoxicity (ISO 10993-5:2009), irritation and sensitization (ISO 10993-10:2010), acute systemic toxicity (ISO 10993-11:2017), hemocompatibility (ISO 10993-4:2017) , pyrogen test (USP 43-NF38 <151>) and microscopic particle count test (USP 43-NF38 <788>) were carried out for the device in question.

5.3 Clinical Test

No clinical study is included in this submission.

VIII. CONCLUSIONS

The intended use, technological characteristics and method of operation are similar in the subject device and predicate device. Through performance testing, the subject device has demonstrated substantial equivalence to the predicate device.