November 21, 2022

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

Re: K221078
Trade/Device Name: Intravenous Needles for Single Use, Safety Intravenous Needles for Single Use
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: Class II
Product Code: FPA
Dated: October 21, 2022
Received: October 21, 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,

David Wolloscheck, Ph.D.
For Joyce M. Whang, Ph.D.
Acting 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)*
K221078

Device Name
Intravenous Needles for Single Use, Safety Intravenous Needles for Single Use

Indications for Use *(Describe)*
Intravenous Needle for Single Use is intended to administer fluid by using an infusion set to a patient's vascular system through the needle inserted into the vein.

Safety Intravenous Needle for Single Use is intended to administer fluid by using an infusion set to a patient's vascular system through the needle inserted into the vein, and the safety sheath is designed to prevent accidental needle sticks.

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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K221078 - 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: K221078

1. Date of Preparation: 11/21/2022

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

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4. Identification of Proposed Device

Trade Name: Intravenous Needles for Single Use,
Safety Intravenous Needles for Single Use
Common Name: Intravascular Administration Set

Regulatory Information
Classification Name: Intravascular Administration Set
Classification: II
Product Code: FPA
Regulation Number: 21CFR 880.5440
Review Panel: General Hospital;

Indications for Use Statement:

Intravenous Needle for Single Use is intended to administer fluid by using an infusion set to a patient's vascular system through the needle inserted into the vein.

Safety Intravenous Needle for Single Use is intended to administer fluid by using an infusion set to a patient's vascular system through the needle inserted into the vein, and the safety sheath is designed to prevent accidental needle sticks

Device Description
The proposed devices are intended to administer fluid by using an infusion set to a patient's vascular system through the needle inserted into the vein. It has two models, Intravenous Needle for Single Use and Safety Intravenous Needle for Single Use. For the Safety Intravenous Needle for Single Use, the safety sheath is designed to prevent accidental needlesticks. The proposed devices are provided sterile, single use.
The Intravenous Needle for Single Use consists of six components, 1) infusion needle 2) needle handle 3) flexible tube 4) needle protective cover 5) conical fitting 6) conical fitting protective cap. The Safety Intravenous Needle for Single Use consists of seven components, 1) infusion needle 2) needle handle 3) flexible tube 4) needle protective cover 5) conical fitting 6) conical fitting protective cap 7) Safety Sheath.

5. Identification of Predicate Device

510(k) Number: K152323
Product Name: Disposable Infusion Needle,
Safelock Disposable Infusion Needle

6. Substantially Equivalent (SE) Comparison

Table 1 Comparison of Technology Characteristics

ITEM	Proposed Device	Predicate Device K152323	Remark
Product	Intravenous Needle for Single Use Safety Intravenous Needle for Single Use	Disposable Infusion Needle, Safelock Disposable Infusion Needle	/
Product Code	FPA	FPA	Same
Regulation Number	21 CFR 880.5440	21 CFR 880.5440	Same
Class	Class II	Class II	Same
Indication for Use	Intravenous Needle for Single Use is intended to administer fluid by using an infusion set to a patient's vascular system through the needle inserted into the vein. Safety Intravenous Needle for Single Use is intended to administer fluid by using an infusion set to a patient's vascular system through the needle inserted into the vein, and the safety sheath is designed to prevent accidental needle sticks.	Disposable Infusion Needle is intended to administer fluid by using an infusion set to a patient's vascular system through the needle inserted into the vein. Safelock Disposable Infusion Needle is intended to administer fluid by using an infusion set to a patient's vascular system through the needle inserted into the vein, and the safety sheath id designed to prevent accidental needle sticks	Same
Configuration	Needle Protect Cover	Needle Protect Cover	Same
	Infusion Needle	Infusion Needle	Same
	Needle Handle	Double Wing Needle Handle	Same
	Flexing Tube	Flexing Tube	Same
	Safety sheath	Safety sheath	Same
	Conical fitting	Conical fitting	Same
	Conical fitting protective cap	/	Different
Operation Mode	For manual use only	For manual use only	Same
Single Use	Single Use	Single Use	Same
Safety Feature	The needle is locked in safety sheath by withdraw safety needle handle backward.	The needle is locked in safety sheath by withdraw safety needle handle backward	Same
Label/Labeling	Complied with 21 CFR part 801	Complied with 21 CFR part 801	Same
Performance	Complied with ISO 7864, ISO 9626	Complied with ISO 7864, ISO 9626	Same

