September 10, 2021

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

Re: K210227
Trade/Device Name: Sterile syringe for single use with/without needle
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: Class II
Product Code: FMF
Dated: August 6, 2021
Received: August 12, 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)*
K210227

Device Name
Sterile syringes for single use with/without needle

Indications for Use *(Describe)*
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.

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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K210227 510(k) Summary

Date
September 10, 2021

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

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

Predicate Device

Trade name:	Sterile Hypodermic Syringe for Single use with/without Needle (used as Predicate Device) Sterile Insulin Syringe for single use, with needle Sterile Hypodermic Needle for single use
Common name:	Piston Syringe
Classification:	Class II, 21 CFR 880.5860
Product Code:	FMF
Premarket Notification:	K112057
Manufacturer:	Shanghai Kindly Enterprise Division Group Company

Device description
The Sterile Syringes for Single Use with/without Needle are three-piece, sterile, single use hypodermic syringes with a 6% (Luer) male connector/lock fitting in various sizes. Each 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.

Items	Specification										
Type of nozzle	Central nozzle (1, 2, 3, 5, 10ml), Central nozzle or Eccentric nozzle (20, 30, 50, 60, 100ml)										
Structure	Three-piece structure										
Color of needle hub	Yellow	Medium Grey	Brown	Orange	Middle Purple	Deep blue	Black	Deep green	Yellow	Cream	Pink
OD of needle tube	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										

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.

Comparison of technological characteristics with the predicate devices

The Sterile Syringes for Single Use with/without Needle have the same intended use, technology, and are substantially equivalent to the predicate device. The differences between the Sterile Syringes for Single Use with/without Needle and the predicate device 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**	**Predicate Device K112057**
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.	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.
Product code	FMF	FMF
Regulation number	21 CFR 880.5860	21 CFR 880.5860
Class	II	II
Principle of operation	For manual use only	For manual use only
Intended user	Medical professionals and trained care givers	Medical professionals and trained care givers
Environment of use	Hospitals and clinics	Hospitals and clinics
Syringe volume[1]	1ml, 2ml, 3ml, 5ml, 10ml, 20ml, 30ml, 50ml, 60ml, 100ml	1ml, 3ml, 5ml, 6ml, 10ml, 20ml, 30ml, 35ml and 50ml
Nozzle type	Luer slip; Luer lock	Luer slip; Luer lock
Lubricant for barrel	Silicone oil	Silicone oil
Barrel transparency	Transparent and clear	Transparent and clear
Gradations	Legible	Legible

legibility		
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 hub	Color-coded per ISO 6009	Color-coded per ISO 6009
Single use	Yes	Yes
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
Sterilization	EO	EO
SAL	10^{-6}	10^{-6}
Materials[2]	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
Pyrogen	Non-pyrogenic	Non-pyrogenic
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	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

Labeling	Meet the requirements of 21 CFR Part 801	Meet the requirements of 21 CFR Part 801

1) The subject device has larger syringe volume sizes. Differences are addressed through testing per ISO 7886-1:2017.

2) There are material differences between the subject and predicate device. Differences are addressed through biocompatibility testing per ISO 10993.

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	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	USP <788>

Sterilization and shelf life testing

The sterilization method has been validated per ISO 11135, which has thereby determined the routine control and monitoring parameters. The shelf life of the Sterile syringes for single use with/without needle is 3 years, determined based on stability studies which includes accelerated aging.

Sterilization and shelf life testing listed were performed on the proposed device.

EO residue	ISO 10993-7:2008
ECH residue	ISO 10993-7:2008
Shelf Life Evaluation	physical performance, chemical performance and biological performance, including sterility, and single package seal strength test, creep/burst test, leakage test, gross leakage test and antibacterial performance test were performed

Shelf-Life Testing conducted per:

ISO 11607 Packaging for Terminally Sterilized Medical Devices

ASTM F1980-16 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices

ASTM D 4169 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 Pressurization Failure Resistance of Unrestrained Packages
ASTM F1929-15 Standard Test Method for Detecting Deal Leaks in Porous Medical Packaging by Dye Penetration
ASTM F2096-11 Standard Test Method for Detecting Gross Leaks in Packaging by Internal Pressurization (Bubble Test)
DIN 58953-6-2010 Sterilization-Sterile Supply-Part 6: Microbial Barrier Testing of Packaging Materials for Medical Devices Which are to be Sterilized

Performance testing

Performance testing is performed according to the following standards:

ISO 7886-1: 2017	
Cleanliness	Clause 6.1 of ISO 7886-1:2017
Limits for acidity or alkalinity	Clause 6.2 of ISO 7886-1:2017
Limits for extractable metals	Clause 6.3 of ISO 7886-1:2017
Lubricant	Clause 7 of ISO 7886-1:2017
Tolerance on Graduated capacity	Clause 8 of ISO 7886-1:2017
Scale	Clause 9.1 of ISO 7886-1:2017
Numbering of scales	Clause 9.2 of ISO 7886-1:2017
Overall length of scale to nominal capacity line	Clause 9.3 of ISO 7886-1:2017
Position of scale	Clause 9.4 of ISO 7886-1:2017
Dimensions	Clause 10.1 of ISO 7886-1:2017
Barrel flanges	Clause 10.2 of ISO 7886-1:2017
Design	Clause 11.1 of ISO 7886-1:2017
Conical fitting	Clause 12.1 of ISO 7886-1:2017 and ISO 80369-7
Position of nozzle on end of barrel	Clause 12.2 of ISO 7886-1:2017
Nozzle lumen	Clause 12.3 of ISO 7886-1:2017
Dead Space	Clause 13.1 of ISO 7886-1:2017
Freedom from air and liquid leakage past plunger stopper	Clause 13.2 of ISO 7886-1:2017
Force to operate the piston	Clause 13.3 of ISO 7886-1:2017
Fit of plunger stopper/ plunger in barrel	Clause 13.4 of ISO 7886-1:2017
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 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
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

I Conclusion

The Sterile Syringes for Single Use with/without Needle are substantially equivalent to its predicate device with respect to the indications for use, target populations, treatment method, and technological characteristics. The differences between the predicate and the subject device do not raise any new or different questions of safety or effectiveness. Through functional performance testing and biocompatibility testing, the subject device has demonstrated substantial equivalence to the predicate device.