



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](mailto: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

## Indications for Use

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.**

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2. Designated Submission Correspondent

Ms. Diana Hong (Primary Contact Person)

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Email: [info@mid-link.net](mailto: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 | <p>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.</p> | <p>The TERUMOO SURSHIELD™ SAFETY WINGED BLOOD COLLECTION SET is a winged blood collection needle intended for venipuncture to collect blood specimens from patients.</p> <p>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.</p> <p>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.</p> | Different |
| Configuration       | Protective Cover of Patient-end Needle   | Protective Cover of Patient-end Needle  | Different |

|   |   |  |           |
|---|---|--|-----------|
|   | Needle Tube<br>Double Wing<br>Flexible Tube<br>Needle Hub<br>Protective Cap | Needle Tube<br>Double Wing<br>Safety Sheath<br>Flexible Tube<br>Needle Hub<br>Protective Cap |           |
| Operate mode  | Manual  | Manual   | Same      |
| Safety Mechanism  | No  | Yes  | Different |
| Label/Labeling  | Conform with Part 801   | Conform with Part 801  | Same      |
| <p>Different-Indications for use, configuration and safety mechanism</p> <p>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.</p>  |   |  |           |
| Needle gauge and length   | 21G<br>3/4"   | 19G, 21G, 23G, 25G<br>3/4"   | Different |
| Flexible tube length  | 300±5mm   | 19G: 300mm<br>21G: 300mm<br>23G: 180mm or 300mm<br>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   |  |           |
| <p>Different-Needle gauge</p> <p>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.</p> <p>Different-Flexible tube length</p> <p>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</p> |   |  |           |



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<br>Cytotoxicity     | No Cytotoxicity              | Comply with ISO 10993<br>requirements | Same |
| Skin Sensitization           | No Sensitization             |                                       |      |
| Intracutaneous<br>Reactivity | No Intracutaneous Reactivity |                                       |      |
| Acute Systemic<br>Toxicity   | No Systemic Toxicity         |                                       |      |
| Hemolytic<br>Properties      | No Hemolytic                 |                                       |      |
| Pyrogen                      | No Pyrogen                   |                                       |      |
| In Vivo<br>Thromboresistance | No                           |                                       |      |
| Complement<br>Activation     | No                           |                                       |      |
| Sterilization                |                              |                                       |      |
| Method                       | EO sterilized                | EO sterilized                         | Same |
| SAL                          | 10 <sup>-6</sup>             | 10 <sup>-6</sup>                      | Same |
| Endotoxin Limit              | 20EU per device              | 20EU per device                       | Same |

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 | <p>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.</p> | <p>The TERUMOO SURSHIELD™ SAFETY WINGED BLOOD COLLECTION SET is a winged blood collection needle intended for venipuncture to collect blood specimens from patients.</p> <p>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.</p> | Same   |
| Configuration       | Protective Cover of Patient-end Needle   | Protective Cover of Patient-end Needle   | Same   |

|  |  |  |           |
|--|--|--|-----------|
|  | Needle Tube<br>Double Wing<br>Safety Sheath<br>Flexible Tube<br>Needle Hub<br>Protective Cap | Needle Tube<br>Double Wing<br>Safety Sheath<br>Flexible Tube<br>Needle Hub<br>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<br>3/4"  | 19G, 21G, 23G, 25G<br>3/4"   | Different |
| Flexible tube length   | 300±5mm  | 19G: 300mm<br>21G: 300mm<br>23G: 180mm or 300mm<br>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  |  |           |
| <p>Different-Needle gauge</p> <p>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.</p> <p>Different-Flexible tube length</p> <p>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.</p> <p>Different-Patient-contact material</p> <p>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.</p> |  |  |           |

