September 8, 2023

Wepon Medical Technology Co., Ltd.
% Esther Zhang
Official Correspondent
Shanghai Ling Fu Technology Co., Ltd.
4F No. 585-2, Wanyuan Rd. Minhang District
Shanghai, Shanghai 201102
China

Re: K231727
Trade/Device Name: Sterile Auto-Disable Syringes with/without Needle for Single Use
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: Class II
Product Code: FMF, FMI
Dated: June 8, 2023
Received: June 13, 2023

Dear Esther Zhang:

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 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)*
K231727

Device Name
Sterile Auto-Disable syringes with/without needle for single use

Indications for Use *(Describe)*
The Sterile Auto-Disable syringes with/without needle for single use is used for aspiration of fluids from vials and ampoules and a variety of fluid injections below the surface of the skin except phlebotomy.

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."

510(k) summary

K231727

I Submitter

Device submitter: Wepon Medical Technology CO., LTD.
Floor 4, Building A, No. 58, Jinhu Road, Chengdong Street,
Wenling Zhejiang, CN 317500

Contract manufacturer: Zhejiang Kangkang Medical-Devices CO., Ltd.
Longwang Industrial District, Chumen Town, Yuhuan, Zhejiang, 317605, China
Registration number: 3015042030

Contact person: Di Zhao
Deputy General Manager
Phone: 928-5922380
Email: dizhao@wepon-ppe.com

Date: September 8, 2023

II Correspondent

Shanghai Ling Fu Technology Co., Ltd.
4F No. 585-2, Wanyuan Rd. Minhang District, Shanghai, P.R.China
Contact: Esther ZHANG
Email: Esther.zhang@llins-tech.com

III Device

Trade Name of Device: Sterile Auto-Disable syringes with/without needle for single use
Common Name: Piston Syringe
Regulation Number: 21 CFR 880.5860
21 CFR 880.5570
Regulation Name: Piston Syringe
Regulatory Class: II
Product code: FMF, FMI
Review Panel: General Hospital

IV Predicate Devices

Trade name:	Safety Auto-Disable Syringe with Needle (Auto-Lock)
Common name:	Piston Syringe

Classification: Class II, 21 CFR 880.5860
Product Code: MEG, FMF, FMI
Premarket Notification: K143497
Manufacturer: Guangdong Intmed Medical Appliance Co., Ltd.

V Device description

The Sterile Auto-Disable syringes with/without needle for single use is a syringe with or without needle, sterile, single use hypodermic syringe with a 6% (Luer) male connector/lock fitting in various sizes. The syringe assembly consists of a lubricated polypropylene barrel with a graduated scale, a lubricated synthetic rubber stopper and a polypropylene plunger rod. The plunger rod is pulled back to aspirate fluids or depressed to inject or expel fluids. The main principle of the syringe is that after the injection is completed, the plunger can be locked for self-locking.

Syringe Size	Needle Gauge	Needle Length
Available in 1ml, 3ml, 5ml and 10ml.	Available in 18G, 19G, 20G, 21G, 22G, 23G, 24G, 25G, 26G, 27G, 30G	Available in 1/2", 5/8", 1", 1 1/4", 1 1/2"

VI Indications for use

The Sterile Auto-Disable syringes with/without needle for single use is used for aspiration of fluids from vials and ampoules and a variety of fluid injections below the surface of the skin except phlebotomy.

VII Comparison of technological characteristics with the predicate devices

The Sterile Auto-Disable syringes with/without needle for single use have the same intended use, technology, design, and performance specifications are either identical or substantially equivalent to existing legally marketed predicate devices. The differences between the Sterile Auto-Disable syringes with/without needle for single use and predicate devices do not alter suitability of the proposed device for its intended use.

Table 5-1 Substantial equivalence discussion – Sterile Auto-Disable syringes with/without needle for single use

Device feature	Subject Device K231727	Predicate Device K143497	Comment
Indications for use	The Sterile Auto-Disable syringes with/without needle for single use is used for aspiration of fluids from vials and ampoules and a variety of	The Safety Auto-Disable Syringe with Needle (Auto-Lock) is used for aspiration of fluids from vials and ampoules and a variety of	Different Comment #1

Device feature	Subject Device K231727	Predicate Device K143497	Comment
	fluid injections below the surface of the skin except phlebotomy.	fluid injections below the surface of the skin except phlebotomy. It has a detachable needle with a dedicated fitting. The Safety Auto-Disabled Syringe with Needle (Auto-Lock) contains an inner mechanism used to allow the needle to be retracted inside the plunger rod of the syringe after the operator's thumb force released. After activation the needle is fully contained inside the syringe guarding against accidental needle sticks during normal handling and disposal of the used needle/syringe combination.	
Product code	FMF, FMI	MEG, FMF, FMI	Different Comment #2
Regulation number	21 CFR 880.5860	21 CFR 880.5860	Same
Class	II	II	Same
Principle of operation	For manual use only	For manual use only	Same
Safety Features	Active safety feature, manually activated by user	Active safety feature, manually activated by user	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
Syringe volume	1 ml, 3 ml, 5 ml, 10 ml	1ml, 3ml, 5ml, 10ml	Same
Nozzle type	Luer slip; Luer lock	Needle hub Luer connector	
Lubricant	Silicone oil	PDMS	Same
Barrel transparency	Transparent and clear	Clear as required by ISO 7886-1	Same
Gradations legibility	Legible	Legible according to ISO 7886-1	Same

