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: K221069
Trade/Device Name: Infusion Sets for Single Use with Needles
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)*
K221069

Device Name
Infusion Sets for Single Use with Needles

Indications for Use *(Describe)*
The Infusion Sets for Single Use with Needles is intended to administer fluids from a container to a patient's vascular system through a needle or catheter inserted into the vein.

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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K220169 - 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: K220169

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

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: Infusion Sets for Single Use with Needles
Common Name: Intravascular Administration Set

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

Indications for Use Statement:

The Infusion Sets for Single Use with Needles is intended to administer fluids from a container to a patient's vascular system through a needle or catheter inserted into the vein.

Device Description

The Infusion Sets for Single Use with Needles is intended to administer fluids from a container to a patient's vascular system through a needle or catheter inserted into the vein. It consists of basic configuration and optional components. The basic configuration consists of protective cap of spike, spike, drip chamber, flow regulator, flexible tube, conical fitting, and injection needle/intravenous needle. Air vent, fluid filter, clamp, and injection site are optional components. The device is provided sterile and single use.

5. Identification of Predicate Device

510(k) Number: K163160
Product Name: Sterile Single-use Infusion Set

6. Substantially Equivalent (SE) Comparison

Table 1 Comparison of Technology Characteristics

ITEM	Proposed Device	Predicate Device K163160	Remark
Product	Infusion Sets for Single Use with Needles	Sterile Single-use Infusion Set	/
Product Code	FPA	FPA	Same
Regulation Number	21 CFR 880.5440	21 CFR 880.5440	Same
Class	Class II	Class II	Same

Indications for Use	The Infusion Sets for Single Use with Needles is intended to administer fluids from a container to a patient's vascular system through a needle or catheter inserted into the vein.		The Sterile Single-use Infusion Set is intended to administer fluids from a container to a patient's vascular system through a needle or catheter inserted into the vein.	Same
Configuration	Basic Configuration	Protective cap of spike	Protector Cap of Spike	Same
		Spike	Spike	Same
		Drip chamber	Drip chamber	Same
		Flow Regulator	Flow Regulator	Same
		Flexible Tube	Flexible Tube	Same
		Conical fitting (luer lock or luer slip)	Conical fitting (luer lock or luer slip)	Same
		Intravenous Needle or hypodermic needles	Needle	Different
	Optional configuration	Injection site	Injection Site	Same
		Fluid filter	Fluid filter	Same
		Air vent	Air vent	Same
		Clamp	Clamp	Same
Operation Mode	For manual use only		For manual use only	Same
Filter Characteristics	15μm		15μm	Same
Capacity (ml)	18ml		19, 21ml	Different
Needle Gauge	Intravenous Needle: 18G, 19G, 20G, 21G, 22G, 23G, 24G, 25G, 26G, 27G Hypodermic Needles: 16G, 18G, 19G, 20G, 21G, 22G, 23G, 24G, 25G, 26G, 27G, 28G, 29G, 30G		21G	Different
Tubing Diameter	3.9mm		3.9mm	Same
Length (mm)	1635mm, 1665mm		1610, 1900mm	Different
Infusion Set Performance	Comply with ISO 8536-4		Comply with ISO 8536-4	Same
Needle Performance	Comply with ISO 7864 and ISO 9626		Comply with ISO 7864 and ISO 9626	Same
Patient contact Material				
Spike	Acrylonitrile Butadiene Styrene (ABS)		High-density Polyethylene (HDPE)	Different
Drip Chamber	Poly Vinyl Chloride (PVC)		Acrylonitrile Butadiene Styrene (ABS)	Different
Flexible Tube	Poly Vinyl Chloride (PVC)		Poly Vinyl Chloride (PVC)	Same

