Jiangsu Kangbao Medical Equipment Co., Ltd.
% Ms. Diana Hong
General Manager
Mid-Link Consulting Co., Ltd.
P.O.Box 120-119, Shanghai, 200120 CHN

March 22, 2022

Re: K192681
Trade/Device Name: Vein Set, Safety vein set, Blood collection needle (vein set type), Blood collection needle (needle holder type), Safety blood collection needle (vein set type), Safety blood collection needle (needle holder type)
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular administration set
Regulatory Class: Class II
Product Code: FPA, JKA

Dear Ms. Diana Hong :

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated July 28, 2020. Specifically, FDA is updating this SE Letter to correct the company name as an administrative correction.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Payal Patel by phone at 240-402-6029 or email at payal.patel@fda.hhs.go.

Sincerely,

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

July 28, 2020

Jiangsu Kangbao Medical Experiment Co., Ltd.
% Diana Hong
General Manager
Mid-link Consulting Co., Ltd
P.O. Box 120-119
Shanghai, 200120
China

Re: K192681
Trade/Device Name: Vein set, Safety vein set, Blood collection needle (vein set type), Blood collection needle (needle holder type), Safety blood collection needle (vein set type), Safety blood collection needle (needle holder type)
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: Class II
Product Code: FPA, JKA
Dated: June 23, 2020
Received: June 25, 2020

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,

Payal Patel
Acting Asst. Director, General Hospital
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K192681

Device Name
Vein set, Safety vein set, Blood collection needle (vein set type), Blood collection needle (needle holder type), Safety blood collection needle (vein set type), Safety blood collection needle (needle holder type)

Indications for Use *(Describe)*
Vein set is intended for vein puncture to collect blood specimens for patients. It is also indicated for intravenous administration of fluids after removing the attached luer adapter from the blood collection set connector and attaching a syringe, or other compatible/appropriate device. This device may be used for any patient population with consideration given to patient size, appropriateness for the solution being infused, and duration of therapy

Safety vein set is intended for vein puncture to collect blood specimens for patients. It is also indicated for intravenous administration of fluids after removing the attached luer adapter from the blood collection set connector and attaching a syringe, or other compatible/appropriate device. This device may be used for any patient population with consideration given to patient size, appropriateness for the solution being infused, and duration of therapy. Additionally, after withdraw of the needle from the patient's vein, the attached needle safety shield can be manually activated to cover the needle immediately after use to minimize risk of accidental needle stick.

Blood collection needle (vein set type) is intended for use in the blood collection or short-term infusion (up to 2 hours) of intravenous fluids.

Blood collection needle (needle holder type) is intended for use in the blood collection or short-term infusion (up to 2 hours) of intravenous fluids.

Safety blood collection needle (vein set type) is intended for use in the blood collection or short-term infusion (up to 2 hours) of intravenous fluids. The device is designed with a safety mechanism to help reduce the risk of needle stick injury.

Safety blood collection needle (needle holder type) is intended for use in the blood collection or short-term infusion (up to 2 hours) of intravenous fluids. The device is designed with a safety mechanism to help reduce the risk of needle stick injury

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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510(k) Summary: K192681

Date of Preparation: 7/22/2020

1. Sponsor Identification

Jiangsu Kangbao Medical Equipment Co., Ltd.
78#, North Suzhong Road Baoying 225800 Yangzhou PEOPLE'S REPUBLIC OF CHINA

Establishment Registration Number: 3009742443

Contact Person: Rujun Tang
Position: Management Representative
Tel: +86-514-88223540
Fax: +86-514-88232089
Email: 76823131@qq.com

2. 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

3. Identification of Proposed Device

Trade Name: Vein set
Safety vein set
Blood collection needle (vein set type)
Blood collection needle (needle holder type)
Safety blood collection needle (vein set type)
Safety blood collection needle (needle holder type)

Common Name: Blood Collecting Needle and Set

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

4. Identification of Predicate device

Product Code: FPA
510(k) Number: K031279
Regulation Number: 21 CFR 880.5440
Product Name: SURSHIELD™ Safety Winged Blood Collection Set

5. Indications for Use

Vein set is intended for vein puncture to collect blood specimens for patients. It is also indicated for intravenous administration of fluids after removing the attached luer adapter from the blood collection set connector and attaching a syringe, or other compatible/appropriate device. This device may be used for any patient population with consideration given to patient size, appropriateness for the solution being infused, and duration of therapy.

