October 14, 2021

Jiangxi Hongda Medical Equipment Group Ltd.
℅ Diana Hong
General Manager
Mid-Link Consulting Co., Ltd
P.O.box 120-119
Shanghai, 200120
China

Re: K211753
Trade/Device Name: Sterile Syringe with Safety Needle
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: Class II
Product Code: FMF, FMI, MEG
Dated: September 8, 2021
Received: September 14, 2021

Dear Diana Hong:

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K211753

Device Name
Sterile Syringe with Safety Needle

Indications for Use *(Describe)*
The Sterile Syringe with Safety Needle is 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 needle sticks.

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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K211753.510KSummary

1. Date of Preparation: 10/14/2021

2. Sponsor Identification

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3. Designated Submission Correspondent

Ms. Diana Hong (Primary Contact Person)
Ms. Ying Xu (Alternative Contact Person)

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Fax: 360-925-3199
Email: info@mid-link.net

4. Identification of Subject Device: Trade Name: Sterile Syringe with Safety Needle
   Common Name: Safety Piston Syringe with Needle

   Classification Name: Syringe Antistick
   Classification: II
   Product Code: MEG
   Regulation Number: 21 CFR 880.5860
   Review Panel: General Hospital

   Classification Name: Piston Syringe
   Classification: II
   Product Code: FMF
   Regulation Number: 21 CFR 880.5860
   Review Panel: General Hospital

   Classification Name: Hypodermic single lumen needle
   Classification: II
   Product Code: FMI
   Regulation Number: 21 CFR 880.5570
   Review Panel: General Hospital

5. Predicate Device K193526, Syringe with Safety Needle

6. Device Description

   The Sterile Disposable Syringe with Safety Needle is intended for manual and single use only. It consists of a hypodermic needle with a safety sheath attached to the needle hub and a luer slip or luer lock syringe. The subject device is available in a variety of syringe volumes and needle sizes. The safety sheath is manually activated to cover the needle immediately after use to minimize risk of accidental needle sticks.

Gauge	Length	Wall Type
26G	13mm, 16mm	RW
25G	16mm, 25mm, 38mm	RW
24G	16mm, 25mm, 38mm	RW
23G	25mm, 32mm, 38mm	TW
22G	25mm, 32mm, 38mm	TW
21G	25mm, 32mm, 38mm	TW
20G	25mm, 32mm, 38mm	TW
18G	25mm, 32mm, 38mm	TW

7. 7. Indication for Use

Characteristics	**Subject Device**	**Predicate**

	Sterile Syringe with Safety Needle K211753	Syringe with Safety Needle K193526
Indication for Use	The Sterile Syringe with Safety Needle is 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 needle sticks.	The Sterile Disposable Syringe with Safety Needle is 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 needle sticks.
Prescription Only or Over the counter	Prescription Only	Prescription Only

8. Technological Characteristics

Table 1 Comparison of Technology Characteristics

ITEM	Subject Device K211753	Predicate Device K193526	Remark
Product Code	FMF FMI MEG	FMF FMI MEG	Same
Regulation No.	21 CFR 880.5860 21 CFR 880.5570	21 CFR 880.5860 21 CFR 880.5570	Same
Class	Class II	Class II	Same
Indication for Use	The Sterile Syringe with Safety Needle is 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 needle sticks.	The Sterile Disposable Syringe with Safety Needle is 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 needle sticks.	Same
Configuration	Barrel	Barrel	Same
	Plunger	Plunger	
	Piston	Piston	
	Needle hub	Needle hub	
	Protective cap	Protective cap	
	Needle tube	Needle tube	

	Safety sheath	Safety sheath	
Operation Mode	For manual use only	For manual use only	Same
Safety Feature	Slide over the needle to prevent from needle sticks	Slide over the needle to prevent from needle sticks	Same
Single Use	Yes	Yes	Same
Label/Labeling	Complies with 21 CFR part 801	Complies with 21 CFR part 801	Same
Syringe Volume	1ml, 3ml, 5ml, 10ml	1ml, 2ml, 3ml, 5ml, 10ml, 20ml, 30ml, 50ml, 60ml	Different/ See Comment #1
Connector Type	Luer Lock/ Luer slip	Luer Lock	Different/ See Comment #2
Syringe Performance	Complied with ISO 7886-1	Complied with ISO 7886-1	Same
Needle Gauge	18G, 20G, 21G, 22G, 23G, 24G, 25G, 26G	16G, 18G, 19G, 20G, 21G, 22G, 23G, 25G, 26G, 27G, 28G, 29G, 30G, 31G	Different/ See Comment #3
Needle Length	13mm, 16mm, 25mm, 32mm, 38mm	13mm, 16mm, 20mm, 25mm, 32mm, 38mm	Different/ See Comment #4
Wall Type	TW: 18G, 20G, 21G, 22G, 23G RW: 24G, 25G, 26G	TW: 16G, 18G, 19G, 20G, 21G, 22G, 23G, 25G, 26G, 27G, 28G, 29G, 30G, 31G RW: 16G, 18G, 19G, 20G, 21G, 22G, 23G, 25G, 26G, 27G, 28G, 29G, 30G, 31G	Different/ See Comment #5
Bevel Design	LB	LB/SB	Different/ See Comment #6
Needle Performance	Complies with ISO 7864 ISO 9626	Complies with ISO 7864 ISO 9626	Same
Luer Connector Performance	Complied with ISO 80369-7	Complied with ISO 80369-7	Same
Patient contact material			
Barrel	Polypropylene (PP)	Polypropylene (PP)	Same
Plunger	Polypropylene (PP)	Polypropylene (PP)	
Piston	Polyisoprene	Polyisoprene	
Needle tube	Stainless Steel, SUS304	Stainless Steel, SUS304	
Biocompatibility			
Cytotoxicity	Comply with ISO 10993 standards, biocompatibility was leveraged on the data of K163161	No cytotoxicity	Same
Irritation		No intracutaneous reactivity	
Sensitization		No skin sensitization	
Systemic Toxicity		No systemic toxicity	
Hemolysis		No Hemolysis	
Pyrogen		No Pyrogen	

