October 6, 2023

Weihai Shengjie Medical Technology Co., Ltd
Huihui Wang
Manager
No.58, Chuhe South Road
High-Tech Industrial District, Weihai
Weihai, Shandong 264210
China

Re: K221777
Trade/Device Name: Disposable Sterile Syringe
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: Class II
Product Code: FMF, FMI
Dated: August 28, 2023
Received: August 29, 2023

Dear Huihui Wang:

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
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)*
K221777

Device Name
Disposable Sterile Syringe

Indications for Use *(Describe)*
Disposable Sterile Syringe is intended to inject fluids into or withdraw fluids from the body.

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.

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Tab #5 510(k) Summary

This 510(k) Summary is being submitted in accordance with requirements of Title 21, CFR Section 807.92.

The assigned 510(k) Number: K221777

1. Date of Preparation: 03/20/2022

2. Sponsor Identification

Weihai Shengjie Medical Technology Co., Ltd.
No.58, Chuhe South Road, High-Tech Industrial District, Weihai, Shandong, China

Establishment Registration Number:3014632157

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3.Identification of Proposed Device

Trade Name: Disposable Sterile Syringe
Common Name: Piston Syringe
Common Name: Hypodermic Single Lumen Needle

Regulatory Information:
Classification: II
Product Code: FMF
Regulation Number: 21 CFR 880.5860
Review Panel: General Hospital

Regulatory Information:

Classification: II

Product Code: FMI

Regulation Number: 21 CFR 880.5570

Review Panel: General Hospital

Indications for use:

Disposable Sterile Syringe is intended to inject fluids into or withdraw fluids from the body.

Device Description:

Disposable Sterile Syringe, is a plastic syringe designed for intended to inject fluids into or withdraw fluids from the body. The product is a single use, sterile, non-toxic, non-pyrogenic, disposable syringe that consists of a barrel, plunger, Piston, Needle tube, Needle hub and Needle cap.

All specifications of product subject to the same design and the difference between each specification is syringe volume and needle size. The product is available in a variety combination of needle size and syringe volume. The syringe size, needle gauges and lengths are provided in following table.

Syringe Size	Needle Gauge	Needle Length
0.5 ML	27G,28G, 29G, 30G	1/2",3/8",5/8"
1 ML	26G	1/2’’,5/8’’,3/8’’,1’’
	25G,24G	5/8’’,3/8’’,3/4’’,1’’
	23G	3/4’’,1’’
2 ML,2.5 ML, 3 ML,5 ML	26G	1/2’’,5/8’’,3/8’’,1’’
	25G,24G	5/8’’,3/8’’,3/4’’,1’’
	23G	3/4’’,1’’
	22G	1’’,11/4’’,11/5’’
10 ML,20 ML,30 ML, 50 ML,60 ML	18G,19G, 20G,21G,22G	1’’,1 1/4’’,1 1/2’’,1 1/5’’
100 ML	16G,18G,19G, 20G,21G	1 1/4’’,1 1/2’’,1 1/5’’

4.Predicate Device Identification

510(k) Number: K163161

Product Name: Sterile Single-use Syringe with Needle

Manufacturer: JiangXi HongDa Medical Equipment Group Ltd.

5. Comparison of technological characteristics with the predicate devices

Table 1 General Comparison

Item	**Proposed Device** Disposable Sterile Syringe	**Predicate Device (K163161)** Sterile Single-use Syringe with Needle	**Remark**
Product Code	FMF, FMI	FMF, FMI	SAME
Regulation Number	21 CFR 880.5860 21 CRF 880.5570	21 CFR 880.5860 21 CRF 880.5570	SAME
Class	II	II	SAME
Indications for Use	Disposable Sterile Syringe is intended to inject fluids into or withdraw fluids from the body.	Sterile Single-use Syringe with Needle is intended to inject fluids into or withdraw fluids from the body.	SAME
Operation Mod	For manual use only	For manual use only	SAME
Principle of operation	The syringe is composed of a syringe with a small hole at the front end and a matching piston core rod. It uses the "hydraulic" principle to transport liquid. Through the action of force, when the core rod is pushed in, the liquid is pushed from the place with high pressure to the place where the pressure is high. Low pressure place. Inject a small amount of fluid into a muscle, subcutaneously, or into a vein. Or when the mandrel is pulled out, the liquid or gas is sucked from the small hole at the front end of the syringe.	The syringe is composed of a syringe with a small hole at the front end and a matching piston core rod. It uses the "hydraulic" principle to transport liquid. Through the action of force, when the core rod is pushed in, the liquid is pushed from the place with high pressure to the place where the pressure is high. Low pressure place. Inject a small amount of fluid into a muscle, subcutaneously, or into a vein. Or when the mandrel is pulled out, the liquid or gas is sucked from the small hole at the front end of the syringe.	SAME
Intended user	Medical professionals and trained care givers	Medical professionals and trained care givers	SAME
Environment of use	Hospitals and clinics	Hospitals and clinics	SAME