Specification			
Needle Gauge	18G, 19G, 20G, 21G, 22G, 23G, 24G, 25G, 26G, 27G	18G, 21G, 23G, 25G	Different
Needle Length	16mm, 19mm, 25mm 28mm	3/4″	Different
Patient Contact Material			
Needle	Stainless Steel (SUS304)	Stainless Steel (SUS316)	Different
Needle Handle	Poly Vinyl Chloride (PVC)	Acrylonitrile Butadiene Styrene (ABS)	Different
Flexible Tube	Poly Vinyl Chloride (PVC)	Polyvinyl Chloride (PVC)	Same
Conical fitting	Poly Vinyl Chloride (PVC)	Acrylonitrile Butadiene Styrene (ABS)	Different
Lubricants	Polydimethylsiloxane	Polydimethylsiloxane	Same
Adhesive	Epoxy adhesive	Epoxy adhesive	Same
Biocompatibility			
Cytotoxicity	No Cytotoxicity	No Cytotoxicity	Similar
Irritation	No intracutaneous reactivity	No intracutaneous reactivity	
Sensitization	No skin sensitization	No skin sensitization	
Systemic Toxicity	No systemic toxicity	No systemic toxicity	
Hemolysis	No Hemolysis	No Hemolysis	
Pyrogen	No Pyrogen	No Pyrogen	
Thromboresistance	No thrombosis	/	
Complement Activation	No different from control group	/	
Subacute Systemic Toxicity	No Subacute Systemic Toxicity	/	
Sterilization			
Method	EO sterilized	EO sterilized	Same
SAL	10^{-6}	10^{-6}	Same
Endotoxin Limit	20EU/device	20EU/device	Same

Different-Configuration

Compared with predicate device, the proposed device has an additional component conical fitting protective cap, which is intended to protective the conical fitting, while this difference does not affect the intended use. Therefore, the difference does not raise new questions of safety and effectiveness for the proposed device.

Different – Needle Gauge

The subject device is available in ten specifications, the proposed specification 18G, 21G, 23G and 25G can be covered by the predicate device, while other gauges beyond the predicate device range. The different gauges will be selected by physician per patients' condition. In addition, the needle performance has been tested and results demonstrate that the needle meets the requirements of ISO 7864 and ISO 9626. Therefore, the difference does raise new questions of safety and effectiveness for

the proposed device.

Different – Needle Length

The needle length for the proposed device is different from the predicate device, however, the needle performance has been tested and results demonstrate that the needle meets the requirements of ISO 7864 and ISO 9626. Therefore, the difference does not raise new questions of safety and effectiveness for the proposed device.

Different – Patient Contact Material

The patient contact material for proposed device is different from predicate device. However, the biocompatibility test for proposed device was performed and the result show there is no adverse effect. Therefore, the difference does not raise new questions of safety and effectiveness for the proposed device.

Similar- Biocompatibility

The biocompatibility test was performed on the proposed device and three additional endpoints were evaluated compared to the predicate device, which are subacute toxicity, in vivo Thromboresistance and Complement Activation. The test results for these endpoints show there are no adverse effect on the material. Therefore, the provided biocompatibility testing supports substantial equivalence to the predicate device.

7. 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 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 - Requirements and test methods.
- ISO 9626:2016, Stainless steel needle tubing for the manufacture of medical devices - Requirements and test methods.
- ASTM F88/F88M-15, Standard Test Method for Seal Strength of Flexible Barrier Materials.
- ASTM F1929-15 Standard Test Method for Detecting Seal Leaks in Porous Medical Package by Dye Penetration.
- ASTM F1886/F1886M-16 Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection
- ISO 10993-7:2008, Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals.

- USP <85> Bacterial Endotoxins Test.
- USP <788> Particular Matter in Injections.
- ISO 10993-5:2009 Biological evaluation of medical devices - Part 5: Test for in vitro cytotoxicity.
- ISO 10993-4: 2017, Biological Evaluation of Medical Devices - Part 4: Selection of Test for Interaction with Blood.
- ISO 10993-10: 2010, Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization.
- ISO 10993-11: 2017, Biological evaluation of medical devices - Part 11: Tests for systemic toxicity.
- ASTM F756-2017 Standard Practice for Assessment of Hemolytic Properties of Materials.
- USP <151> Pyrogen Test.

8. Clinical Test Conclusion

No clinical study is included in this submission.

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 with respect to the indications for use, target populations, treatment method, and technological characteristics.