Safety vein set is intended for vein puncture to collect blood specimens for patients. It is also indicated for intravenous administration of fluids after removing the attached luer adapter from the blood collection set connector and attaching a syringe, or other compatible/appropriate device. This device may be used for any patient population with consideration given to patient size, appropriateness for the solution being infused, and duration of therapy. Additionally, after withdraw of the needle from the patient's vein, the attached needle safety shield can be manually activated to

cover the needle immediately after use to minimize risk of accidental needle stick.

Blood collection needle (vein set type) is intended for use in the blood collection or short-term infusion (up to 2 hours) of intravenous fluids.

Blood collection needle (needle holder type) is intended for use in the blood collection or short-term infusion (up to 2 hours) of intravenous fluids.

Safety blood collection needle (vein set type) is intended for use in the blood collection or short-term infusion (up to 2 hours) of intravenous fluids. The device is designed with a safety mechanism to help reduce the risk of needle stick injury.

Safety blood collection needle (needle holder type) is intended for use in the blood collection or short-term infusion (up to 2 hours) of intravenous fluids. The device is designed with a safety mechanism to help reduce the risk of needle stick injury.

6. Device Description

The proposed device is a blood collection device that forms a passage between the patient's vein and a vacuum blood collection tube for collecting blood. The proposed device can also be used for short-term infusion. The proposed devices are divided into several types, some have safety devices and some do not have safety devices, and the safety mechanism helps to reduce the risk of needle stick injuries. The proposed devices are provided sterile, single use. The propose device can be used for vein collect blood/infusion as well as peripheral vein collect blood/infusion, but not central vein collect blood/infusion.

7. Substantially Equivalent (SE) Comparison

Table 1 Comparison of Technology Characteristics for Vein set

ITEM	Proposed Device	Predicate Device K031279	Remark
Product code	FPA	FPA	Same
Regulation No.	21 CFR 880.5440	21 CFR 880.5440	Same
Class	II	II	Same
Indications for Use	Vein set is intended for vein puncture to collect blood specimens for patients. It is also indicated for intravenous administration of fluids after removing the attached luer adapter from the blood collection set connector and attaching a syringe, or other compatible/appropriate device. This device may be used for any patient population with consideration given to patient size, appropriateness for the solution being infused, and duration of therapy.	The TERUMOO SURSHIELD™ SAFETY WINGED BLOOD COLLECTION SET is a winged blood collection needle intended for venipuncture to collect blood specimens from patients. The TERUMOB SURSHIELD™ SAFETY WINGED BLOOD COLLECTION SET is also indicated for intravenous administration of fluids after removing the attached luer adapter from the blood collection set connector and attaching a syringe, or other compatible/appropriate device. This device may be used for any patient population with consideration given to patient size, appropriateness for the solution being infused, and duration of therapy. Additionally, after withdraw of the needle from the patient's vein, the attached needle safety shield can be manually activated to cover the needle immediately after USC to minimize risk of accidental needlestick.	Different
Configuration	Protective Cover of Patient-end Needle	Protective Cover of Patient-end Needle	Different

