August 30, 2022

Jiangsu Jichun Medical Devices Co., Ltd.
℅ Charles Mack
Principal Engineer
Irc
2950 E Lindrick Drive
Chandler, Arizona 85249

Re: K212846
Trade/Device Name: Sterile Hypodermic Syringe for Single Use, with/without 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: July 27, 2022
Received: August 2, 2022

Dear Charles Mack:

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)*

K212846

Device Name
Sterile Hypodermic Syringe for Single Use, with/without needle
Sterile Hypodermic Needle for Single use

Indications for Use *(Describe)*

Sterile Hypodermic Syringe for Single Use, with/without needle:
The sterile hypodermic syringe for single use, with/without needle is intended for use in the aspiration and injection of fluids for medical purposes.

Sterile Hypodermic Needle for Single use:
The sterile hypodermic needle for single use is intended for use with syringes in the aspiration and injection of fluids for medical purposes.

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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Jichun JJMD Medical Devices

510(k) Summary (21 CFR §807.92)

Date of Preparation: July 29, 2022

I. Submitter Information:

Submitter Name: Jiangsu Jichun Medical Devices Co., Ltd.

Address: NO.98, Baiyang Bridge, Zhenglu Town, Tianning, Changzhou, Jiangsu, China 213111

Contact Person: Zhu Pingnan/Head of Firm

US Agent and Correspondent

Mr. Charles Mack

Principal Engineer

IRC

2950 E Lindrick Drive, Chandler, Arizona 85249 USA

Tel: 931-625-4938

Email: charliemack@irc-us.com

II. Device

Trade Name: Sterile Hypodermic Syringe for Single Use, with/without needle

Common Name: syringe, piston

Regulation Number: 21 CFR §880.5860

Regulation Name: Piston syringe

Regulatory Class: II

Product Code: FMF

Classification Panel: General Hospital

Trade Name: Sterile Hypodermic Needle for Single Use

Common Name: needle, hypodermic, single lumen

Regulation Number: 21 CFR §880.5570

Regulation Name: Hypodermic single lumen needle

Regulatory Class: II

Product Code: FMI

Classification Panel: General Hospital

III. Predicate Device Information

Manufacturer	Predicate Device	510(k) Number	Submitted Device
Shanghai Kohope Medical Devices Co., Ltd	Sterile Hypodermic Syringe for Single use, with/without needle Sterile Hypodermic needle for Single use	K190002	Sterile Hypodermic Syringe for Single Use, with/without needle, and Sterile Hypodermic Needle for Single Use

IV. Device Description:

Sterile Hypodermic Syringe for Single Use, with/without needle:

The sterile hypodermic syringe for single use, with/without needle is intended for used in the aspiration and injection of fluids for medical purposes.

Sterile Hypodermic Needle for Single use:

The sterile hypodermic needle for single use is intended for use with syringes in the aspiration and injection of fluids for medical purposes.

The device is delivered in the following configurations:

Needle Gauge	18,19,20,21,22,23,24,25,26,27,28,29,30G
Needle Length	1/6”-1 1/2”
Syringe Volume	1,2,3,5,10,20,30,50,60,100 ml

The specifications noted below are available for the subject devices:

Needle Gauge	Compatible Needle Length	Compatible Syringe Volume	Compatible Wall Type
18G	1” , 1 1/2”	50 ml, 60 ml, 100 ml	RW, TW
19G	1”, 1 1/2”	50 ml, 60 ml, 100 ml	RW, TW
20G	1”, 1 1/2”	10ml, 20ml, 30ml, 50 ml	RW, TW
21G	1”, 1 1/4”, 1 1/2”	5ml, 10ml, 20ml, 30ml	RW, TW
22G	1”, 1 3/16”, 1 1/4”, 1 1/2”	3ml, 5ml, 10ml, 20ml	RW, TW
23G	1”, 1 1/8”, 1 1/4”, 1 1/2”	3ml, 5ml, 10ml	RW, TW
24G	3/4”, 1”	1ml, 2ml, 3ml, 5ml	RW, TW
25G	5/8”, 1”, 1 1/2”	1ml, 2ml, 3ml	RW, TW
26G	1/2”, 1”	1ml, 2ml	RW, TW
27G	1/2”, 3/4”, 1”, 1 1/2”	1ml	RW, TW
28G	1/3”, 1/2”	1ml	RW, TW
29G	1/4”, 1/2”	1ml	RW, TW
30G	1/6”, 1/2”	1ml	RW, TW