conical fitting		Poly Vinyl Chloride (PVC)	Poly Vinyl Chloride (PVC)	Same
Injection site		Poly Vinyl Chloride (PVC)	Acrylonitrile Butadiene Styrene (ABS)	Different
Fluid filter		Polyamide Acrylonitrile Butadiene Styrene (ABS)	Acrylonitrile Butadiene Styrene (ABS)	Different
Intravenous Needle	Flexible Tube	Poly Vinyl Chloride (PVC)	/	Different
	Needle Handle	Poly Vinyl Chloride (PVC)	/	Different
	Needle	Stainless Steel	/	Different
	Conical Fitting	Poly Vinyl Chloride (PVC)	/	Same
Hypodermic Needle	Needle	Stainless Steel	Stainless Steel	Same
	Needle Hub	Polypropylene (PP)	Polypropylene (PP)	Same
Biocompatibility				
Cytotoxicity		No Cytotoxicity	No Cytotoxicity	Similar
Intracutaneous Reactivity		No Intracutaneous Reactivity	No Intracutaneous Reactivity	
Skin Sensitization		No Skin Sensitization	No Skin Sensitization	
Acute Systemic Toxicity		No Acute Systemic Toxicity	No Acute Systemic Toxicity	
Hemolysis		No Hemolysis	No Hemolysis	
Pyrogen		No Pyrogen	No Pyrogen	
Subacute Toxicity		No Subacute Systemic Toxicity	/	
Complement Activation		No different from control device	/	
In vivo vein thromboresistance		No thrombosis	/	
Sterilization				
Method		EO sterilized	EO sterilized	Same
SAL		10^{-6}	10^{-6}	Same
Endotoxin Limit		20 EU per device	20 EU per device	Same

Different-Configuration

The configuration for the proposed device includes basic configuration and optional configuration. The optional configuration for the proposed device can be covered by the predicate device. The only difference between the proposed device and predicate device is the needle. Both the proposed device and predicate device are a single use infusion set with a pre-attached needle. However, the pre-attached needle for the proposed device is different from predicate device. The pre-attached needle for the proposed device is available in two types, which are hypodermic needle and intravenous needle. These two type needles can be provided with/without a safe feature. While the pre-attached needle for the predicate device is a hypodermic needle. Although the pre-attached needle

for the proposed device cannot be covered by the pre-attached needle for the predicate device. The needle performance has been tested and results demonstrate that the needle meets the requirements of ISO 7864 and ISO 9626. Therefore, the differences do not raise new questions of safety and effectiveness for the proposed device.

Different-Capacity

The total capacity for the proposed device is different from predicate device. However, the performance test has been conducted on the proposed device and the test result can meet the requirements of ISO 8536-4. Therefore, this difference does not raise new questions of safety and effectiveness for the proposed device.

Different – Needle Gauge

The subject device is available in more gauges compared to 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, this difference does not raise new questions of safety and effectiveness for the proposed device.

Different-Length

The total length for the proposed device is different from predicate device. However, the performance test has been conducted on the proposed device and the test result meet the requirements of ISO 8536-4. Therefore, the differences do not raise new questions of safety and effectiveness for the proposed device.

Different –Patient Contact Material

The patient contact materials for proposed device are different from predicate device. However, the biocompatibility testing per ISO 10993-1 was performed and the results show there are no adverse effect. Therefore, the differences do 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 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
- ISO 10993-7:2008 Biological Evaluation of Medical Devices-Part 7:Ethylene Oxide Sterilization Residuals
- 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
- ASTM F1886/F1886M-16 Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection
- 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 80369-20:2015 Small-bore connectors for liquids and gases in healthcare applications-Part 20: Common test methods.
- ISO 8536-4:2019 Infusion equipment for medical use- Part 4: Infusion sets for single use, gravity feed.
- ISO 8536-14:2016 Clamps and flow regulators for transfusion and infusion equipment without fluid contact
- USP <151>Pyrogen Test
- USP <85> Bacterial Endotoxins Test
- USP <788> Particular Matter in Injections.

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.