October 4, 2022

Sichuan Prius Biotechnology Co., Ltd.
% Diana Hong
General Manager
Mid-Link Consulting Co., Ltd
P.O.box 120-119
Shanghai, 200120
China

Re: K221068
Trade/Device Name: Sterile Hypodermic Syringes for Single Use with Needles
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: Class II
Product Code: FMF, FMI
Dated: August 26, 2022
Received: September 8, 2022

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 and Part 809); 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 Stevens
Assistant Director
Injection Team
Devision of Drug Delivery and General Hospital and General Hospital Devices
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)*
K221068

Device Name
Sterile Hypodermic Syringes for Single Use with Needles

Indications for Use *(Describe)*
The Sterile Hypodermic Syringes for Single Use with Needles is intended for use in the aspiration and injection of fluids for medical purpose.

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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K221068 -510(k) Summary

1. Date of Preparation: 10/08/2022

2. Sponsor Identification

Sichuan Prius Biotechnology Co., Ltd.
No.2 Prius Road, Luo Long Industrial Park Nanxi District, 644104 Yibin City, Sichuan Province, PEOPLE'S REPUBLIC OF CHINA

Establishment Registration Number: Not registered yet

Contact Person: Yan Liu
Position: Management Representative
Tel: +86-831-3839889
Fax: +86-831-3839887
Email: 48363603@qq.com

3. Designated Submission Correspondent

Ms. Diana Hong (Primary Contact Person)
Ms. Tingting Su (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 Hypodermic Syringes for Single Use with Needles
Common Name: Syringe with Needle

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

Classification Name: Hypodermic, Syringe Lumen
Classification: II;
Product Code: FMI;
Regulation Number: 21CFR 880.5570;
Review Panel: General Hospital;

5. Identification of Predicate Device

Predicate Device
510(k) Number: K211329
Product Name: Sterile Disposable Syringes with Needles

6. Device Description

The Sterile Hypodermic Syringes for Single Use with Needles is intended for manual and single use only to aspirate and inject of fluids for medical purpose, which consists of piston, barrel, plunger and a hypodermic needle. The proposed device is available in a variety combination of syringe volume and needle size.

Syringe Volume	Needle Sizes		
	Needle Length (mm)	Needle gauge	Wall
1ml,	32	16G	TW
2ml,	38	16G	TW
3ml,	32	18G	TW
5ml,	38	18G	TW
10ml,	32	19G	TW
20ml,	38	19G	TW
30ml,	32	20G	TW
50ml,	38	20G	TW

60ml, 100ml	32	21G	TW
	38	21G	TW
	32	22G	TW
	38	22G	TW
	19	23G	TW
	25	23G	TW
	32	23G	TW
	19	24G	RW
	25	24G	RW
	32	24G	RW
	16	25G	RW
	19	25G	RW
	25	25G	RW
	13	26G	RW
	16	26G	RW
	19	26G	RW
	13	27G	RW
	16	27G	RW
	19	27G	RW
	13	28G	RW
	16	28G	RW
	13	29G	RW
	16	29G	RW
	13	30G	RW
	16	30G	RW

All gauges can be used with 1mL, 2mL, 3mL, 5mL, 10mL, 20mL, 30mL, 50mL, 60mL, 100mL syringe.

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

7. Indication for Use:

Characterization	Proposed device Sterile Hypodermic Syringes for Single Use with Needles K221068	Predicate Device Sterile Disposable Syringe with Needle K211329
Indication for Use	The Sterile Hypodermic Syringes for Single Use with Needles is	The Sterile Disposable Syringe with Needle is intended for use in the

	intended for use in the aspiration and injection of fluids for medical purpose.	aspiration and injection of fluids for medical purpose.
Prescription or OTC (over the counter)	Prescription use	Prescription use

8. Technology Characteristics

The table below includes a comparison of the technological characteristics between the new device and those of the predicate.

Table 1 Comparison of Technology Characteristics

Technological Characteristic	Proposed Device Sterile Hypodermic Syringes for Single Use with Needles K221068	Predicate Device Sterile Disposable Syringe with Needle K211329	Remark
Configuration	Barrel	Barrel	Same
	Plunger	Plunger	
	Piston	Piston	
	Needle hub	Needle hub	
	Protective cap	Protective cap	
	Needle	Needle	
Operation Mode	For manual use only	For manual use only	Same
Single Use	Single Use	Single Use	Same
Volume	1ml, 2ml, 3ml, 5ml, 10ml, 20ml, 30ml, 50ml, 60ml, 100ml	1ml, 2ml, 3ml, 5ml, 10ml, 20ml, 30ml, 50ml, 60ml	Different See comment #1
Connector Type	Luer Lock/ Luer Slip	Luer Lock/ Luer Slip	Same
Syringe Performance	Complied with ISO 7886-1	Complied with ISO 7886-1	Same
Luer Connector Performance	Complied with ISO 80369-7	Complied with ISO 80369-7	Same
Needle Performance	Complied with ISO 7864, ISO 9626	Complied with ISO 7864, ISO 9626	Same
Needle Gauge	16G, 18G, 19G, 20G, 21G,	23G	Different

