March 25, 2022

Jiangsu Suyun Medical Materials Co., Ltd.
% Diana Hong
General Manager
Mid-Link Consulting Co., Ltd.
P.O. Box 120-119
Shanghai, 200120
China

Re: K202437
Trade/Device Name: Infusion Sets for Single Use
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: Class II
Product Code: FPA
Dated: February 22, 2022
Received: February 24, 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,

Gang Peng for
Payal Patel
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)*
K202437

Device Name
Infusion Sets for Single Use

Indications for Use *(Describe)*
The device is intended to administer fluids from a container to a patient's vascular system through a needle or catheter inserted into the vein. The maximum use time of the infusion sets shall not exceed 24 hours. The intravenous infusion needle should be used for only single dose administration and not to be left in place for more than 2 hours.

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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K202437 510(k) Summary

1. Date of Preparation: 3/22/2022

2. Sponsor Identification

Jiangsu Suyun Medical Materials Co., Ltd.
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3. Designated Submission Correspondent

Ms. Diana Hong (Primary Contact Person)
Ms. Ying Xu (Alternative Contact Person)

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4. Identification of Proposed Device

Trade Name: Infusion Sets for Single Use
Common Name: Disposable Infusion Set

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

5. Identification of Predicate Device

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

6. Indication for Use Statement:
The device is intended to administer fluids from a container to a patient's vascular system through a needle or catheter inserted into the vein. The maximum use time of the infusion sets shall not exceed 24 hours. The intravenous infusion needle should be used for only single dose administration and not to be left in place for more than 2 hours.

7. Device Description

The proposed devices are indicated for the delivery of fluids from a container to a patient's vascular system through an infusion needle under the action of gravity. The proposed devices have 8 different configurations with 4 different filter sizes, and they are provided sterile and single use.

The proposed devices include 32 models. The differences between models are described below:

Table 1 the differences in components for each model

Component		Model							
		D3 D1-3 D2-3 D3-3	D3-2 D1-3-2 D2-3-2 D3-3-2	D4 D1-4 D2-4 D3-4	D5 D1-5 D2-5 D3-5	D6 D1-6 D2-6 D3-6	D7 D1-7 D2-7 D3-7	D8 D1-8 D2-8 D3-8	D9 D1-9 D2-9 D3-9
Air Filter		X	N.A.	X	N.A.	X	N.A.	X	X
Protective Cap of Spike		X	X	N.A.	X	N.A.	X	N.A.	X
Protective Cap of Spike (Steel Needle)		N.A.	N.A.	X	N.A.	X	N.A.	X	N.A.
Spike	Spike with Air Filter	N.A.	X	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.
	Spike with Drip Tube and Air Filter	N.A.	N.A.	N.A.	X	N.A.	X	N.A.	N.A.
	Spike (Plastic)	X	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	X
	Spike (Steel Needle)	N.A.	N.A.	X	N.A.	X	N.A.	X	N.A.
Tee		N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	X	X
Pinch Clamp		X	X	X	N.A.	X	N.A.	X	X
Drip Tube		X	X	X	N.A.	X	N.A.	X	X
Drip Chamber		X	X	X	X	X	X	X	X
Flexible Tube		X	X	X	X	X	X	X	X
Roller Clamp		X	X	X	X	X	X	X	X
Injection Site		X	X	X	X	X	X	X	X
Fluid Filter		D3: 5um D1-3: 3um D2-3: 2um D3-3: 15um	D3-2: 5um D1-3-2: 3um D2-3-2: 2um D3-3-2: 15um	D4: 5um D1-4: 3um D2-4: 2um D3-4: 15um	D5: 5um D1-5: 3um D2-5: 2um D3-5: 15um	D6: 5um D1-6: 3um D2-6: 2um D3-6: 15um	D7: 5um D1-7: 3um D2-7: 2um D3-7: 15um	D8: 5um D1-8: 3um D2-8: 2um D3-8: 15um	D9: 5um D1-9: 3um D2-9: 2um D3-9: 15um

External Cone Lock Connector	X	X	X	X	X	X	X	X
Protector Cap of Lock Connector	X	X	X	X	X	X	X	X
Intravenous Infusion Needle	X	X	X	X	X	X	X	X

Note: X= the proposed device has this component; N.A. = the proposed device does not have this component

