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: K231723
Trade/Device Name: Sterile Safety 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K231723

Device Name
Sterile Safety Hypodermic Needles for Single Use

Indications for Use *(Describe)*
The Sterile Safety Hypodermic Needles for Single Use are intended for use in the aspiration and injection of fluids for medical purpose. After withdrawal of the needle from the body, the attached needle safety shield can be manually activated to cover the needle immediately after use to minimize risk of accidental needlesticks

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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"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."

K231723

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
Deputy General Manager
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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:	Sterile Safety Hypodermic Needles for Single Use
Common Name:	Hypodermic Single Lumen Needle
Regulation Number:	21 CFR 880.5570
Regulation Name:	Hypodermic Single Lumen Needle
Device Class:	Class II
Product code:	FMI

IV Predicate Devices

Trade name:	TK Safety Needle
Common name:	Hypodermic Single Lumen Needle
Classification:	Class II, 21 CFR 880.5570
Product Code:	FMI
Premarket Notification:	K191644
Manufacturer:	Anhui Tiankang Medical Technology Co., Ltd

V Device description

The Sterile Safety Hypodermic Needles for Single Use are composed of a hypodermic

needle with a needle safety shield attached to the needle hub, which can be manually activated to cover the needle immediately after use to minimize risk of accidental needlesticks. The device is compatible for use with standard luer slip and luer lock syringes. The Sterile Safety Hypodermic Needles for Single Use is for single use only. It is provided sterile. The sterilization method is EO sterilization and the sterilization assurance level is 10^{-6}.

Connection type	Luer										
Color of needle hub	Yellow	Medium Grey	Brown	Orange	Middle Purple	Deep blue	Black	Deep green	Yellow	Cream	Pink
Gauge	30G	27G	26G	25G	24G	23G	22G	21G	20G	19 G	18 G
Length of needle tube	1/2"		1/2"、5/8"、1"	5/8"、1"	5/8"、1"	1"、1 1/4"、1 1/2"					
Length of needle covers (mm)	12.5		12.5、16、25	16、25	16、25	25、32、38					
Color of needle covers	Transparent										
Type of wall	Normal wall and thin wall										
Blade angle	Short bevel and long bevel										

VI Indications for use

The Sterile Safety Hypodermic Needles for Single Use are intended for use in the aspiration and injection of fluids for medical purpose. After withdrawal of the needle from the body, the attached needle safety shield can be manually activated to cover the needle immediately after use to minimize risk of accidental needlesticks.

VII Comparison of technological characteristics with the predicate devices

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

Table 5-1 Substantial equivalence discussion

Device feature	Subject Device	Predicate Device K191644	Comments
Indications for use	The Sterile Safety Hypodermic Needles for Single Use are intended for use in the aspiration and injection of fluids for	The TK Safety Needle device is intended for use in the aspiration and injection of fluids for medical purposes. The	Comment 1

Device feature	Subject Device		Predicate Device K191644		Comments
	medical purpose. After withdrawal of the needle from the body, the attached needle safety shield can be manually activated to cover the needle immediately after use to minimize risk of accidental needlesticks.		TK Safety Needle is compatible for use with standard luer slip and luer lock syringes. Additionally, after withdrawal of the needle from the body, the attached needle safety shield can be manually activated to cover the needle immediately after use to minimize risk of accidental needle-stick.		
Product code	FMI		FMI		Identical
Regulation number	21 CFR 880.5570		21 CFR 880.5570		Identical
Class	CLASS II		CLASS II		Identical
Principle of operation	Normal		Normal		Identical
Needle gauge	18G, 19G, 20G, 21G, 22G, 23G, 24G, 25G, 26G, 27G, 30G		16G、17G、18G、19G、20G、21G、22G、23G、24G、25G、26G、27G、28G、29G、30G		Substantially equivalent Comment 2
Length	$1/2$", $5/8$", 1", $1\,1/4$", $1\,1/2$"		1/2" to 1 1/2"		
Type of wall	Thin wall and normal wall		From 16G to 23G: thin wall From 24G to 30G：regular wall		
blade angle	Short bevel and long bevel		Bevel		
main structure and materials	Needle hub	Polypropylene	Needle Hub	Polypropylene	Identical
	Needle tube	Stainless steel	Needle	Stainless Steel	
	protective cover	Polypropylene	Needle Sheath	Polypropylene	
Needle hub Colors	Various Colors		Various Colors		Identical
Sharps injury	Needle safety shield		Needle safety shield		Identical

Device feature	Subject Device	Predicate Device K191644	Comments
Prevention Features			
Lubricant for Needle	Silicone Oil	Silicone Oil	Identical
Performance specifications	Conforms to ISO 7864	Conforms to ISO 7864	Identical
Sterilization	EO sterilization	EO sterilization	Identical
Biocompatibility	Conforms to ISO 10993	Conforms to ISO 10993	Identical
Labeling	Meet the requirements of 21 CFR Part 801	Meet the requirements of 21 CFR Part 801	Identical

Discussion:

Comment 1

Minor rewording of the Intended use statement has been made. However, the general purpose of the device and its function remain unchanged. The subject devices are also compatible with standard slip tip and luer lock syringes, even though the IFU does not exclusively say that. The minor rewording of the Intended use statement does not raise different questions of safety and effectiveness.

Comment 2

The subject device's needle gauge and needle length are smaller than the predicate device's needle gauge range of 16G to 30G and length range of 1/2" to 1 1/2". The type of wall and needle bevel are different from the predicate device. The range is within the same range as the predicate device. The differences do not raise new 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 Safety 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

Particulate matter testing was conducted in accordance with Method 1 of 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 Safety Hypodermic Needles for Single Use is determined based on stability study which includes ageing test.

The testing is performed according to the following standards:

- ISO 11135:2014 Sterilization of health-care products — Ethylene oxide — Requirements for the development, validation and routine control of a sterilization process for medical devices
- ISO 10993-7:2008 Biological evaluation of medical devices — Part 7: Ethylene oxide sterilization residuals
- ISO 11607-1: 2019 Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
- ISO 11607-2: 2019 Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes
- 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 Safety Hypodermic Needles for Single Use — Requirements and test methods
- ISO 9626:2016, Stainless Steel Needle Tubing For The Manufacture of Medical Devices
- ISO 80369-7:2016 Small-bore connectors for liquids and gases in healthcare applications — Part 7: Connectors for intravascular or hypodermic applications
- ISO 23908 Sharps Injury protection- Requirements and test methods
- Medical Devices with Sharps Injury Prevention Features - Guidance for Industry and FDA Staff

IX Conclusion

The minor differences between the predicate and subject device do not raise any new or

different questions of safety or effectiveness. The Sterile Safety Hypodermic Needles for Single Use are substantially equivalent to its predicate device (TK Safety Needle) with respect to the indications for use, treatment method and technological characteristics. The non-clinical testing demonstrates that the device is as safe, as effective and performs as well as the legally marketed device.