March 23, 2023

Shandong Weigao Group Medical Polymer Co., Ltd.
% Diana Hong
General Manager
Mid-Link Consulting Co.,Ltd
P.O.box 120-119
Shanghai, 200120
China

Re: K212207
Trade/Device Name: Sterile Hypodermic Syringe with needle for Single Use
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: Class II
Product Code: FMF, FMI
Dated: November 15, 2022
Received: February 21, 2023

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)*
K212207

Device Name
Sterile Hypodermic Syringe with needle for Single Use

Indications for Use *(Describe)*
The Sterile Hypodermic Syringe with needle, for Single Use is intended to be used for medical purposes to inject fluid into 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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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: K212207

1. Date of Preparation: 3/18/2023

2. Sponsor Identification

Shandong Weigao Group Medical Polymer Co., Ltd.
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3. Designated Submission Correspondent

Ms. Diana Hong (Primary Contact Person)
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4. Identification of Proposed Device

Trade Name: Sterile Hypodermic Syringe with needle for Single Use
Common Name: Syringe, Piston

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

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

Indication for use:
The Sterile Hypodermic Syringe with needle, for Single Use is intended to be used for medical purposes to inject fluid into body.

Patient population:
The patient population of the proposed device is very wide, and it is suitable for all populations. Based on CDRH Premarket Review Submission Cover Sheet (FORM FDA 3514), Section D, the "Intended Use Population" has been updated as following:
Adults and Pediatrics
Neonate/Newborn (birth through 28 days)
Infant (from 29 days to 2 years of age)
Child (from 2 years to 12 years of age)
Adolescent (from 12 years to 18 years of age)
Transitional Adolescent A (18 through 21 years of age)
Transitional Adolescent B (18 through 21 years of age)

Device Description
The Sterile Hypodermic Syringe for Single Use is intended for manual and single use only to aspirate and inject of fluids for medical purpose, which consists of a hypodermic needle and a luer lock syringe. The proposed device is available in a variety combination of syringe volume and needle gauge (refer to Table 1).

Table 1 Combinations of syringe and needles configurations of the proposed device

1mL luer Lock Syringe with 18G×1-1/2″ Needle

1mL luer Lock Syringe with 23G×1″ Needle
1mL luer Lock Syringe with 23G×1-1/4″ Needle
1mL luer Lock Syringe with 25G×3/4″ Needle
1mL luer Lock Syringe with 25G×1″ Needle
1mL luer Lock Syringe with 25G×1-1/2″ Needle
1mL luer Lock Syringe with 26G×5/8″ Needle
1mL luer Lock Syringe with 27G×1/2″ Needle
30mL luer Lock Syringe with 18G×1-1/2″ Needle
30mL luer Lock Syringe with 23G×1″ Needle
30mL luer Lock Syringe with 23G×1-1/4″ Needle
30mL luer Lock Syringe with 25G×3/4″ Needle
30mL luer Lock Syringe with 25G×1″ Needle
30mL luer Lock Syringe with 25G×1-1/2″ Needle
30mL luer Lock Syringe with 26G×5/8″ Needle
30mL luer Lock Syringe with 27G×1/2″ Needle

5. Identification of Predicate Device

510(k) Number: K190002
Product Name: Sterile Hypodermic Syringe for Single use, with/without needle

6. Non-Clinical Test Conclusion

Non-clinical tests were conducted to verify that the proposed device met all design specifications as was 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
- ASTM F1886 / F1886M-16, Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection
- 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 80369-7:2016 Small-bore connectors for liquids and gases in healthcare applications-Part 7: Connectors for intravascular or hypodermic applications
- ISO 7886-1:2017 Sterile hypodermic syringes for single use- Part 1: Syringes for manual use

- ISO 10993-7:2008 Biological Evaluation of Medical Devices-Part 7: Ethylene Oxide Sterilization Residuals
- USP <85> Bacterial Endotoxins Test
- USP<788> Particulate Matter in Injections

7. Clinical Test Conclusion

No clinical study is included in this submission.

