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

October 4, 2022

Re: K221079
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 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); 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
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)*
K221079

Device Name
Sterile Hypodermic Syringes for Single Use

Indications for Use *(Describe)*
The Sterile Hypodermic Syringes for Single Use are intended to be used for medical purpose to inject fluid into or withdraw fluid from 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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K221079 -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

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3. Designated Submission Correspondent

Ms. Diana Hong (Primary Contact Person)
Ms. Tingting Su (Alternative Contact Person)

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

4. Identification of Proposed Device

Trade Name: Sterile Hypodermic Syringes for Single Use
Common Name: Syringe

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

5. Identification of Predicate Device

510(k) Number: K180417
Product Name: Sterile Hypodermic Syringes for Single Use

6. Device Description

The Sterile Disposable Syringe is intended for manual and single use only, which consists of barrel, plunger and piston. The syringe is available in luer slip and luer lock two connector types which are intended to be connected with a hypodermic needle. The proposed device is available in a variety syringe volume. Syringe volume: 1ml, 2ml, 3ml, 5ml, 10ml, 20ml, 30ml, 50ml, 60ml, 100ml

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

The Sterile Hypodermic Syringes for Single Use are intended to be used for medical purpose to inject fluid into or withdraw fluid from body.

Characterization	Proposed device Sterile Hypodermic Syringes for Single Use K221079	Predicate Device Sterile Hypodermic Syringes for Single Use K180417
Indication for Use	The Sterile Hypodermic Syringes for Single Use are intended to be used for medical purpose to inject fluid into or withdraw fluid from body.	The Sterile Hypodermic Syringes for Single Use are intended to be used for medical purpose to inject fluid into or withdraw fluid from body.

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 K221079	Predicate Device Sterile Hypodermic Syringes for Single Use K180417	Remark
Configuration	Barrel	Barrel	Same
	Plunger	Plunger	
	Piston	Piston	
Operation Mode	For manual use only	For manual use only	Same
Single Use	Single Use	Single Use	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
Volume	1ml, 2ml, 3ml, 5ml, 10ml, 20ml, 30ml, 50ml, 60ml, 100ml	1ml, 2ml, 3ml, 5ml, 10ml, 20ml, 30ml, 50ml	Different See comment # 1
Connector Type	Luer Lock/ Luer Slip	Luer Lock/ Luer Slip	Same
Barrel	Polypropylene (PP)	Polypropylene (PP)	Same
Plunger	Polypropylene (PP)	Polypropylene (PP)	Same
Piston	Polyisoprene	Polyisoprene	Same
Lubricants	Polydimethylsiloxane	Polydimethylsiloxane	Same

Discussions of differences in technological characteristics

Comment #1– Syringe Volume

The proposed device has the additional 60ml and 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.

9. Non-Clinical Test Conclusion

The device described in this summary the Sterile Hypodermic Syringes for Single Use, 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

Biocompatibility

In accordance with ISO10993-1 the syringe 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

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 20EU/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 ASTMD4169-16 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 is as safe, as effective, and performs as well as the legally marketed predicative device cleared under K180417.