December 17, 2021

Jiangsu Suyun Medical Material Co., Ltd.
% Diana Hong
General Manager
Mid-Link Consulting Co.,Ltd
P.O.box 120-119
Shanghai, 200120
China

Re: K210914
Trade/Device Name: Sterile Syringe for Single Use
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: Class II
Product Code: FMF
Dated: November 10, 2021
Received: November 17, 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,

CAPT Alan M. 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)*
K210914

Device Name
Sterile Syringe for Single Use

Indications for Use *(Describe)*
The Sterile Syringe for Single Use is intended for use by health care professionals for general purpose aspiration and injection of fluids.

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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Tab #6 510(k) Summary

This 510(k) Summary is being submitted in accordance with requirements of Title 21, CFR Section 807.92. The assigned 510(k) Number: ___K210914_____

1. Date of Preparation: 9/3/2021

2. Sponsor Identification

Jiangsu Suyun Medical Materials Co., Ltd.
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3. Designated Submission Correspondent

Ms. Diana Hong (Primary Contact Person)
Ms. Jing Cheng (Alternative Contact Person)

Mid-Link Consulting Co., Ltd
P.O. Box 120-119, Shanghai, 200120, China

Tel: +86-21-22815850,
Fax: 360-925-3199
Email: info@mid-link.net

4. Identification of Proposed Device

Trade Name: Sterile Syringe for Single Use
Common Name: Piston Syringe

Regulatory Information

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

Indication for Use Statement:
The Sterile Syringe for Single Use is intended for use by health care professionals for general purpose aspiration and injection of fluids.

Device Description

Syringe with needle
The Syringe with needle is intended for manual and single use only. It consists of six components 1) Barrel (luer lock or luer slip) 2) Plunger 3) Piston 4) Needle Tube 5) Protective Cap and 6) Needle Hub.

The proposed device is available in various combination of syringe volume, connector type (luer lock or luer slip), connector location (central type or eccentric type) and needle size.

Syringe without needle
The Syringe without needle is intended for manual and single use only. It consists of three components 1) Barrel (luer lock or luer slip) 2) Plunger and 3) Piston.

The proposed syringe is available in various combination of syringe volume, connector type (luer lock or luer slip), and connector location (central type or eccentric type).

The proposed device is sterilized by Ethylene Oxide to achieve a SAL of 10^{-6} and supplied in sterility maintenance package which could maintain the sterility of the device during the shelf life of 5 years.

5. Identification of Predicate Device

510(k) Number: K113241
Product Name: BD Emerald™, Single Use, Hypodermic Syringe

6. Non-Clinical Testing

Non-clinical tests were conducted to verify that the proposed device met all design specifications and is Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

- ISO 10993-5:2009 Biological evaluation of medical Devices-Part 5: Tests for in Vitro Cytotoxicity
- ISO 10993-10:2010 Biological evaluation of medical devices- Part 10: Test for irritation and skin sensitization
- ISO 10993-11:2017 Biological evaluation of medical devices- Part 11: Tests for systemic toxicity
- ISO 10993-4:2017 Biological Evaluation of Medical Devices--Part 4: Selection of Tests for Interactions with Blood
- ASTM F756-17 Standard Practice for Assessment of Hemolytic Properties of Materials
- USP<788> Particulate Matter for Injections (Method 1 Light Obscuration Particle Count Test)
- ASTM F88/F88M-15, Standard Test Method for Seal Strength of Flexible Barrier Materials. (Sterility)
- ASTM F1929-15 Standard Test Method for Detecting Seal Leaks in Porous Medical Package by Dye Penetration
- 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 6009:2016 Hypodermic needles for single use — Colour coding for identification
- 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 7886-1:2017 Sterile hypodermic syringes for single use- Part 1: Syringes for manual use

7. Clinical Test Conclusion

No clinical study is included in this submission.

