October 5, 2021

Jiangsu Kangyou Medical Instrument Co., Ltd.
Xiang Yao
Product Manager
Tangzhuang Yaotang Town
Jintan, Jiangsu 213223
China

Re: K211728
Trade/Device Name: Sterile hypodermic syringes for single use
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: Class II
Product Code: FMF
Dated: August 20, 2021
Received: August 30, 2021

Dear Xiang Yao:

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 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)*
K211728

Device Name
Sterile hypodermic syringes for single use

Indications for Use *(Describe)*
The Sterile hypodermic syringes for single use are intended to inject fluids into or withdraw fluids from the 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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K211728 510(k) summary

Preparation Date: October 5, 2021

I Submitter

Device submitter: Jiangsu Kangyou Medical Instrument Co., Ltd.
Tangzhuang, Yaotang Town 213223 Jintan, Jiangsu, People's Republic of China

Contact person: Xiang Yao
Product Manager
Phone: 13813652889
Fax: 86 519 82582461
Email: export@kym.cn

II Device

Trade Name of Device: Sterile hypodermic syringes for single use
Common Name: Piston Syringe with Needle
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe with Needle
Regulatory Class: II
Product code: FMF
Review Panel: General Hospital

III Predicate Devices

Trade name:	Sterile Single-use Syringe with Needle
Common name:	Piston Syringe with Needle
Classification:	Class II, 21 CFR 880.5860
Product Code:	FMF
Premarket Notification:	K163161
Manufacturer:	JiangXi HongDa Medical Equipment Group Ltd.

IV Device description

The Sterile hypodermic syringes for single use are intended for manual and single use only to aspirate and inject of fluids for medical purpose, and consist of syringe (barrel, plunger, piston) and hypodermic needle (needle tube, hub, needle cap). The proposed device is available in a variety of syringe and needle sizes.

Syringe Size	Needle Gauge	Needle Length
Available in 1ml、2ml、3ml、	Available in 16G, 18G,	Available in 8mm (5/16"),

5ml、10ml、20ml、30ml、50ml, 60ml	20G, 21G, 22G, 23G, 24G, 25G, 26G, 27G, 29G, 30G	13mm (1/2"), 15mm (3/5"), 20mm (4/5"), 25mm (1"), 30mm (1 1/6"), 32mm (1 1/4"), 33mm(1 3/10"), 38mm (1 1/2")

The different gauge of needles could fit every specification of syringes. The needle is optional.

Gauge / Syringe	30G	29G	27G	26G	25G	24G	23G	22G	21G	20G	18G	16G
1ml	●	●	●	●	●	●	●	●	●	●	●	●
2ml	●	●	●	●	●	●	●	●	●	●	●	●
3ml	●	●	●	●	●	●	●	●	●	●	●	●
5ml	●	●	●	●	●	●	●	●	●	●	●	●
10ml	●	●	●	●	●	●	●	●	●	●	●	●
20ml	●	●	●	●	●	●	●	●	●	●	●	●
30ml	●	●	●	●	●	●	●	●	●	●	●	●
50ml	●	●	●	●	●	●	●	●	●	●	●	●
60ml	●	●	●	●	●	●	●	●	●	●	●	●

V Indications for use

The Sterile hypodermic syringes for single use are intended to inject fluids into or withdraw fluids from the body.

VI Comparison of technological characteristics with the predicate devices

The Sterile hypodermic syringes 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 Sterile hypodermic syringes for single use and predicate devices are the specification of syringe volume, needle gauge and needle length. However, syringes will be selected by physician per injection requirement and this difference does not affect indication for use. Additionally, the performance of syringe and needle has been evaluated and the test results met the requirements of ISO 7886-1 and ISO 7864. Therefore, this difference does not affect substantially equivalency on safety and effectiveness.