Sterile Hypodermic Syringe for Single Use, with/without needle and Sterile Hypodermic Needle for Single use materials are as noted in the table below:

Name	Material
Needle cap	PP
Needle tube	Stainless Steel
Needle hub	PP
Barrel	PP
Plunger stopper	Isoprene rubber
Plunger	PP
Ink	Black
Lubricant	Silicone oil
Adhesive	Epoxy resin
Colorant	PP masterbatch

The contact level of the subject device is blood path, indirect, and the contact duration is limited contact (<24 hours).

V. Indications for Use

Sterile Hypodermic Syringe for Single Use, with/without needle:
The sterile hypodermic syringe for single use, with/without needle is intended for use in the aspiration and injection of fluids for medical purposes.

Sterile Hypodermic Needle for Single use:
The sterile hypodermic needle for single use is intended for use with syringes in the aspiration and injection of fluids for medical purposes.

VI. Comparison of Technological Characteristics with the Predicate Device

Table 1 - Sterile Hypodermic Syringe for Single Use, with/without needle

Features & Description	Subject Device	Predicate Device	Comparison
510(k) Numbers	K212846	K190002	-
Device Name	Sterile Hypodermic Syringe for Single Use, with/without Needle	Sterile Hypodermic Syringe for Single Use, with/without needle	-
Product Code	FMF	FMF	Identical
21CFR Regulation	880.5860	880.5860	Identical
Class	2	2	Identical
Indication for Use	The sterile hypodermic syringe for single use, with/without needle is intended for use in the aspiration and injection of fluids for medical purposes.	The sterile hypodermic syringe for single use, with/without needle is intended to be used for medical purposes to inject fluid into or withdraw fluid from body.	Identical
Configuration	Piston Plunger Barrel	Piston Plunger Barrel	Identical
Operation mode	For Manual Use Only, For Single Use only	For Manual Use Only, For Single Use only	Identical
Syringe Volume	1ml, 2ml, 3ml, 5ml, 10ml, 20ml, 30ml, 50ml, 60ml and 100ml	1ml, 3ml, 5ml, 6ml, 10ml, 20ml, 30ml, 35ml, 50ml and 60ml	The difference does not raise new questions of safety and effectiveness of the proposed device. The subject devices' syringe volume is different from the predicate device but still conforms to the same applicable performance standards as predicate device.
Needle Gauge	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	Identical
Needle Length	4~38 mm (1/6'' ~ 1 1/2'')	4~38 mm	Identical

Features & Description	Subject Device	Predicate Device	Comparison
Material:			
Barrel	PP	PP	Identical
Needle	PP, SUS304	PP, SUS304	Identical
Plunger	PP	PP	Identical
Plunger stopper	Isoprene Rubber	Isoprene Rubber	Identical
Performance	ISO 7886-1 ISO 7864 ISO 9626 ISO 80369-7 ISO 80369-20	ISO 7886-1 ISO 7864 ISO 9626	Identical
Biocompatibility	ISO10993-1	ISO10993-1	Identical
Sterilization	EO	EO	Identical
SAL	10^{-6}	10^{-6}	Identical
Label/labeling	21 CFR Part 801	21 CFR Part 801	Identical