8. Substantially Equivalent (SE) Comparison

Table 1 General Comparison of the Sterile Syringe for Single Use

ITEM	Proposed Device		Predicate Device K113241		Remark
Product	Sterile Syringe for Single Use		BD Emerald™, Single Use, Hypodermic Syringe		/
Product Code	FMF		FMF		Same
Regulation Number	21 CFR 880.5860		21 CFR 880.5860		Same
Class	Class II		Class II		Same
Indication for Use	The Sterile Syringe for Single Use is intended for use by health care professionals for general purpose aspiration and injection of fluids.		The BD Emerald™ Single Use, Hypodermic Syringe is intended for use by health care professionals for general purpose aspiration and injection of fluids.		Same
Components and materials	Barrel	Polypropylene (PP)	Barrel	Polypropylene (PP)	Different
	Plunger	Polypropylene (PP)	plunger	Polypropylene (PP)	
	Piston	Synthetic rubber	Piston	Unknown	
	Needle hub	Polypropylene (PP)	Needle hub	Polypropylene (PP)	
	Protective cap	Polypropylene (PP)	Protective cap	Unknown	
	Needle tube	Stainless Steel SUS304	Needle tube	Stainless Steel	
Operation Mode	For manual use only		For manual use only		Same
Single Use	Single Use		Single Use		Same
Label/Labeling	Complied with 21 CFR part 801		Complied with 21 CFR part 801		Same

Different - Components and materials

The components of the proposed device are same with the predicate device but the materials are not exactly the same. However, the proposed device had been tested for biocompatibility and the result does not show any adverse effect. Therefore, the difference on the proposed device doesn't raise new questions of safety and effectiveness.

Table 2 Performance Comparison of the Sterile Syringe for Single Use

ITEM		Proposed Device	Predicate Device K113241	Remark
Product		Sterile Syringe for Single Use	BD Emerald™, Single Use, Hypodermic Syringe	/
Syringe	Volume	1ml, 2ml, 5ml, 10ml, 20ml, 30ml, 50ml	2m1, 3ml, 5ml, l0ml	Different
	Connector Type	Luer Lock/ Luer Slip	Luer Lock/ Luer Slip	
	Connector location	Central/Eccentric	Central	
Needle	Gauge	22G	21G	Different
	Length	30mm, 32mm	40mm	
Syringe Performance		Complied with ISO 7886-1	Complied with ISO 7886-1	Same
Needle Performance		Complied with ISO 7864, ISO 9626	Complied with ISO 7864, ISO 9626	Same

Different - Syringe

The volume and connector location of proposed device is different from the predicate device. For the volume, the proposed device has more volumes, 1ml, 20ml, 30ml and 50ml. For the connector location, the proposed device has more connector locations. In addition, all specifications of proposed device had been tested for performance and the test results could meet the requirements according to ISO 7886-1:2017. The differences do not raise new questions of safety and effectiveness.

Different- Needle Gauge and Length

The needle gauge and length of the proposed device is different from the predicate device. However, the needle with a diameter of 0.7mm (21G) and a length of 30mm or 32mm are covered by the performance standards. The needles have been tested and the test results comply with related standards requirements. The differences do not raise new questions of safety and effectiveness.

Table 3 Safety Comparison of the Sterile Syringe for Single Use

ITEM	Proposed Device	Predicate Device K113241		Remark
Product	Sterile Syringe for Single Use	BD Emerald™, Single Use, Hypodermic Syringe		/
Patient-contact Material				
Barrel	Polypropylene (PP)	Barrel	Polypropylene (PP)	Different
Plunger	Polypropylene (PP)	Plunger	Polypropylene (PP)	
Piston	Synthetic rubber	Piston	Unknown	
Needle tube	Stainless Steel SUS304	Needle tube	Stainless Steel	
Needle hub	Polypropylene (PP)	Needle hub	Polypropylene (PP)	
Biocompatibility				
Cytotoxicity	No cytotoxicity	Conforms to ISO 10993 series standards		Different
Irritation	No intracutaneous reactivity			
Sensitization	No skin sensitization			
Systemic Toxicity	No systemic toxicity			
Hemolysis	No Hemolysis			
Pyrogen	No Pyrogen			
Sterilization	EO Sterilization	EO Sterilization		Same
SAL	10^{-6}	10^{-6}		Same
Endotoxin Limit	20 EU per device	20 EU per device		Same

Different- Patient-contact material

The patient-contact material of piston of the predicate device is unknown. However, the biocompatibility tests were conducted on the material consisted of the proposed device and the test result shows that the material are biocompatible.

9. Substantially Equivalent (SE) Conclusion

Based on the comparison and analysis above, the proposed device is determined to be Substantially Equivalent (SE) to the predicate device.