Table 6-1 Substantial equivalence discussion

Device feature	Subject Device	Predicate Device K163161	Comment

Device feature	Subject Device		Predicate Device K163161		Comment
Syringe type	Standard piston syringe		Standard piston syringe		Same
Indications for use	The Sterile hypodermic syringes for single use are intended to inject fluids into or withdraw fluids from the body.		Sterile Single-use Syringe with Needle is intended to inject fluids into or withdraw fluids from the body.		Same
Product code	FMF		FMF		Same
Regulation number	21 CFR 880.5860		21 CFR 880.5860		Same
Class	II		II		Same
Principle of operation	For manual use only		For manual use only		Same
Needle gauge	16G, 18G, 20G, 21G, 22G, 23G, 24G, 25G, 26G, 27G, 29G, 30G,		18G, 20G, 21G, 22G, 23G, 25G, 26G, 27G, 28G, 29G, 30G		Difference 1
Needle Length	5/16", 1/2", 3/5", 4/5", 1", 1 1/6", 1 1/4", 1 3/10", 1 1/2"		1/2", 5/8", 1", 1 1/4", 1 1/2"		
Syringe Volume	1ml、2ml、3ml、5ml、10ml、20ml、30ml、50ml、60ml		1ml, 3ml, 5ml, 10ml, 20ml, 60ml		
Connector Type	Luer Slip and Luer Lock		Luer Slip and Luer Lock		Same
main structure and materials	Barrel	Polypropylene	Barrel	Polypropylene (PP)	Same
	Plunger	Polypropylene	Plunger	Polypropylene (PP)	
	Piston	Polyisoprene	Piston	Polyisoprene	
	Needle tube	Stainless steel	Needle tube	Stainless Steel, SUS304	
	Hub	Polypropylene	Needle hub	Polypropylene (PP)	
	Needle cap	Polypropylene	Needle cap	Polypropylene (PP)	
Performance specifications	Complies with ISO 7886-1		Complies with ISO 7886-1		Same
Single Use	Yes		Yes		Same

Device feature	Subject Device		Predicate Device K163161		Comment
Sterilization	EO Sterilization		EO Sterilization		Same
SAL	10^{-6}		10^{-6}		Same
Biocompatibility	Cytotoxicity	No cytotoxicity	Cytotoxicity	No cytotoxicity	Same
	Intracutaneous reactivity	No intracutaneous reactivity	Irritation	No intracutaneous reactivity	Same
	Sensitization	No skin sensitization	Sensitization	No skin sensitization	Same
	Systemic Toxicity	No systemic toxicity	Systemic Toxicity	No systemic toxicity	Same
	Hemolysis	No Hemolysis	Hemolysis	No Hemolysis	Same
	Pyrogen	No Pyrogen	Pyrogen	No Pyrogen	Same
Labeling	Complied with 21 CFR part 801		Complied with 21 CFR part 801		Same

Difference 1

The syringe volume, needle gauge and length of subject devices are different from the predicate device. However, this difference is just in dimension. Different needle specification will be selected by physician per patient's condition. This difference does not affect intended use. In addition, differences were addressed through ISO 7886-1, ISO 7864, ISO 9626 and ISO 80369-7. Therefore, the differences on syringe volume, needle gauge and length do not raise different question of 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 syringes 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	USP <788>

Sterilization and shelf life testing

The sterilization method has been validated to ISO11135, which has thereby determined the routine control and monitoring parameters. Bacteria Endotoxin Limit is carried out according to USP42-NF37 <85> Bacterial Endotoxins Test.

The testing is performed according to the following standards:

EO residue	ISO 10993-7:2008
ECH residue	ISO 10993-7:2008
Bacteria Endotoxin	USP42-NF37 <85>

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

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 testing is performed according to the following standards:

Seal strength	ASTM F88/F88M-15
Seal integrity	ASTM F 1929-2015

Performance testing

Performance testing is performed according to the following standards:

- ISO 7886-1: 2017

Appearance	Clause 5 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- 9.4 of ISO 7886-1:2017
Barrel flanges	Clause 10.2 of ISO 7886-1:2017
Plunger stopper / Plunger assembly	Clause 11 of ISO 7886-1:2017
Nozzle	Clause 12 of ISO 7886-1:2017 and ISO 80369-7
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	Clause 4.10 of ISO 7864: 2016 and ISO 9626:2016
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

Leakage by pressure decay	Clause 6.1.2 of ISO 80369-7: 2021
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

Stiffness	Clause 5.8 of ISO 9626:2016
Resistance to breakage	Clause 5.9 of ISO 9626:2016

VIII Conclusion

The Sterile hypodermic syringes for single use are substantially equivalent to its predicate devices. The non-clinical testing demonstrates that the device is as safe, as effective and performs as well as the legally marketed device.