	Needle Tube Double Wing Flexible Tube Needle Hub Protective Cap	Needle Tube Double Wing Safety Sheath Flexible Tube Needle Hub Protective Cap	
Operate mode	Manual	Manual	Same
Safety Mechanism	No	Yes	Different
Label/Labeling	Conform with Part 801	Conform with Part 801	Same
Different-Indications for use, configuration and safety mechanism The Configuration of the proposed device is different from the predicate device. There is no safety mechanism in the propose device, and the predicate device has a safety mechanism. Whether there is a safety mechanism or not will not affect the indication for use of the equipment itself. The two devices both can be used for blood collection and infusion. Therefore, this difference is not determined to affect substantially equivalence on safety and effectiveness.			
Needle gauge and length	21G 3/4"	19G, 21G, 23G, 25G 3/4"	Different
Flexible tube length	300±5mm	19G: 300mm 21G: 300mm 23G: 180mm or 300mm 25G: 180mm or 300mm	Different
Patient-contact material			
Needle Tube	ABS (Acrylonitrile Butadiene Styrene)	Unknown	Different
Flexible Tube	PVC (Polyvinyl Chloride)		
Needle Tube	Stainless steel		
Different-Needle gauge The needle gauge for proposed device is different from the predicate device. However, this difference is just in dimension. This difference does not affect indication for use. And the needle gauge of proposed product needle is included in the needle gauge of the predicate product. Therefore, this difference does not affect substantially equivalence on safety and effectiveness. Different-Flexible tube length The flexible tube length for the proposed device is 300mm, while the flexible tube length for predicate device is available in two different lengths, which are 180mm and 300mm. However, the flexible tube length for the proposed device is same as the predicate device for 21G specification. Therefore, this difference is not			

<table>
<tr><td colspan="4">considered to affect substantially equivalence on safety and effectiveness.

Different-Patient-contact material
The patient-contact material for predicate device is unknown. However, the biocompatibility test for proposed device has been conducted and the test result conform with requirements of ISO 10993 standards. Therefore, this difference does not affect substantially equivalence on safety and effectiveness.</td></tr>
<tr><td colspan="4">Biocompatibility</td></tr>
<tr><td>In Vitro Cytotoxicity</td><td>No Cytotoxicity</td><td rowspan="8">Comply with ISO 10993 requirements</td><td rowspan="8">Same</td></tr>
<tr><td>Skin Sensitization</td><td>No Sensitization</td></tr>
<tr><td>Intracutaneous Reactivity</td><td>No Intracutaneous Reactivity</td></tr>
<tr><td>Acute Systemic Toxicity</td><td>No Systemic Toxicity</td></tr>
<tr><td>Hemolytic Properties</td><td>No Hemolytic</td></tr>
<tr><td>Pyrogen</td><td>No Pyrogen</td></tr>
<tr><td>In Vivo Thromboresistance</td><td>No</td></tr>
<tr><td>Complement Activation</td><td>No</td></tr>
<tr><td colspan="4">Sterilization</td></tr>
<tr><td>Method</td><td>EO sterilized</td><td>EO sterilized</td><td>Same</td></tr>
<tr><td>SAL</td><td>10^{-6}</td><td>10^{-6}</td><td>Same</td></tr>
<tr><td>Endotoxin Limit</td><td>20EU per device</td><td>20EU per device</td><td>Same</td></tr>
</table>

Table 2 Comparison of Technology Characteristics for Safety vein set

ITEM	Proposed Device	Predicate Device K031279	Remark
Product code	FPA	FPA	Same
Regulation No.	21 CFR 880.5440	21 CFR 880.5440	Same
Class	II	II	Same
Indications for Use	Safety vein set is intended for vein puncture to collect blood specimens for patients. It is also indicated for intravenous administration of fluids after removing the attached luer adapter from the blood collection set connector and attaching a syringe, or other compatible/appropriate device. This device may be used for any patient population with consideration given to patient size, appropriateness for the solution being infused, and duration of therapy. Additionally, after withdraw of the needle from the patient's vein, the attached needle safety shield can be manually activated to cover the needle immediately after use to minimize risk of accidental needle stick.	The TERUMOO SURSHIELD™ SAFETY WINGED BLOOD COLLECTION SET is a winged blood collection needle intended for venipuncture to collect blood specimens from patients. The TERUMOB SURSHIELD™ SAFETY WINGED BLOOD COLLECTION SET is also indicated for intravenous administration of fluids after removing the attached luer adapter from the blood collection set connector and attaching a syringe, or other compatible/appropriate device. This device may be used for any patient population with consideration given to patient size, appropriateness for the solution being infused, and duration of therapy. Additionally, after withdraw of the needle from the patient's vein, the attached needle safety shield can be manually activated to cover the needle immediately after USC to minimize risk of accidental needlestick.	Same
Configuration	Protective Cover of Patient-end Needle	Protective Cover of Patient-end Needle	Same