Sterilization			
Method	EO Sterilized	EO Sterilized	Same
SAL	10^{-6}	10^{-6}	Same
Endotoxin Limit	20 EU per device	20 EU per device	Same

Comment 1 - Syringe Volume

The syringe specification for the subject device is less than the predicate device. However, the specification can be covered by the predicate device. In addition, the syringe performance has been tested and test results demonstrate that the syringe meets the requirements of ISO 7886. Therefore, this difference is not considered to affect substantial equivalence.

Comment 2 - Luer Connector

The subject device is available in luer slip and luer lock two types connectors and luer lock connector is not covered by the predicate device. However, the luer connector has been tested per ISO 80369-7 and the test results demonstrate that the luer connector meets the requirements of ISO 80369-7. Therefore, this difference is not considered to affect substantial equivalence.

Comment 3 - Needle Gauge

The subject device has the additional gauge 24G compared to the predicate device, while other gauges can be covered by the predicate device. The needle performance has been tested and results demonstrate that the needle meets the requirements of ISO 7864 and ISO 9626. Therefore, this difference is not considered to affect substantial equivalence.

Comment 4 - Needle Length

The length specification of the subject device is within the range covered by the predicate device. In addition, the needle performance has been tested and the results demonstrate that the syringe meets the requirements of ISO 7864 and ISO 9626. Therefore, this difference is not considered to affect substantial equivalence.

Comment 5 - Wall Type

The wall type of the subject device under the same needle gauge can be covered by the predicate device. In addition, the needle performance has been tested and results demonstrate that the syringe meets the requirements of ISO 7864 and ISO 9626. Therefore, this difference is not considered to affect substantial equivalence.

Comment 6 - Bevel Design

The bevel design of the subject device can be covered by the predicate device. In addition, the needle performance has been tested and the results demonstrate that the syringe meets the requirements of ISO 7864 and ISO 9626. Therefore, this difference is not considered to affect substantial equivalence.

9. Non-Clinical Test Conclusion

A. Syringe

The sterile, single piston syringe described in this summary were tested and demonstrated to be in conformance with the following FDA recognized standards:

- ISO 7886-1: 2017 Sterile Hypodermic Syringes for Single Use - Part 1: Syringes for Manual Use

B. Anti- Stick Needle

The Sterile Antistick Needles described in this summary were tested and demonstrated to be in conformance with the following FDA recognized standards:

- ISO 7864: 2016, Sterile Hypodermic Needles for Single Use.
- 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 80369-20: 2015 Small-bore connectors for liquids and gases in healthcare applications - Part 20: Common test methods
- ISO 23908: 2011 Sharps injury protection-Requirements and test methods-Sharp protection features for single-use hypodermic needles, introducers for catheters and needles used for blood sampling.

C. Biocompatibility

The patient contact materials of the subject device, Sterile Syringe with Safety Needle, are identical to the material of Sterile Single-Use Syringe With Needle as it was cleared in K163161in 03/20/2017. There are no differences in formulation, processing and sterilization, and no other chemicals have been added. (e.g., plasticizers, filters, color additives, cleaning agents, mold release agents, etc.). Therefore, new biocompatibility test was not conducted on the proposed device. Bacterial endotoxin limit and particulate testing were evaluated on the proposed device per following standards

- USP <85> Bacterial Endotoxins Test
- USP <788> Particulate Matter in Injections

D. Sterility, Shipping, and Shelf-life

The subject devices were sterilized by Ethylene Oxide Gas to achieve a SAL of 10^{-6} and the sterilization method was validated per over kill method as qualified in accordance ISO 11135:2014, Annex B.

Package integrity testing, after environmental conditioning and simulated transportation in accordance with ASTM D4169-16, was conducted on the final, packaged, and sterile devices. All packaging deemed acceptable for protection of product and sterility maintenance.

Sterile Barrier Packaging Testing performed on the subject device:

- Visual inspection ASTM F1886/1886M-16
- Seal strength ASTM F88/F88-15

- Dye penetration ASTM F1929-15

Shelf life of 3 years is validated using the FDA recognized standard ASTM F1980-16 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Device

The EO ECH residue testing was performed on the subject device:

- ISO 10993-7:2008 Biological Evaluation of Medical Devices-Part 7: Ethylene Oxide Sterilization Residuals.

10. Conclusions

The differences between the predicate and the subject device do not raise any new or different questions of safety or effectiveness. The Sterile Syringe with Safety Needle is substantially equivalent to the Syringe with Safety Needle with respect to the indications for use, target populations, treatment method, and technological characteristics.