Table 2 - Sterile Hypodermic Needle for Single use

Features & Description	Subject Device	Predicate Device	Comparison
510(k) Numbers	K212846	K190002	-
Device Name	Sterile Hypodermic Needle for Single Use	Sterile Hypodermic Needle for Single Use	-
Product Code	FMI	FMI	Identical
21CFR Regulation	880.5570	880.5570	Identical
Class	2	2	Identical
Indication for Use	The sterile hypodermic needle for single use is intended for use with syringes in the aspiration and injection of fluids for medical purpose.	The sterile hypodermic needle for single use is intended for use with syringes and injection devices for general purpose fluid injection/aspiration.	Identical
Configuration	Protective cap Needle tube Adhesives Needle hub	Protective cap Needle tube Adhesives Needle hub	Identical
Operation mode	For Manual Use Only, For Single Use only	For Manual Use Only, For Single Use only	Identical
Needle Gauge	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	Identical
Needle Length	4~38 mm (1/6'' ~ 1 1/2'')	4~38 mm	Identical
Material:			
Protective cap	PP	PP	Identical
Needle tube	Stainless steel (SUS304)	Stainless steel (SUS304)	Identical
Needle hub	PP	PP	Identical
Adhesives	Epoxy Resin	Epoxy Resin	Identical
Performance	ISO 7864 ISO 9626 ISO 80369-7 ISO 80369-20	ISO 7864 ISO 9626	Identical
Biocompatibility	ISO10993-1	ISO10993-1	Identical

Features & Description	Subject Device	Predicate Device	Comparison
Sterilization	EO	EO	Identical
SAL	10^{-6}	10^{-6}	Identical
Label/labeling	21 CFR Part 801	21 CFR Part 801	Identical

VII. Performance Data

Performance testing was provided in support of the substantial equivalence determination and to validate and verify that the Sterile Hypodermic Syringe for Single Use, with/without needle and Sterile Hypodermic Needle for Single use met all requirements of related international standards, including biocompatibility, sterility, and product specifications. Results of these tests demonstrate compliance with the requirements of the consensus standards noted below.

Non-clinical Testing

Performance Testing

Performance Testing

The subject device meets all performance standards for Sterile Hypodermic Needle:

ISO 80369-7, Second edition 2020-12

ISO 80369-20, First edition 2015-05-15

ISO 7886-1 Second edition 2017-05

ISO 7864, Fourth edition 2016-08-01

ISO 9626, Second edition 2016-08-01

For the finished device, it meets the defined performance requirements through bench testing.

Clinical Study

No clinical testing was performed.

Biocompatibility

The new device complies with the biocompatibility requirement defined in ISO10993-1. Patient contact classification: The contact level of the subject device is blood path, indirect, and the contact duration is limited contact (<24 hours). The verification test shows that the new devices comply with the biocompatibility requirement defined in ISO10993-1, the same as the predicate device.

- In Vitro Cytotoxicity Test (ISO10993-5: 2009)
- Skin Sensitization Test (ISO10993-10: 2010)
- Intradermal Reactivity Test (ISO10993-10: 2010)
- Coagulation test (ISO10993-4: 2002Amd1:2006(E)
- Complement activity Test (ISO10993-4: 2002 Amd1: 2006(E)
- Hemolytic Properties Test (ASTM F756-13)
- Pyrogen Test (ISO 10993-11:2006)
- USP 788 Particulate Matter in Injections

All of the pre-determined acceptance criteria were met.

Sterility Information

The devices are EO sterilized. The sterilization validation conducted according to below standards:

- ISO11135
- ISO11737-1
- ISO11737-2
- ISO 10993-7
- ANSI/AAMI ST72

All of the pre-determined acceptance criteria were met.

Package and Shelf Life:

We conducted the package and shelf life verification testing noted below to support the shelf life claim:

- AAMI/ANSI/ISO 11137-1:2006/(R) 2010
- AAMI/ANSI/ISO 11737-2:2009
- AAMI/ANSI/ISO 11607-1:2006/(R) 2010
- ASTM F1929-98 (2004)
- ASTM D4169-16
- ASTM F1980-07
- ASTM D3078-02 (2008)
- ASTM F88/F88M-09

The testing was conducted as noted below:

- Product Performance Inspection (Chemical performance and Physical performance)
- Sterile Test
- Vacuum Leak Test
- Dye penetration test
- Agar Contact-Attack Test
- Tensile Seal Strength Test
- Accelerated Aging Test

The test result supports the 5 years shelf life claim for the subject device from the sterilization date.

All of the pre-determined acceptance criteria were met.

Clinical Test:

No clinical study is included in this submission.

VIII. Conclusions:

Based on the information defined above, we conclude that the subject device is substantially equivalent to the marketed predicate device. Any difference between them does not pose a new question of safety and performance.