	Needle Tube Double Wing Safety Sheath Flexible Tube Needle Hub Protective Cap	Needle Tube Double Wing Safety Sheath Flexible Tube Needle Hub Protective Cap	
Operate mode	Manual	Manual	Same
Safety Mechanism	Yes	Yes	Same
Label/Labeling	Conform with Part 801	Conform with Part 801	Same
Needle gauge and length	21G 3/4”	19G, 21G, 23G, 25G 3/4"	Different
Flexible tube length	300±5mm	19G: 300mm 21G: 300mm 23G: 180mm or 300mm 25G: 180mm or 300mm	Different
Patient-contact material			
Needle Tube	ABS (Acrylonitrile Butadiene Styrene)	Unknown	Different
Flexible Tube	PVC (Polyvinyl Chloride)		
Safety Sheath	PP (Polypropylene)		
Needle Tube	Stainless steel		

Different-Needle gauge

The needle gauge for proposed device is different from the predicate device. However, this difference is just in dimension. This difference does not affect indication for use. And the needle gauge of proposed product needle is included in the needle gauge of the predicate product. Therefore, this difference does not affect substantially equivalence on safety and effectiveness.

Different-Flexible tube length

The flexible tube length for the proposed device is 300mm, while the flexible tube length for predicate device is available in two different lengths, which are 180mm and 300mm. However, the flexible tube length for the proposed device is same as the predicate device for 21G specification. Therefore, this difference is not considered to affect substantially equivalence on safety and effectiveness.

Different-Patient-contact material

The patient-contact material for predicate device is unknown. However, the biocompatibility test for proposed device has been conducted and the test result conform with requirements of ISO 10993 standards. Therefore, this difference does not affect substantially equivalence on safety and effectiveness.

Biocompatibility			
In Vitro Cytotoxicity	No Cytotoxicity	Comply with ISO 10993 requirements	Same
Skin Sensitization	No Sensitization		
Intracutaneous Reactivity	No Intracutaneous Reactivity		
Acute Systemic Toxicity	No Systemic Toxicity		
Hemolytic Properties	No Hemolytic		
Pyrogen	No Pyrogen		
In Vivo Thromboresistance	No		
Complement Activation	No		
Sterilization			
Method	EO sterilized	EO sterilized	Same
SAL	10^{-6}	10^{-6}	Same
Endotoxin Limit	20EU per device	20EU per device	Same

Table 3 Comparison of Technology Characteristics for Blood collection needle (vein set type)

Item	Proposed Device	Predicate Device K031279	Remark
Product code	FPA	FPA	Same
Regulation No.	21 CFR 880.5440	21 CFR 880.5440	Same
Class	II	II	Same
Indications for Use	Blood collection needle (vein set type) is intended for use in the blood collection or short-term infusion (up to 2 hours) of intravenous fluids.	The TERUMOO SURSHIELD™ SAFETY WINGED BLOOD COLLECTION SET is a winged blood collection needle intended for venipuncture to collect blood specimens from patients. The TERUMOB SURSHIELD™ SAFETY WINGED BLOOD COLLECTION SET is also indicated for intravenous administration of fluids after removing the attached luer adapter from the blood collection set connector and attaching a syringe, or other compatible/appropriate device. This device may be used for any patient population with consideration given to patient size, appropriateness for the solution being infused, and duration of therapy. Additionally, after withdraw of the needle from the patient's vein, the attached needle safety shield can be manually activated to cover the needle immediately after USC to minimize risk of accidental needlestick.	Different
Configuration	Protective Cover of Patient-end Needle Needle Tube Double Wing Flexible Tube Needle Hub Non-patient end Needle	Protective Cover of Patient-end Needle Needle Tube Double Wing Safety Sheath Flexible Tube Needle Hub	Different