Table 2 Performance Comparison

Item	**Proposed Device** Disposable Sterile Syringe	**Predicate Device (K163161)** Sterile Single-use Syringe with Needle	**Remark**
Syringe Volume	0.5,1,2,2.5,3,5,10,20,30,50,60, 100ml	1ml, 3ml, 5ml, 10ml, 20ml, 60ml	Different Comment #1
Nozzle type	Luer Slip and Luer Lock	Luer Slip and Luer Lock	SAME
Lubricant	Silicone oil	Silicone oil	SAME
Barrel transparency	Clear as required by ISO 7886-1	Clear as required by ISO 7886-1	SAME
Gradations legibility	Clear as required by ISO 7886-1	Clear as required by ISO 7886-1	SAME
Needle Length	1/2",5/8",3/8",1",1 1/4",1 1/2"	1/2", 5/8", 1", 1 1/4", 1 1/2"	Different Comment #2
Needle Gauge	16G, 18G, 19G, 20G, 21G, 22G, 23G, 24G, 25G, 26G, 27G,28G, 29G, 30G	18G, 20G, 21G, 22G, 23G, 25G, 26G, 27G,28G, 29G, 30G	Different Comment #3
Configuration of the tip	Short bevel, long bevel.	Short bevel, long bevel.	SAME
Needle hub	Colorless according to ISO 7864	Colorless according to ISO 7864	SAME
Single Use	Yes	Yes	SAME
Performance specifications	Complies with ISO 7864, ISO 7886-1, ISO 7886-4	Complies with ISO 7864, ISO 7886-1, ISO 7886-4	SAME
Sterilization	EO Sterilization	EO Sterilization	SAME
SAL	10^{-6}	10^{-6}	SAME

Comment #1

Differences in specifications and models can provide users with more flexible choices in terms of injection volume and injection accuracy, and have no impact on clinical applications.

Comment #2

The subject device is available in gauges 16G-30G and the predicate device is available in 18G-30G. Performance testing was done per ISO 9626 and ISO 7864 done to demonstrate that the differences in needle gauges do not affect the clinical safety or effectiveness of the devices.

Comment #3

Differences in specifications and models can provide users with more flexible choices in terms of injection volume and injection accuracy, and have no impact on clinical applications.

Table 3 Safety Comparison

Item	**Proposed Device** Disposable Sterile Syringe		**Predicate Device (K163161)** Sterile Single-use Syringe with Needle		**Remark**
Configuration and material	Barrel	Polypropylene (PP)	Barrel	Polypropylene (PP)	SAME
	Plunger	Polypropylene (PP)	Plunger	Polypropylene (PP)	
	Piston	Polyisoprene	Piston	Polyisoprene	
	Needle tube	Stainless Steel, SUS304	Needle tube	Stainless Steel, SUS304	
	Needle hub	Polypropylene (PP)	Needle hub	Polypropylene (PP)	
	Needle cap	Polypropylene (PP)	Needle cap	Polypropylene (PP)	
Cytotoxicity	No cytotoxicity		No cytotoxicity		SAME
Irritation	No intracutaneous reactivity		No intracutaneous reactivity		SAME
Sensitization	No skin sensitization		No skin sensitization		SAME
Systemic Toxicity	No systemic toxicity		No systemic toxicity		SAME
Hemolysis	No Hemolysis		No Hemolysis		SAME
Pyrogen	No Pyrogen		No Pyrogen		SAME
Labeling	Complied with 21 CFR part 80 1		Complied with 21 CFR part 801		SAME

