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: K221080
Trade/Device Name: Sterile Safety Hypodermic Needles for Single Use
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic single lumen needle
Regulatory Class: Class II
Product Code: FMI
Dated: August 25, 2022
Received: September 6, 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)*
K221080

Device Name
Sterile Safety Hypodermic Needles for Single Use

Indications for Use *(Describe)*
The Sterile Safety Hypodermic Needles for Single Use are intended to be used with a luer slip or luer lock syringe for 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 needlestick.

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.

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K221080 -510(k) Summary

1. Date of Preparation: 10/08/2022

2. Sponsor Identification

Sichuan Prius Biotechnology Co., Ltd.
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3. Designated Submission Correspondent

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

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4. Identification of Proposed Device

Trade Name: Sterile Safety Hypodermic Needles for Single Use
Common Name: Safety Needle

Regulatory Information

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

5. Identification of Predicate Device

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

6. Device Description

The Sterile Safety Hypodermic Needles for Single Use is intended for manual and single use only to aspirate and inject of fluids for medical purpose which consists of 1) Needle, 2) Safety shield, 3) Protective Cap, 4) Needle Hub. The proposed device is available in a variety needle length and needle gauge. The proposed device is compatible for use with a luer slip or luer lock syringe. After withdrawal of the needle from the body, the attached needle safety mechanism can be manually activated to cover the needle immediately after use to minimize risk of accidental needlesticks.
Needle specification:

Needle Sizes		
Needle Length	Needle gauge	Wall
32mm	16G	TW
38mm	16G	TW
32mm	18G	TW
38mm	18G	TW
32mm	19G	TW
38mm	19G	TW
32mm	20G	TW
38mm	20G	TW
32mm	21G	TW
38mm	21G	TW
32mm	22G	TW
38mm	22G	TW

19mm	23G	TW
25mm	23G	TW
32mm	23G	TW
19mm	24G	RW
25mm	24G	RW
32mm	24G	RW
16mm	25G	RW
19mm	25G	RW
25mm	25G	RW
13mm	26G	RW
16mm	26G	RW
19mm	26G	RW
13mm	27G	RW
16mm	27G	RW
19mm	27G	RW
13mm	28G	RW
16mm	28G	RW
13mm	29G	RW
16mm	29G	RW
13mm	30G	RW
16mm	30G	RW

7. Indication for Use

Characterization	Proposed device Sterile Safety Hypodermic Needles for Single Use K221080	Predicate Device Sterile Safety Hypodermic Needles for Single Use K180417
Indication for Use	The Sterile Safety Hypodermic Needles for Single Use are intended to be used with a luer slip or luer lock syringe for 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 needlestick.	The Sterile Safety Hypodermic Needles for Single Use are intended to be used with a luer slip or luer lock syringe for 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 needlestick.
Prescription or OTC (over the counter)	Prescription use	Prescription use

8. Technological 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 Safety Hypodermic Needles for Single Use K221080	Predicate Device Sterile Safety Hypodermic Needles for Single Use K180417	Remark
Configuration	Needle hub	Needle hub	Same
	Protective cap	Protective cap	
	Needle	Needle	
	Safety shield	Safety shield	
Operation Mode	For manual use only	For manual use only	Same
Single Use	Single Use	Single Use	Same
Needle Performance	Complied with ISO 7864, ISO 9626	Complied with ISO 7864, ISO 9626	Same
Needle Gauge	16G, 18G, 19G, 20G, 21G, 22G, 23G, 24G, 25G, 26G, 27G, 28G, 29G, 30G	18G, 19G, 20G, 21G, 22G, 23G, 24G, 25G, 26G, 27G	See comment # 1
Needle Length	13mm, 16mm, 19mm, 25mm, 32mm, 38mm	12mm, 13mm, 16mm, 20mm, 25mm, 30mm, 32mm, 38mm, 40mm	See comment # 2
Wall type	TW: 16G, 18G, 19G, 20G, 21G, 22G, 23G RW: 24G, 25G, 26G, 27G, 28G, 29G, 30G	TW: 18G, 19G, 20G, 21G, 22G, 23G RW: 20G, 21G, 22G, 23G, 24G, 25G, 26G, 27G	See comment # 3
Material			
Needle	Stainless Steel SUS304	Stainless Steel SUS304	Same
Needle hub	Polypropylene (PP)	Polypropylene (PP)	Same
Needle cap	Polypropylene (PP)	Polypropylene (PP)	Same
Safety shield	Polypropylene (PP)	Polypropylene (PP)	Same
Lubricants	Polydimethylsiloxane	Polydimethylsiloxane	Same
Adhesive	Epoxy adhesive	HTU-3312 Glue	See comment #4

Discussions of differences in technological characteristics

Comment # 1– Needle Gauge

The proposed device has the additional gauge 16G, 28G, 29G and 30G compared to the predicate device, while other gauges can be covered by the predicate device. The differences do not impact the intended use and do not raise new questions of safety and effectiveness. The needle performance has been evaluated and test results comply with ISO 7864 and ISO 9626.

Comment #2 – Needle Length

The proposed device has less needle lengths compared to the predicate device and the proposed needle length specifications can be covered by the predicate device. 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 – Wall Type

The proposed device is available in thin wall and normal wall. The predicate device also has thin wall and normal wall. The needle gauge of the proposed device and the predicate device is different under the same wall thickness. However, all the wall type and needle gauge of proposed device has been tested and results demonstrate that the needle meets the requirements of ISO 7864 and ISO 9626.

Comment #4– Material of Adhesive

The proposed device has different adhesive compared to the predicate device. This difference does not impact the intended use and does not raise new questions of safety and effectiveness. Biocompatibility testing has been conducted on the proposed device and the test results do not show any adverse effect.

9. Non-Clinical Test Conclusion

The device described in this summary the Sterile Safety Hypodermic Needles for Single Use were tested and demonstrated to be in conformance with the following FDA recognized standards:

- 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

Simulated Clinical Study

A simulated clinical study was performed on proposed device according to FDA Guidance, Guidance for Industry and FDA Staff: Medical Device with Sharps Injury Prevention Feature, issued on August 9, 2005 and ISO 23908:2011 to evaluate the safety mechanism of the proposed device. The results demonstrated that the proposed device met the pre-established criteria.

Safety Feature Test

The safety feature test was performed on both proposed device and predicate device to determine its safety feature. The results demonstrated that both the proposed device and predicate device meet the acceptance criteria.

Biocompatibility testing

In accordance with ISO10993-1 the syringe and needle 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.

- Simulated transportation testing in accordance to ASTM D4169-16 on final, packaged, and sterile device.
- 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
- 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 Safety Hypodermic Needles for Single Use is as safe, as effective, and performs as well as the legally marketed predicate device cleared under K180417.