	22G, 23G, 24G, 25G, 26G, 27G, 28G, 29G, 30G		See comment #2
Needle Length	13mm, 16mm, 19mm, 25mm, 32mm, 38mm	13mm, 16mm, 20mm, 25mm, 32mm, 38mm	Different See comment #3
Wall type	TW: 16G, 18G, 19G, 20G, 21G, 22G, 23G RW: 24G, 25G, 26G, 27G, 28G, 29G, 30G	TW	Different See comment #4
Bevel Design	LB/SB	LB/SB	Same
Syringe Hubs	Central/Eccentric	Central/Eccentric	Same
Material			
Barrel	Polypropylene (PP)	Polypropylene (PP)	Same
Plunger	Polypropylene (PP)	Polypropylene (PP)	Same
Piston	Polyisoprene	Polyisoprene	Same
Needle	Stainless Steel SUS304	Stainless Steel SUS304	Same
Needle hub	Polypropylene (PP)	Polypropylene (PP)	Same
Needle cap	Polypropylene (PP)	Polypropylene (PP)	Same
Lubricants	Polydimethylsiloxane	Silicone oil	Different See comment #5
Adhesive	Epoxy adhesive	UV adhesive	Different See comment #5

Discussions of differences in technological characteristics

Comment #1 – Syringe Volume

The proposed device has the additional 100ml syringe volume which is out of the volume range of predicate device. This does not change the intended use and does not raise new questions of safety and effectiveness. In addition, the syringe performance has been tested and test results demonstrate that the syringe meets the requirements of ISO 7886.

Comment #2 – Needle Length

The range of needle lengths is the same as the predicate. The predicate device does not have a 19mm needle length. This difference is not a new intended use and does not raise new questions of safety and

effectiveness. In addition, the needle performance has been tested and the results demonstrate that the needle meets the requirements of ISO 7864 and ISO 9626.

Comment #3– Needle Gauge
The subject device has the more gauges compared to the predicate device. This difference is not a new intended use and does not raise new questions of safety and effectiveness. In addition, all the needle gauges of proposed device has been tested. The needle performance has been tested and results demonstrate that the needle meets the requirements of ISO 7864 and ISO 9626. Therefore, this difference will not raise new questions on safety and effectiveness of the proposed device.

Comment #4– Wall Type
The proposed device is available in thin wall and normal wall two types, the predicate device only has thin wall type. This difference is not a new intended use and does not raise new questions of safety and effectiveness. In addition, the all the wall type of proposed device has been tested and results demonstrate that the needle meets the requirements of ISO 7864 and ISO 9626.

Comment #5– Material of Lubricants and Adhesive
The proposed device has different adhesive and lubricants material compared to the predicate device However, biocompatibility test has been conducted on the proposed device and the test result does not show any adverse effect. This difference is not a new intended use and does not raise new questions of safety and effectiveness.

9. Non-Clinical Test Conclusion

The device described in this summary Sterile Hypodermic Syringes for Single Use with Needles, 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
- 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 7864: 2016, Sterile Hypodermic Needles for Single Use.
- ISO 9626:2016 Stainless Steel Needle Tubing for the Manufacture of Medical Devices

<u>Biocompatibility</u>
In accordance with ISO10993-1 the device are classified as: Externally Communicating Device, Blood Path Indirect, Limited Contact (< 24hrs). The following testing was conducted:

- Cytotoxicity
- Irritation
- Skin Sensitization

- Acute Systemic Toxicity
- Pyrogenicity
- Hemolysis
- Material Mediated Toxicity

Particulate matter testing was conducted in accordance with USP <788> Particulate Matter in Injections and met the USP acceptance criteria.

Sterility, Shipping, and Shelf -life

The proposed device sterilization process using Ethylene Oxide (EO) has been validated in accordance with ISO 11135:2014 to achieve a sterility assurance level (SAL) of 10^{-6}. EO and Ethylene Chlorohydrin (ECH) residuals were below the limits specified in ISO 10993-7:2008. Bacterial Endotoxin Levels were below the level of 20 EU/device in accordance with USP <85>. Both baseline and accelerated shelf life testing were conducted demonstrating the device will perform as intended to support the proposed 5 year shelf-life.

- Sterile Barrier Packaging performed on the proposed device:
  - Visual Inspection ASTM F1886 / F1886M-16
  - Seal Strength ASTM F88/F88-15
  - Dye penetration ASTM F1929-15
- Simulated transportation testing in accordance to ASTM D4169-16 on final, packaged, and sterile device.
- Shelf-life of 5-years is validated using FDA recognized standard ASTM F1980-16 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices.

10. Clinical Test Conclusion

No clinical study is included in this submission.

11. Conclusion

The differences between the predicate and the subject device do not raise any new or different questions of safety or effectiveness. The Sterile Hypodermic Syringes for Single Use with Needles is as safe, as effective, and performs as well as the legally marketed predicate device cleared under K211329.