6.Performance data

Nonclinical 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 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: Test for irritation and skin sensitization.
- ISO 10993-11:2017 Biological evaluation of medical devices- Part 11: Tests for systemic toxicity
- ISO 10993-4:2017 Biological Evaluation of Medical Devices--Part 4: Selection of Tests for Interactions with Blood
- ASTM F1886 / F1886M-16, Standard Test Method for Determining Integrity of Seals for

Flexible Packaging by Visual Inspection

- 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
- 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
- ISO 6009:2016 Hypodermic needles for single use – Colour coding for identification
- ISO 7886-1:2017 Sterile hypodermic syringes for single use- Part 1: Syringes for manual use
- ISO 11737-2:2019 Sterilization of health care products — Microbiological methods — Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process

Physical, Mechanical, Chemical testing listed in following table were performed on the proposed device.

The test results show that the device meets the requirements of related standards.

Item	**Standard**
Cleanliness	Clause 4.3 of ISO 7864:2016
Limits for acidity or alkalinity	Clause 4.4 of ISO 7864:2016
Limits for extractable metals	Clause 4.5 of ISO 7864:2016
Size designation	Clause 4.6 of ISO 7864:2016
Color coding	Clause 4.7 of ISO 7864:2016
Needle hub	Clause 4.8 of ISO 7864:2016
Sheath	Clause 4.9 of ISO 7864:2016
Needle tube	Clause 4.10 of ISO 7864:2016
Needle point	Clause 4.11 of ISO 7864:2016
Bond between hub and needle tube	Clause 4.12 of ISO 7864:2016
Patency of lumen	Clause 4.13 of ISO 7864:2016

Item	**Standard**
Surface finish	Clause 5.1 of ISO 9626:2016
Cleanliness	Clause 5.3 of ISO 9626:2016

Limits for acidity and alkalinity	Clause 5.4 of ISO 9626:2016
Size designation	Clause 5.5 of ISO 9626:2016
Dimensions	Clause 5.6 of ISO 9626:2016
Stiffness	Clause 5.7 of ISO 9626:2016
Resistance to breakage	Clause 5.8 of ISO 9626:2016
Resistance to corrosion	Clause 5.9 of ISO 9626:2016

Item	**Standard**
Extraneous matter	Clause 6 of ISO 7886-1:2017
Lubricant	Clause 7 of ISO 7886-1:2017
Tolerance on graduated capacity	Clause 8 of ISO 7886-1:2017
Graduated scale	Clause 9 of ISO 7886-1:2017
Barrel	Clause 10 of ISO 7886-1:2017
Piston/ plunger assembly	Clause 11 of ISO 7886-1:2017
Nozzle	Clause 12 of ISO 7886-1:2017
Performance	Clause 13 of ISO 7886-1:2017

Sterile barrier packaging testing were performed on the proposed device, which include visual inspection (ASTM F1886/F1886M-16), seal strength (ASTM F88/F88-15) and dye penetration test (ASTM F1929-15). The test result showed that the device package can maintain its integrity.

Sterilization and shelf-life testing listed in following table were performed on the proposed device. EO residue did not exceed the limit of ISO 11737-2:2019. Endotoxin limit did not exceed 20EU/device. Shelf-life test result showed that the device can maintain its performance during the claimed shelf life.

Item	**Standard**
EO residue	ISO 11737-2:2019
Shelf-Life Evaluation	Physical, Mechanical, Chemical, Package Tests were performed on aging samples to verify the claimed shelf life of the device

Biocompatibility testing

The contact level of the proposed device is blood path, indirect, and the contact duration is limited contact (<24 hours). The proposed device was evaluated for the following tests. The results for the

biocompatibility testing showed that there are no negative impacts from the materials that are used in the proposed device.

- Cytotoxicity
- Skin Sensitization
- Intracutaneous Reactivity (Irritation)
- Acute Systemic Toxicity
- Material-Mediated Pyrogens
- Hemolysis

7.Conclusions

The differences between the predicate and the subject device do not raise any new or different questions of safety or effectiveness. The subject Device, Disposable Sterile Syringe, is substantially equivalent to the predicate Device, Sterile Single-use Syringe with Needle, K163161.