		Protective Cap	
Operate mode	Manual	Manual	Same
Safety Mechanism	No	Yes	Different
Label/Labeling	Conform with Part 801	Conform with Part 801	Same
Different-Indications for use, configuration and safety mechanism The Configuration of the proposed device is different from the predicate device. There is no safety mechanism and have non-patient end needle in propose device, and the predicate device have a safety mechanism and no non-patient end needle. Whether there is a safety mechanism and non-patient end needle or not will not affect the indication for use of the equipment itself. The two devices both can be used for blood collection and infusion. Therefore, this difference is not determined to affect substantially equivalence on safety and effectiveness.			
Needle gauge and length	21G 3/4"	19G, 21G, 23G, 25G 3/4"	Different
Flexible tube length	300±5mm	19G: 300mm 21G: 300mm 23G: 180mm or 300mm 25G: 180mm or 300mm	Different
Patient-contact material			
Needle Tube	ABS (Acrylonitrile Butadiene Styrene)	Unknown	Different
Flexible Tube	PVC (Polyvinyl Chloride)		
Needle Tube	Stainless steel		
Different-Needle gauge The needle gauge for proposed device is different from the predicate device. However, this difference is just in dimension. This difference does not affect indication for use. And the needle gauge of proposed product needle is included in the needle gauge of the predicate product. Therefore, this difference does not affect substantially equivalence on safety and effectiveness. Different-Flexible tube length The flexible tube length for the proposed device is 300mm, while the flexible tube length for predicate device is available in two different lengths, which are 180mm and 300mm. However, the flexible tube length for the proposed device is same as the predicate device for 21G specification. Therefore, this difference is not considered to affect substantially equivalence on safety and effectiveness. Different-Patient-contact material The patient-contact material for predicate device is unknown. However, the biocompatibility test for proposed device has been conducted and the test result conform with requirements of ISO 10993 standards. Therefore,			

this difference does not affect substantially equivalence on safety and effectiveness.			
Biocompatibility			
In Vitro Cytotoxicity	No Cytotoxicity	Comply with ISO 10993 requirements	Same
Skin Sensitization	No Sensitization		
Intracutaneous Reactivity	No Intracutaneous Reactivity		
Acute Systemic Toxicity	No Systemic Toxicity		
Hemolytic Properties	No Hemolytic		
Pyrogen	No Pyrogen		
In Vivo Thromboresistance	No		
Complement Activation	No		
Sterilization			
Method	EO sterilized	EO sterilized	Same
SAL	10^{-6}	10^{-6}	Same
Endotoxin Limit	20EU per device	20EU per device	Same

Table 4 Comparison of Technology Characteristics for Blood collection needle (needle holder type)

ITEM	Proposed Device	Predicate Device K031279	Remark
Product code	FPA	FPA	Same
Regulation No.	21 CFR 880.5440	21 CFR 880.5440	Same
Class	II	II	Same
Indications for Use	Blood collection needle (needle holder type) is intended for use in the blood collection or short-term infusion (up to 2 hours) of intravenous fluids.	The TERUMOO SURSHIELD™ SAFETY WINGED BLOOD COLLECTION SET is a winged blood collection needle intended for venipuncture to collect blood specimens from patients. The TERUMOB SURSHIELD™ SAFETY WINGED BLOOD COLLECTION SET is also indicated for intravenous administration of fluids after removing the attached luer adapter from the blood collection set connector and attaching a syringe, or other compatible/appropriate device. This device may be used for any patient population with consideration given to patient size, appropriateness for the solution being infused, and duration of therapy. Additionally, after withdraw of the needle from the patient's vein, the attached needle safety shield can be manually activated to cover the needle immediately after USC to minimize risk of accidental needlestick.	Different
Configuration and material	Protective Cover of Patient-end Needle Needle Tube Double Wing Flexible tube Needle Hub Non-patient end Needle	Protective Cover of Patient-end Needle Needle Tube Double Wing Safety Sheath Flexible Tube Needle Hub	Different

