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

September 8, 2023

Re: K231720
Trade/Device Name: Sterile Hypodermic Needles for Single Use
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: Class II
Product Code: 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K231720

Device Name
Sterile Hypodermic Needles for Single Use

Indications for Use *(Describe)*
The Sterile Hypodermic Needles for Single Use are intended to be used with a luer lock or luer slip syringe 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Section 5 510(k) summary

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
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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 Hypodermic Needles for Single Use
Common Name: Hypodermic Single Lumen Needle
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: II
Product code: FMI
Review Panel: General Hospital

IV Predicate Devices

Trade name:	Sterile Hypodermic Needles for Single Use (used as the predicate device);
Common name:	Hypodermic single lumen needle
Classification:	Class II, 21 CFR 880.5570
Product Code:	FMI
Premarket Notification:	K180417

Manufacturer: Berpu Medical Technology Co., Ltd

V Device description

The Sterile Hypodermic Needles for Single Use is composed of a needle hub, protective cover, needle tube and jointing, connected with a luer lock or luer slip syringe and injection devices for general purpose fluid injection/aspiration. The Sterile Hypodermic Needles for Single Use is for single use only. After opening the inner packaging and taking out the product, tighten the needle to the syringe and remove the protective cover, extract the drug liquid, exhaust the air and then inject. It is provided sterile. The sterilization method is EO sterilization and the sterilization assurance level is 10^{-6}.

Table 1 specification of proposed device

Gauge / Length	30G	27G	26G	25G	24G	23G	22G	21G	20G	19G	18G
1/2"	●	●	●								
5/8"			●	●	●						
1"			●	●	●	●	●	●	●	●	●
1 1/4"						●	●	●	●	●	●
1 1/2"						●	●	●	●	●	●

VI Indications for use

The Sterile Hypodermic Needles for Single Use are intended to be used with a luer lock or luer slip syringe and injection devices for general purpose fluid injection/aspiration.

VII Comparison of technological characteristics with the predicate devices

The Sterile Hypodermic Needles 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 Hypodermic Needles for Single Use and predicate devices do not alter suitability of the proposed device for its intended use.

Device feature	Subject Device	Predicate Device K180417	Comments
Indications for use	The Sterile Hypodermic Needles for Single Use are intended to be used with a luer lock or luer slip syringe and injection devices for general purpose fluid injection/aspiration.	The Sterile Hypodermic Needles for Single Use are intended to be used with a luer slip or luer slip syringe and injection devices for general purpose fluid injection/aspiration.	Same
Product code	FMI	FMI	Same
Regulation	21 CFR 880.5570	21 CFR 880.5570	Same

Device feature	Subject Device		Predicate Device K180417		Comments
number					
Class	II		II		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
Needle gauge	30G, 27G, 26G, 25G, 24G, 23G, 22G, 21G, 20G, 19G, 18G		14G, 15G, 16G, 17G, 18G, 19G, 20G, 21G, 22G, 23G, 24G, 25G, 26G, 27G, 29G, 30G		Difference 1
Length	$1/2$", $5/8$", 1", $1\,1/4$", $1\,1/2$"		6-60mm		
Type of wall	normal wall or thin wall		not provide		
blade angle	short bevel or long bevel		not provide		
Needle hub	Needle hub	Polypropylene	Needle hub	Polypropylene	Same
main structure and materials	Needle tube	Stainless steel	Needle	Stainless steel	
	protective cover	Polypropylene	protective cap	Polypropylene	
Needle hub	Color-coded per ISO 6009		Color-coded per ISO 6009		Same
Single use	Yes		Yes		Same
Performance specifications	Complies with ISO 7864; ISO 9626; ISO 80369-7		Complies with ISO 7864; ISO 9626; ISO 80369-7		Same
Sterilization	EO		EO		Same
SAL	10^{-6}		10^{-6}		Same
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: Evaluation and Testing Within a Risk		Comply with ISO 10993. The test is as follows: The devices meet biocompatibility endpoints for cytotoxicity, irritation, sensitization, systemic toxicity, hemolysis and material-mediated pyrogens.		Same

Device feature	Subject Device	Predicate Device K180417	Comments
	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; Skin sensitization; Hemolysis; Intracutaneous reactivity; Acute systemic toxicity; Pyrogenicity. 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

Different 1

The needle gauge and length of subject devices are different from the predicate device, and the type of wall and needle bevel are unknown. The subject device specifications are within the range of the predicate device. This difference does not affect intended use and does not raise different questions of 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 Hypodermic Needles for Single Use were 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	ISO 10993-5: 2009
Skin sensitization	ISO 10993-10: 2010
Hemolysis	ISO 10993-4: 2017
Intracutaneous reactivity	ISO 10993-10: 2010
Acute systemic toxicity	ISO 10993-11: 2017
Pyrogenicity	ISO 10993-11: 2017

All evaluation acceptance criteria were met.

Particulate matter testing was conducted in accordance with USP <788> Particulate Matter in Injections and met the USP acceptance criteria.

Sterilization and shelf life testing

The sterilization method has been validated to ISO11135, which has thereby determined the routine control and monitoring parameters. The shelf life of the Sterile Hypodermic Needles for Single Use is determined based on stability study which includes ageing test. The shelf-life of the Sterile Hypodermic Needles for Single Use is five (5) years.

Sterilization Evaluation	ISO11135: 2014
EO residue	ISO 10993-7:2008
ECH residue	ISO 10993-7:2008
Bacterial Endotoxin testing	USP42-NF37<85>
Sterile barrier packaging testing & Shelf Life Evaluation	Seal Strength ASTM F88/F88M-15 Dye Penetration ASTM F1929-15 Creep/Burst Testing ASTMF1140/F1140M-13 Gross Leakage ASTM F2096-11 Antibacterial Testing DIN 58953-6:2010

Performance testing

Performance testing is performed according to the following standards:

- ISO 7864: 2016

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
Tubular needle designation	Clause 4.6 of ISO 7864: 2016
Colour coding	Clause 4.7 of ISO 7864: 2016
Needle hub	Clause 4.8 of ISO 7864: 2016, ISO 80369-7 and ISO 6009
Needle cap	Clause 4.9 of ISO 7864: 2016
Needle tube (Tolerance on length, Freedom from defects, Lubricant)	Clause 4.10 of ISO 7864: 2016

Needle Point	Clause 4.11 of ISO 7864: 2016
Bond between Tube and Hub	Clause 4.12 of ISO 7864: 2016
Patency of Lumen	Clause 4.13 of ISO 7864: 2016

- ISO 9626:2016

Surface finish and visual appearance	Clause 5.2 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 5.8 of ISO 9626:2016
Resistance to breakage	Clause 5.9 of ISO 9626:2016
Resistance to corrosion	Clause 5.10 of ISO 9626:2016

- ISO 80369-7:2016

Dimensional requirements for luer connectors.	Clause 5 of ISO 80369-7: 2021
Fluid leakage (Positive pressure liquid leakage)	Clause 6.1.3 of ISO 80369-7: 2021
Sub-atmospheric pressure air leakage	Clause 6.2 of ISO 80369-7: 2021
Stress cracking	Clause 6.3 of ISO 80369-7: 2021
Resistance to separation from axial load	Clause 6.4 of ISO 80369-7: 2021
Resistance to separation from unscrewing	Clause 6.5 of ISO 80369-7: 2021
Resistance to overriding	Clause 6.6 of ISO 80369-7: 2021

IX Conclusion

The Sterile Hypodermic Needles for Single Use are substantially equivalent to its predicate device. The non-clinical testing demonstrates that the device is as safe, as effective and performs as well as the legally marketed device.