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: K231729
Trade/Device Name: Sterile syringes for single use with/without needle
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)*
K231729

Device Name
Sterile syringes for single use with/without needle

Indications for Use *(Describe)*
The Sterile syringes for single use with/without needle is intended to be used for medical purposes to inject fluid into or withdraw fluid from 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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*"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

## K231729

**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: | Sterile syringes for single use with/without needle |
| Common Name: | Piston Syringe |
| Regulation Number: | 21 CFR 880.5860 |
| Regulation Name: | Piston Syringe |
| Device Class: | Class II |
| Product code: | FMF, FMI |
| Review Panel: | General Hospital |

**IV Predicate Devices**

| | |
|---|---|
| Trade name: | Sterile Hypodermic Syringe for Single use with/without Needle |
| Common name: | Piston Syringe |
| Classification: | Class II, 21 CFR 880.5860 |

Product Code: FMI
Premarket Notification: K112057
Manufacturer: Shanghai Kindly Enterprise Division Group Company

**V Device description**

The Sterile Syringes for Single Use with/without Needle is a three-piece, 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.

**VI Indications for use**

The Sterile syringes for single use with/without needle are intended to be used for medical purposes to inject fluid into or withdraw fluid from body.

**VII Comparison of technological characteristics with the predicate devices**

The Sterile Syringes for Single Use with/without Needle have the same intended use, technology, design and performance specifications are either similar or substantially equivalent to existing legally marketed predicate devices. The differences between the Sterile Syringes for Single Use with/without Needle and predicate devices do not alter suitability of the proposed device for its intended use.

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

| Device feature | Subject Device K231729 | Predicate Device K112057 | Comments |
|---|---|---|---|
| Indications for use | The Sterile Syringes for Single Use with/without Needle is intended to be used for medical purposes to inject fluid into or withdraw fluid from body. | 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. | Same |
| Product code | FMF, FMI | FMF | Same |
| Regulation number | 21 CFR 880.5860 | 21 CFR 880.5860 | Same |
| Principle of operation | For manual use only | For manual use only | 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 |
| Nozzle type | Luer slip; Luer lock | Luer slip; Luer lock | Same |
| Lubricant for barrel | Silicone oil | Silicone oil | Same |
| Barrel transparency | Transparent and clear | Transparent and clear | Same |
| Gradations legibility | Legible | Legible | Same |
| Syringe volume | 1ml, 2ml, 3ml, 5ml, 10ml, 20ml, 30ml, 50ml, 60ml, 100ml | 1ml, 3ml, 5ml, 6ml, 10ml, 20ml, 30ml, 35ml and 50ml | Different 1 |
| Needle gauge | 18G, 19G, 20G, 21G, 22G, 23G, 24G, 25G, 26G,27G, 30G | 18G, 19G, 20G, 21G, 22G, 23G, 24G, 25G, 26G, 27G, 28G, 29G, 30G | |
| Needle length | $^{1}/_{2}$", $^{5}/_{8}$", 1", $1\,^{1}/_{4}$", $1\,^{1}/_{2}$" | Not available | |
| Needle hub | Color-coded per ISO 6009 | Color-coded per ISO 6009 | Same |
| Single use | Yes | Yes | Same |
| Performance specifications | Complies with ISO 7886-1:2017 Sterile Hypodermic syringes for single use - Part 1: Syringes for manual use | Complies with ISO 7886-1:2017 Sterile Hypodermic syringes for single use - Part 1: Syringes for manual use | Same |
| Sterilization | EO | EO | Same |
| SAL | $10^{-6}$ | $10^{-6}$ | Same |
| Materials | Barrel: PP Plunger: PP Piston: Silicone Rubber Needle: Stainless 304 Needle hub: PP | Barrel: PP Plunger: PP Piston: Isoprene Rubber Needle: Stainless 304 Needle hub: PP | Different 2 |
| Pyrogen | 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: | 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: | Same |

| | | | |
|---|---|---|---|
| | Evaluation and Testing Within a Risk Management Process," as 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:<br>Cytotoxicity;<br>Skin sensitization;<br>Hemolysis;<br>Intracutaneous reactivity;<br>Acute systemic toxicity;<br>Pyrogenicity.<br>The evaluation of the above testing items meet the requirements | Evaluation and Testing Within a Risk Management Process," as 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;<br>Skin sensitization;<br>Hemolysis;<br>Intracutaneous reactivity;<br>Acute systemic toxicity;<br>Pyrogenicity.<br>The evaluation of the above testing items meets the requirements | |
| Labeling | Meet the requirements of 21 CFR Part 801 | Meet the requirements of 21 CFR Part 801 | Same |

Discussion:

Different 1

The syringe volume, needle gauge and length of subject devices are different from the predicate device. The differences do not raise new questions of safety and effectiveness.

Different 2

The material of subject device is similar as predicate device. However, the

subjected products were tested and demonstrated that they complied with ISO 10993 series standards. The differences on material does not affect substantially equivalence on safety and effectiveness.

**VIII Performance data**

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

**Biocompatibility testing**

Biocompatibility of the Sterile syringes for single use with/without needle was evaluated in accordance with ISO 10993-1:2018 for the body contact category of "External communication device – Blood path indirect" with a contact duration of "Limited (< 24 hours)". The following tests were performed, as recommended: Cytotoxicity; Skin sensitization; Hemolysis; Intracutaneous reactivity; Acute systemic toxicity; Pyrogenicity. All evaluation acceptance criteria were met.

**Sterilization and shelf-life testing**

The sterilization method has been validated to ISO11135:2014, which has thereby determined the routine control and monitoring parameters.

The testing is performed according to the following standards:

| | |
|---|---|
| EO residue | ISO 10993-7:2008 |
| ECH residue | ISO 10993-7:2008 |
| Pyrogen testing | USP <85> Bacterial Endotoxin Test |
| Simulated shipping per | ASTM D4169 |

Package integrity testing was conducted on the final, packaged, and sterile devices after environmental conditioning and simulated transportation. All packaging deemed acceptable for protection of product and sterility maintenance.

The shelf life of 5 year is determined based on stability studies which include ageing test according to FDA recognized standard ASTM F1980-16.

The testing is performed according to the following standards:

| | |
|---|---|
| Seal strength | ASTM F88/F88M-15 |
| Dye penetration | ASTM F 1929-2015 |

| | |
|---|---|
| Bubble leak testing | ASTM D3078-02(2013) |

**Performance testing**

Performance testing is performed according to the following standards:

- ISO 7864:2016 Sterile Safety 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 7886-1:2017 Sterile hypodermic syringes for single use- Part 1: Syringes for manual use.
- USP <788> Particulate Matter in Injections

**IX Conclusion**

The predicate device submission was cleared with Sterile Hypodermic Syringe for Single use with/without Needle, Sterile Insulin Syringe for single use, with needle and Sterile Hypodermic Needle for single use. The subject device is being compared to only the predicate Sterile Hypodermic Syringe for Single use with/without Needle. The subject device, Sterile Syringes for Single Use with/without Needle, is substantially equivalent to its predicate devices (Sterile Hypodermic Syringe for Single use with/ without Needle). The non-clinical testing demonstrates that the device is as safe, as effective and performs as well as the legally marketed device. Therefore, it is substantially equivalent.