September 23, 2021

Zhejiang Kangkang Medical-Devices CO., Ltd.
Chun Guo
Quality Manager
Longwang Industrial District, Chumen Town
Yuhuan, Zhejiang 317605
China

Re: K210232
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: August 23, 2021
Received: August 27, 2021

Dear Chun Guo:

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,

For 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)*
K210232

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.

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K210232 510(k) summary

I Submitter

Device submitter: Zhejiang Kangkang Medical-Devices CO., Ltd.
Longwang Industrial District, Chumen Town, Yuhuan, Zhejiang,
317605, China

Contact person: Chun Guo
General Manager
Phone: 13586180908 / 89902728
Fax: 0576-87427630
Email: guochun@vip.126.com

Date: 09/23/2021

II 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

III Predicate Devices

Trade name:	Self-destruction Safety Syringes for Single Use; Sterile Hypodermic Syringes for Single Use; Sterile Hypodermic Needles for Single Use (used as the predicate device); Sterile Safety Hypodermic Needles for Single Use
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

IV Device description

The Sterile Hypodermic Needles for Single Use is composed of a needle hub, protective cover, needle tube and jointing, connected with a syringe for general purpose fluid injection/aspiration.

Device	Needle length	Needle gauge	Type of wall	Blade angle
Sterile Hypodermic Needles for Single Use	$1/2$", $5/8$", 1", $1\ 1/4$", $1\ 1/2$"	30G, 27G, 26G, 25G, 24G, 23G, 22G, 21G, 20G, 19G, 18G	Normal wall and thin wall	Short bevel and long bevel

V 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.

VI Comparison of technological characteristics with the predicate devices

The Sterile Hypodermic Needles for Single Use have the same or equivalent intended use, technology, design and performance specifications 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 number	21 CFR 880.5570		21 CFR 880.5570		Same
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 provided		
blade angle	short bevel or long bevel		not provided		
Needle hub	Needle hub	Polypropylene	Needle hub	Polypropylene	Same

Device feature	Subject Device		Predicate Device K180417		Comments
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 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		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
Labeling	Meet the requirements of 21 CFR Part 801		Meet the requirements of 21 CFR Part 801		Same

Difference 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. However, this difference is just in dimension. Different needle specifications will be selected by the HCP per the patient’s condition. This difference does not affect intended use. In addition, differences were addressed through ISO 7864, ISO 9626 and ISO 80369-7. Therefore, these differences do not affect safety and effectiveness

VII 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, 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

USP <788> Particulate Matter Testing

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, 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
- ASTM D4169-16 Standard Practice for Performance Testing of Shipping Containers and Systems
- ASTM F88/F88M-15 – Standard Test Method for Seal Strength of Flexible Barrier Materials

- ASTM F1140/F1140M-13 – Standard Test Methods for Internal Pressurized Failure of Unrestrained Packages
- ASTM F1929-15 – Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by De Penetration
- ASTMF2096-11 – Standard Test Method for Detecting Gross Leakes in Packaging by Internal Pressurization (Bubble Test)

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 80369-7:2016 Small-bore connectors for liquids and gases in healthcare applications — Part 7: Connectors for intravascular or hypodermic applications

VIII 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.