Device feature	Subject Device K231727	Predicate Device K143497	Comment
Needle Length	1/2", 5/8", 1", 1 1/4", 1 1/2"	12-38mm	Same
Needle Gauge	18G, 19G, 20G, 21G, 22G, 23G, 24G, 25G, 26G, 27G, 30G	21G, 22G, 23G, 24G, 25G, 26G, 27G, 28G	Different Comment #3
Configuration of the tip	Short bevel, long bevel.	15 °C regular point	Different Comment #4
Needle hub	Color-coded per ISO 6009	Colorless according to ISO 7864	Same
Single use	Yes	Yes	Same
Performance specifications	Complies with ISO 7864, ISO 7886-1, ISO 7886-4	Conforms to ISO 7864, ISO 7886-1, ISO 7886-4	Same
Sterilization	EO	EO	Same
SAL	10^{-6}	10^{-6}	Same
Materials	Barrel: PP Plunger: PP Piston: Silicone Rubber Needle: Stainless steel Needle hub: PP	Barrel: Polypropylene Plunger: Polypropylene Piston: Isoprene rubber Needle Hub: Polypropylene Needle: Stainless Steel Needle Sheath: Stainless Steel O Ring : Silicone rubber	Different Comment #5
Pyrogen	Non-pyrogenic	Non-pyrogenic	Same
Biocompatibility	Conforms to ISO 10993 See below	Conforms to ISO10993	Same
Labeling	Meet the requirements of 21 CFR Part 801	Meet the requirements of 21 CFR Part 801	Same

Comment #1

The subject device does not have a needle safety feature, but has a disc on the plunger which could be stuck by the buckle of the syringe to prevent re-use of the syringe. The subject device and the predicate device both have the same intended use, this difference does not affect the clinical safety of the subject device.

Comment #2

The subject device and the predicate device are both syringes that render the syringe unusable after injection, the predicate device also has a needle safety feature.

Comment #3

The subject device is available in gauges 18g-30g and the predicate device is available in 21g-28g. 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 #4
The bevel of subject device is different from the predicate device. However, this difference does not affect intended use. The difference was addressed through ISO 9626 and ISO 7864. Therefore, the differences on bevel do not raise different question of safety and effectiveness.

Comment #5
The material of subject device is different from the predicate device. The piston of subject device is silicone rubber while the predicate device is isoprene rubber. And the configurations of subject device do not include Needle Sheath compared with predicate device, which does not affect its intended use and does not introduce new materials. However, biocompatibility testing was performed with the subject device and found it to be biocompatible. Therefore, the differences on materials do not raise new questions about safety and effectiveness.

VIII Performance data
The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility testing
In accordance with ISO 10993-1, the device is classified as Externally Communicating Device, Blood Path Indirect, Limited Contac (<24 hours). The following tests were conducted:

- Cytotoxicity
- Skin Sensitization
- Intracutaneous Reactivity (Irritation)
- Acute Systemic Toxicity
- Material-Mediated Pyrogens
- Hemolysis
- Particulate Matter per USP <788>

Sterilization, Shipping, and shelf-life testing
- EO sterilization validation per ISO11135:2014
- Pyrogen testing per USP <85> Bacterial Endotoxin Test
- EO residuals per ISO 10993-7
- Simulated shipping per ASTM D4169
- Sterile Barrier Package testing performed on the proposed device:
    - Seal Strength ASTM F88/F88M-2015

    - Bubble leak testing ASTM D3078-02(2013)
    - Dye Penetration ASTM F1929-2015
- Shelf life of 5 years validated using FDA recognized standards ASTM F1980-16 Standard Guide for Accelerated Aging of sterile barrier Systems for Medical Devices

Performance testing

Performance testing is performed according to the following standards:

- 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 80369-7:2021 Small-bore connectors for liquids and gases in healthcare applications — Part 7: Connectors for intravascular or hypodermic applications
- ISO 7886-4:2018 sterile hypodermic syringes for single use — part 4: syringes with re-use prevention feature.
- ISO 7886-1:2017 Sterile hypodermic syringes for single use- Part 1: Syringes for manual use

IX Conclusion

The differences between the predicate and subject device do not raise any new or different questions of safety and effectiveness. The Sterile Auto-Disable syringes with/without needle for single use are substantially equivalent to The Safety Auto-Disable Syringe with Needle (Auto-Lock) with respect to indications for use, target population, and technological characteristics.