	Needle Holder	Protective Cap	
Operate mode	Manual	Manual	Same
Safety Mechanism	No	Yes	Different
Label/Labeling	Conform with Part 801	Conform with Part 801	Same
Different-Indications for use, configuration and safety mechanism The Configuration of the proposed device is different from the predicate device. There is no safety mechanism and have non-patient end needle in propose device, and the predicate device have a safety mechanism and no non-patient end needle. Whether there is a safety mechanism and non-patient end needle or not will not affect the indication for use of the equipment itself. The two devices both can be used for blood collection and infusion. Therefore, this difference is not determined to affect substantially equivalence on safety and effectiveness.			
Needle gauge and length	21G 3/4"	19G, 21G, 23G, 25G 3/4"	Different
Flexible tube length	300±5mm	19G: 300mm 21G: 300mm 23G: 180mm or 300mm 25G: 180mm or 300mm	Different
Patient-contact material			
Needle Tube	ABS (Acrylonitrile Butadiene Styrene)	Unknown	Different
Flexible Tube	PVC (Polyvinyl Chloride)		
Needle Tube	Stainless steel		
Different-Needle gauge The needle gauge for proposed device is different from the predicate device. However, this difference is just in dimension. This difference does not affect indication for use. And the needle gauge of proposed product needle is included in the needle gauge of the predicate product. Therefore, this difference does not affect substantially equivalence on safety and effectiveness. Different-Flexible tube length The flexible tube length for the proposed device is 300mm, while the flexible tube length for predicate device is available in two different lengths, which are 180mm and 300mm. However, the flexible tube length for the proposed device is same as the predicate device for 21G specification. Therefore, this difference is not considered to affect substantially equivalence on safety and effectiveness. Different-Patient-contact material The patient-contact material for proposed device is different from the predicate device. However, the			

biocompatibility test for proposed device has been conducted and the test result conform with requirements of ISO 10993 standards. Therefore, this difference does not affect substantially equivalence on safety and effectiveness.			
Biocompatibility			
In Vitro Cytotoxicity	No Cytotoxicity	Comply with ISO 10993 requirements	Same
Skin Sensitization	No Sensitization		
Intracutaneous Reactivity	No Intracutaneous Reactivity		
Acute Systemic Toxicity	No Systemic Toxicity		
Hemolytic Properties	No Hemolytic		
Pyrogen	No Pyrogen		
In Vivo Thromboresistance	No		
Complement Activation	No		
Sterilization			
Method	EO sterilized	EO sterilized	Same
SAL	10^{-6}	10^{-6}	Same
Endotoxin Limit	20EU per device	20EU per device	Same

Table 5 Comparison of Technology Characteristics for Safety blood collection needle (vein set type)

ITEM	Proposed Device	Predicate Device K031279	Remark
Product code	FPA	FPA	Same
Regulation No.	21 CFR 880.5440	21 CFR 880.5440	Same
Class	II	II	Same
Indications for Use	Safety blood collection needle (vein set type) is intended for use in the blood collection or short-term infusion (up to 2 hours) of intravenous fluids. The device is designed with a safety mechanism to help reduce the risk of needle stick injury.	The TERUMOO SURSHIELD™ SAFETY WINGED BLOOD COLLECTION SET is a winged blood collection needle intended for venipuncture to collect blood specimens from patients. The TERUMOB SURSHIELD™ SAFETY WINGED BLOOD COLLECTION SET is also indicated for intravenous administration of fluids after removing the attached luer adapter from the blood collection set connector and attaching a syringe, or other compatible/appropriate device. This device may be used for any patient population with consideration given to patient size, appropriateness for the solution being infused, and duration of therapy. Additionally, after withdraw of the needle from the patient's vein, the attached needle safety shield can be manually activated to cover the needle immediately after USC to minimize risk of accidental needlestick.	Same
Configuration and material	Protective Cover of Patient-end Needle Needle Tube Double Wing Safety Sheath Flexible tube	Protective Cover of Patient-end Needle Needle Tube Double Wing Safety Sheath Flexible Tube	Different