8. Summary of Technological characteristics

Table 2 General Comparison

ITEM	Proposed Device	Predicate Device K163160	Remark
Regulation No.	21 CFR 880.5440	21 CFR 880.5440	Same
Product Code	FPA	FPA	Same
Class	II	II	Same
Indications for Use	The device is intended to administer fluids from a container to a patient's vascular system through a needle or catheter inserted into the vein. The maximum use time of the infusion sets shall not exceed 24 hours. The intravenous infusion needle should be used for only single dose administration and not to be left in place for more than 2 hours.	The device is intended to administer fluids from a container to a patient's vascular system through a needle or catheter inserted into the vein.	Different Analysis 1
Configuration	Protective Cap of Spike	Protective Cap of Spike	Same
	Spike (one plastic spike / one metal spike/ two metal spikes)	Spike (plastic spike)	Different Analysis 2
	Multiple air filters, including: Air filter with tubing integrate with plastic spike (model: D3/D1-3/D2-3/D3-3 and D9/D1-9/D2-9/D3-9); Air filter without tubing integrate with plastic spike (model: D3-2/D1-3-2/D2-3-2/D3-3-2 and D5/D1-5/D2-5/D3-5 and D7/D1-7/D2-7/D3-7) Stand-alone Air filter unit (model: D4/D1-4/D2-4/D3-4 and D6/D1-6/D2-6/D3-6 and D8/D1-8/D2-8/D3-8)	Air filter without tubing integrate with plastic spike	
	Fluid Filter near the patient access	Fluid Filter integrate with the Drip Chamber	
	Drip Chamber integrate with the spike OR, Drip Chamber is several inches below the Spike	Drip Chamber integrate with the spike	
	Flexible Tube		Same

	Roller Clamp		Same
	Drip Tube		Same
	Injection Site		Same
	Luer Lock Connector		Same
	Protector Cap of Lock Connector		Same
Operation Mode	Manual	Manual	Same
Label/Labeling	Conform with 21 CFR Part 801	Conform with 21 CFR Part 801	Same

SE Analysis 1-Indications for Use

The proposed device and the predicate device has the same intended use, they are both intended to administer fluids from a container to a patient's vascular system through a needle or catheter inserted into the vein. The intended duration of use is included in the indications for use of proposed device, and it provides safety information for the end user. Therefore, the difference on indications for use does not raise new question on safety and effectiveness of the proposed device.

SE Analysis 2-Configuraiton

The proposed device and predicate device have the similar configurations (protector cap, spike, air filter, fluid filter, drip chamber, flexible tube, roller clamp, drip tube, injection site and luer lock connector) to achieve the intended use. The differences are mainly in some components structure (spike, air filter, fluid filter and drip chamber) which look different than the predicate device. The detail analysis on components are listed as following:

Spike:

The proposed device has one plastic spike / one metal spike/ two metal spikes, while the predicate device only have one plastic spike. The metal spike of the proposed device is also used to pierce and penetrate the closure of a fluid container, and it facilitates piercing and penetrate because it has lower penetration resistance than the plastic spike. The two metal spikes are applicable to the simultaneous transfusion of two liquid container. In addition, the metal spikes meet the dimensions requirements of closure-piercing device specified in ISO 8536-3.

Air filter:

The proposed device has Multiple air filters, including: Air filter with tubing integrate with plastic spike; Air filter without tubing integrate with plastic spike and Stand-alone Air filter unit. The predicate device only has Air filter without tubing integrate with plastic spike. The air filter with tubing integrate with plastic spike and Stand-alone Air filter unit play the same role as Air filter without tubing integrate with plastic spike; they are all used to make the air entering the fluid bottle during infusion to maintains a balance of pressure inside and outside of the rigid container. In addition, all of the air filters of the proposed device don't affect the flow rate of proposed device when air entering the rigid container passes through the air filter.

The spike of Stand-alone Air filter unit of proposed device is capable of piercing and penetrating the closure of a fluid container without pre-piercing, which is also meet the requirement of ISO 8536-4.

Fluid Filter

The fluid filter of predicate device is within in the drip chamber. The fluid filter of proposed device is near the patient access, this position is acceptable based on ISO 8536-9. The proposed device has four type of fluid filter (2, 3, 5, and 15μm filter size) and they are capable of more than 80% latex particle retention. The fluid filters of proposed device meet the fluid filter requirement specified in ISO 8536-3.

Drip Chamber

The proposed device has drip chamber integrates with the spike OR Drip Chamber being several inches below the Spike. The predicate device's drip chamber only integrates with the spike. The Drip Chamber being several inches below the Spike facilitates the observation of the fall of drops when the liquid container is hung high. In addition, the drip chamber of the proposed device meet the requirement of drip chamber specified in ISO 8536-3.