8. Substantially Equivalent (SE) Comparison

Table 2 Comparison of Technology Characteristics for Sterile Hypodermic Syringe for Single Use

ITEM	Proposed Device		Predicate Device K190002		Remark
Product	Sterile Hypodermic Syringe for Single Use		Sterile Hypodermic Syringe for Single use, with/without needle		/
Product Code	FMF, FMI		FMF, FMI		Same
Regulation Number	21 CFR 880.5860		21 CFR 880.5860		Same
Class	Class II		Class II		Same
Indication for Use	The Sterile Hypodermic Syringe with needle, for Single Use is intended to be used for medical purposes to inject fluid into 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.		Difference 1
Configuration and material	Barrel	Polypropylene	Barrel	Polypropylene	Difference 2
	Plunger	Polypropylene	plunger	Polypropylene	
	Piston	Polyisoprene rubber	Piston	Isoprene Rubber	
	Needle hub	Polypropylene	Needle hub	Polypropylene	
	Protective cap	Polypropylene	Protective cap	Polypropylene	
	Needle tube	Stainless Steel 304	Needle tube	SUS304	
Operation Mode	For Manual Use Only, For Single Use only		For Manual Use Only, For Single Use only		Same
Environment of use	Hospital		Hospital		Same
Intended users	Medical professionals and trained care givers		Medical professionals and trained care givers		Same
Single Use	Single Use		Single Use		Same
Label/Labeling	Complied with 21 CFR part 801		Complied with 21 CFR part 801		Same
Syringe	Volume	1ml, 30ml	1ml, 3ml, 5ml, 6ml, 10ml, 20ml, 30ml, 35ml, 50ml and 60 ml		Difference 3
	Connector Type	Luer Lock	Luer Lock/ Luer Slip		
	Piston Type	Conical/Flat Piston	Conical/Flat Piston		Same
Needle	Gauge	18G, 23G, 25G, 26G, 27G	18G, 19G, 20G, 21G, 22G, 23G, 24G, 25G, 26G, 27G, 28G, 29G, 30G		Difference 4
	Length	21-45.5mm	4–38 mm		
Syringe	Complied with ISO 7886-1		Complied with ISO 7886-1		Same

Performance			
Needle Performance	Complied with ISO 7864, ISO 9626	Complied with ISO 7864, ISO 9626	Same
Biocompatibility			
Cytotoxicity	No cytotoxicity	No cytotoxicity	Difference 5
Irritation	No intracutaneous reactivity	No intracutaneous reactivity	
Sensitization	No skin sensitization	No skin sensitization	
Systemic Toxicity	No systemic toxicity	No systemic toxicity	
Pyrogen	No Pyrogen	No Pyrogen	
Subacute Toxicity	No Subacute Toxicity	No Subacute Toxicity	
Complement Activation	No potential activator of the complement system	Unknown	
Sterilization			
Method	EO Sterilized	EO Sterilized	Same
SAL	10^{-6}	10^{-6}	
Endotoxin Limit	20 EU per device	20 EU per device	

Difference 1 – Indication for Use
The indication for use for proposed device is different from the predicate device. However, the indication for use of the proposed device is covered by that of the predicate device. Therefore, this difference does not impact the safety and effectiveness of the proposed device.

Difference 2 - Configuration and material
The proposed device has the same configurations as the predicate device K190002. However, some of the configuration materials for proposed device are different from predicate device. This difference does not raise new questions of safety and effectiveness for the proposed device. Biocompatibility test for proposed device was performed and the test result does not show any adverse effect.

3 - Syringe Volume and Connector type
The syringe volume for proposed device is different from the predicate device. However, the predicate device includes 1ml and 30ml syringe. Therefore, this difference on syringe volume does not affect the safety and effectiveness of the proposed device.
The syringe connector type for proposed device is different from the predicate device. However, the predicate device includes type of luer lock. Therefore, this difference on syringe connector type does not affect the safety and effectiveness of the proposed device.

Difference 4 - Needle Gauge and Length
The needle gauge of proposed device is covered by that of the predicate device. The length for proposed device is different from the predicate device K190002. This difference does not raise new questions of safety and effectiveness of the proposed device.

Difference 5 - Biocompatibility
The Biocompatibility test items for the proposed device is different from the predicate device K190002. Considering the test results of biocompatibility testing demonstrate that this difference does not affect the safety and effectiveness between the proposed device and predicate device.

9. Substantially Equivalent (SE) Conclusion

Based on the comparison and analysis above, the proposed device, Sterile Hypodermic Syringe with needle for Single Use, is determined to be Substantially Equivalent (SE) to the predicate device K190002.