	Needle Hub Non-patient end Needle	Needle Hub Protective Cap	
Operate mode	Manual	Manual	Same
Safety Mechanism	Yes	Yes	Same
Label/Labeling	Conform with Part 801	Conform with Part 801	Same
Different-Configuration The Configuration of the proposed device is different from the predicate device. There is no non-patient end needle in predicate device, and the proposed device have non-patient end needle. Whether there is a non-patient end needle or not will not affect the indication for use of the equipment itself. The two devices both can be used for blood collection and infusion. Both the proposed device and the predicate has a safety mechanism to prevent needle stick. Therefore, this difference is not determined to affect substantially equivalence on safety and effectiveness.			
Needle gauge and length	21G 3/4"	19G, 21G, 23G, 25G 3/4"	Different
Flexible tube length	300±5mm	19G: 300mm 21G: 300mm 23G: 180mm or 300mm 25G: 180mm or 300mm	Different
Patient-contact material			
Needle Tube	ABS (Acrylonitrile Butadiene Styrene)	Unknown	Different
Flexible Tube	PVC (Polyvinyl Chloride)		
Safety Sheath	PP (Polypropylene)		
Needle Tube	Stainless steel		
Different-Needle gauge The needle gauge for proposed device is different from the predicate device. However, this difference is just in dimension. This difference does not affect indication for use. And the needle gauge of proposed product needle is included in the needle gauge of the predicate product. Therefore, this difference does not affect substantially equivalence on safety and effectiveness. Different-Flexible tube length The flexible tube length for the proposed device is 300mm, while the flexible tube length for predicate device is available in two different lengths, which are 180mm and 300mm. However, the flexible tube length for the proposed device is same as the predicate device for 21G specification. Therefore, this difference is not considered to affect substantially equivalence on safety and effectiveness.			

Different-Patient-contact material The patient-contact material and biocompatibility for proposed device is different from the predicate device. However, the biocompatibility test for proposed device has been conducted and the test result conform with requirements of ISO 10993 standards. Therefore, this difference does not affect substantially equivalence on safety and effectiveness.			
Biocompatibility			
In Vitro Cytotoxicity	No Cytotoxicity	Comply with ISO 10993 requirements	Same
Skin Sensitization	No Sensitization		
Intracutaneous Reactivity	No Intracutaneous Reactivity		
Acute Systemic Toxicity	No Systemic Toxicity		
Hemolytic Properties	No Hemolytic		
Pyrogen	No Pyrogen		
In Vivo Thromboresistance	No		
Complement Activation	No		
Sterilization			
Method	EO sterilized	EO sterilized	Same
SAL	10^{-6}	10^{-6}	Same
Endotoxin Limit	20EU per device	20EU per device	Same

Table 6 Comparison of Technology Characteristics for Safety blood collection needle (needle holder type)

ITEM	Proposed Device	Predicate Device K031279	Remark
Product code	FPA	FPA	Same
Regulation No.	21 CFR 880.5440	21 CFR 880.5440	Same
Class	II	II	Same
Indication for Use	Safety blood collection needle (needle holder type) is intended for use in the blood collection or short-term infusion (up to 2 hours) of intravenous fluids. The device is designed with a safety mechanism to help reduce the risk of needle stick injury.	The TERUMOO SURSHIELD™ SAFETY WINGED BLOOD COLLECTION SET is a winged blood collection needle intended for venipuncture to collect blood specimens from patients. The TERUMOB SURSHIELD™ SAFETY WINGED BLOOD COLLECTION SET is also indicated for intravenous administration of fluids after removing the attached luer adapter from the blood collection set connector and attaching a syringe, or other compatible/appropriate device. This device may be used for any patient population with consideration given to patient size, appropriateness for the solution being infused, and duration of therapy. Additionally, after withdraw of the needle from the patient's vein, the attached needle safety shield can be manually activated to cover the needle immediately after USC to minimize risk of accidental needlestick.	Same
Configuration and material	Protective Cover of Patient-end Needle Needle Tube Double Wing Safety Sheath Flexible tube	Protective Cover of Patient-end Needle Needle Tube Double Wing Safety Sheath Flexible Tube	Different