Based on above analysis, the proposed device and predicate device have the similar configurations to achieve the intended use. The differences that mainly in some components structure (spike, air filter, fluid filter and drip chamber) which look different than the predicate device don't raise new problem on safety and effectiveness of proposed device.

Table 3 Safety and Effectiveness Comparison for Infusion Set for Single Use

Item	Proposed Device		Predicate Device K163160		Remark
Infusion Set Performance	Conform with ISO 8536-4:2010		Conform with ISO 8536-4:2010		Same
Needle performance	Conform with ISO 7864: 2016 ISO 9626: 2016		Conform with ISO 7864: 2016 ISO 9626: 2016		Same
Needle guage	21G		21G		Same
Capacity (ml)	20, 21, 22, 23, 25		19, 21, 23		Different Analysis 3
Patient contact Material	Spike	Acrylonitrile Butadine Styrene (ABS)	Spike	HDPE	Different Analysis 4
		Polyethylene (PE)			
		Stainless Steel 304 (SUS304)			
	Tee	Polyvinyl Chloride (PVC)	Tee	Unknown	
	Drip Tube	Acrylonitrile Butadine Styrene (ABS)	Drip tube	Unknown	
	Drip Chamber	Polyvinyl Chloride (PVC)	Drip Chamber	PVC	
	Flexible Tube	Polyvinyl Chloride (PVC)	Flexible Tube	PVC	
	Fluid Filter	Methyl Metha Acrylate ABS(MABS)	Fluid Filter	ABS	
		Polypropylene (PP)			
	External Cone Lock Connector	Acrylonitrile Butadine Styrene (ABS)	External Cone Lock Connector	Unknown	
	Injection Site	Polyisoprene	Injection Site	ABS	
	Intravenous Infusion Needle	Polyvinyl Chloride (PVC)	Intravenous Infusion Needle	Unknown	
		Acrylonitrile Butadine Styrene (ABS)			
		Stainless Steel 304 (SUS304)			
BiocompatibilitydD					
Cytotoxicity	No Cytotoxicity		No Cytotoxicity		Different Analysis 4
Skin Sensitization	No Skin Sensitization		No Skin Sensitization		
Intracutaneous reactivity	No Intracutaneous reactivity		No Intracutaneous reactivity		

Acute Systematic Toxicity	No Acute Systematic Toxicity	No Acute Systematic Toxicity	
Pyrogen	No Pyrogen	No Pyrogen	
Vivo Thromboresistance	No Thromboresistance	/	
Complement Activation	No Complement Activation	/	
Hemolysis	No Hemolysis	No Hemolysis	
Sterilization			
Method	EO sterilized	EO sterilized	Same
SAL	10-6	10-6	
Endotoxin Limit	20 EU per device	20 EU per device	

SE Analysis 3 - Capacity

The proposed device has different total length and difference configuration, so it has different capacity. The slight difference on the capacity between the proposed device and predicate device capacity cannot affect the devices' intended use. Therefore, the difference on capacity will not raise any safety and effectiveness of proposed device.

SE Analysis 4 - Patient contact Material and Biocompatibility

The patient contact materials for proposed device are different from predicate device. However, the biocompatibility test for proposed device was performed on the proposed device and there are two more biological compatibility test items than those of predicate device, Vivo Thromboresistance and Complement Activation. And the test results show there is no adverse effect on the material. Therefore, this difference does not affect substantially equivalence on safety and effectiveness.

9. Non-Clinical Testing

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:

Performance Testing

- ISO 8536-4:2010 Infusion equipment for medical use- Part 4: Infusion sets for single use, gravity feed.
- ISO 8536-14:2016 Infusion equipment for medical use-Part 14: Clamps and flow regulators for transfusion and infusion equipment without fluid contact.
- 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.

BiocompatibilityTesting

This device is classified as: Externally communicating, Blood path Indirect, Limited contact ≤ 24 hours.

- 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 Interation 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.

Sterility, Shipping and Shelf-life:

- 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 D4169-16 Standard Practice for Performance Testing of Shipping Containers and Systems

No clinical study is included in this submission.

9. Conclusion

The differences between the predicate device and the subject device do not raise any new or different questions of safety or effectiveness. The Infusion Sets for Single Use are substantially equivalent to the Sterile Single Use Infusion Sets K163160 with respect to indications for use, treatment method, and technological characteristics.