	Needle Hub Non-patient end Needle Needle Holder	Needle Hub Protective Cap	
Operate mode	Manual	Manual	Same
Safety Mechanism	Yes	Yes	Same
Label/Labeling	Conform with Part 801	Conform with Part 801	Same
Different-Configuration The Configuration of the proposed device is different from the predicate device. There is no non-patient end needle in predicate device, and the proposed device have non-patient end needle. Both proposed device and the predicate has safety mechanism to prevent needle stick. The two devices both can be used for blood collection and infusion. Therefore, this difference is not determined to affect substantially equivalence on safety and effectiveness.			
Needle gauge and length	21G 3/4"	19G, 21G, 23G, 25G 3/4"	Different
Flexible tube length	300±5mm	19G: 300mm 21G: 300mm 23G: 180mm or 300mm 25G: 180mm or 300mm	Different
Patient-contact material			
Needle Tube	ABS (Acrylonitrile Butadiene Styrene)	Unknown	Different
Flexible Tube	PVC (Polyvinyl Chloride)		
Safety Sheath	PP (Polypropylene)		
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Different-Needle gauge The needle gauge for proposed device is different from the predicate device. However, this difference is just in dimension. This difference does not affect indication for use. And the needle gauge of proposed product needle is included in the needle gauge of the predicate product. Therefore, this difference does not affect substantially equivalence on safety and effectiveness. Different-Flexible tube length The flexible tube length for the proposed device is 300mm, while the flexible tube length for predicate device is available in two different lengths, which are 180mm and 300mm. However, the flexible tube length for the proposed device is same as the predicate device for 21G specification. Therefore, this difference is not considered to affect substantially equivalence on safety and effectiveness.			

Different-Patient-contact material The patient-contact material for proposed device is different from the predicate device. However, the biocompatibility test for proposed device has been conducted and the test result conform with requirements of ISO 10993 standards. Therefore, this difference does not affect substantially equivalence on safety and effectiveness.			
Biocompatibility			
In Vitro Cytotoxicity	No Cytotoxicity	Comply with ISO 10993 requirements	Same
Skin Sensitization	No Sensitization		
Intracutaneous Reactivity	No Intracutaneous Reactivity		
Acute Systemic Toxicity	No Systemic Toxicity		
Hemolytic Properties	No Hemolytic		
Pyrogen	No Pyrogen		
In Vivo Thromboresistance	No		
Complement Activation	No		
Sterilization			
Method	EO sterilized	EO sterilized	Same
SAL	10^{-6}	10^{-6}	Same
Endotoxin Limit	20EU per device	20 EU per device	Same

8. Non-Clinical Test Conclusion

Non clinical tests were conducted to verify that the proposed device met all design specifications and was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

Performance Testing

- ISO 594-1:1986 Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment - Part 1: General requirements
- ISO 594-2:1998 Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment - Part 2: Lock fittings
- ISO 8536-4:2010 Infusion equipment for medical use - Part 4: Infusion sets for single use, gravity feed

- 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;

Biocompatibility

- 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 10993-4:2017 Biological Evaluation of Medical Devices--Part 4: Selection of Tests for Interactions with Blood
- ISO 10993-11:2017 Biological evaluation of medical devices- Part 11: Tests for systemic toxicity
- ISO 11135:2014 Sterilization of health-care products -- Ethylene oxide -- Requirements for the development, validation and routine control of a sterilization process for medical devices
- USP<788> - Particulate Matter testing (Method 1)

Sterility

- USP 41-NF 36 <85> Bacterial Endotoxins Tests
- 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
- ASTM F1929- 15 Standard Test Method for Detecting Seal Leaks in Porous Medical Package by Dye Penetration

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 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 safety feature. The results demonstrated that the proposed device did not show a significant difference from predicate device.

9. Clinical Test Conclusion

No clinical study is included in this submission.

10. Substantially Equivalent (SE) Conclusion
Based on the comparison and analysis above, the proposed devices are determined to be Substantially Equivalent (SE) to the legally marketed predicate devices.