| Biocompatibility             |                              |                                       |      |
|------------------------------|------------------------------|---------------------------------------|------|
| In Vitro<br>Cytotoxicity     | No Cytotoxicity              | Comply with ISO 10993<br>requirements | Same |
| Skin Sensitization           | No Sensitization             |                                       |      |
| Intracutaneous<br>Reactivity | No Intracutaneous Reactivity |                                       |      |
| Acute Systemic<br>Toxicity   | No Systemic Toxicity         |                                       |      |
| Hemolytic<br>Properties      | No Hemolytic                 |                                       |      |
| Pyrogen                      | No Pyrogen                   |                                       |      |
| In Vivo<br>Thromboresistance | No                           |                                       |      |
| Complement<br>Activation     | No                           |                                       |      |
| Sterilization                |                              |                                       |      |
| Method                       | EO sterilized                | EO sterilized                         | Same |
| SAL                          | 10 <sup>-6</sup>             | 10 <sup>-6</sup>                      | 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. | <p>The TERUMOO SURSHIELD™ SAFETY WINGED BLOOD COLLECTION SET is a winged blood collection needle intended for venipuncture to collect blood specimens from patients.</p> <p>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.</p> <p>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.</p> | Different |
| Configuration       | Protective Cover of Patient-end Needle<br>Needle Tube<br>Double Wing<br>Flexible Tube<br>Needle Hub<br>Non-patient end Needle                     | Protective Cover of Patient-end Needle<br>Needle Tube<br>Double Wing<br>Safety Sheath<br>Flexible Tube<br>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      |
| <p>Different-Indications for use, configuration and safety mechanism</p> <p>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.</p>  |                                       |  |           |
| Needle gauge and length   | 21G<br>3/4"                           | 19G, 21G, 23G, 25G<br>3/4"   | Different |
| Flexible tube length  | 300±5mm                               | 19G: 300mm<br>21G: 300mm<br>23G: 180mm or 300mm<br>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                       |  |           |
| <p>Different-Needle gauge</p> <p>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.</p> <p>Different-Flexible tube length</p> <p>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.</p> <p>Different-Patient-contact material</p> <p>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,</p> |                                       |  |           |

|  |                              |                                    |      |
|--|------------------------------|------------------------------------|------|
| this difference does not affect substantially equivalence on safety and effectiveness. |                              |                                    |      |
| Biocompatibility   |                              |                                    |      |
| In Vitro<br>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<br>Thromboresistance   | No                           |                                    |      |
| Complement Activation  | No                           |                                    |      |
| Sterilization  |                              |                                    |      |
| Method   | EO sterilized                | EO sterilized                      | Same |
| SAL  | 10 <sup>-6</sup>             | 10 <sup>-6</sup>                   | 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. | <p>The TERUMOO SURSHIELD™ SAFETY WINGED BLOOD COLLECTION SET is a winged blood collection needle intended for venipuncture to collect blood specimens from patients.</p> <p>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.</p> <p>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.</p> | Different |
| Configuration and material | Protective Cover of Patient-end Needle<br>Needle Tube<br>Double Wing<br>Flexible tube<br>Needle Hub<br>Non-patient end Needle                          | Protective Cover of Patient-end Needle<br>Needle Tube<br>Double Wing<br>Safety Sheath<br>Flexible Tube<br>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      |
| <p>Different-Indications for use, configuration and safety mechanism</p> <p>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.</p>   |                                       |  |           |
| Needle gauge and length  | 21G<br>3/4"                           | 19G, 21G, 23G, 25G<br>3/4"   | Different |
| Flexible tube length   | 300±5mm                               | 19G: 300mm<br>21G: 300mm<br>23G: 180mm or 300mm<br>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                       |  |           |
| <p>Different-Needle gauge</p> <p>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.</p> <p>Different-Flexible tube length</p> <p>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.</p> <p>Different-Patient-contact material</p> <p>The patient-contact material for proposed device is different from the predicate device. However, the</p> |                                       |  |           |

|  |                              |                                    |      |
|--|------------------------------|------------------------------------|------|
| 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 <sup>-6</sup>             | 10 <sup>-6</sup>                   | 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.<br>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.<br>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<br>Needle Tube<br>Double Wing<br>Safety Sheath<br>Flexible tube  | Protective Cover of Patient-end Needle<br>Needle Tube<br>Double Wing<br>Safety Sheath<br>Flexible Tube   | Different |

|   |                                       |  |           |
|---|---------------------------------------|--|-----------|
|   | Needle Hub<br>Non-patient end Needle  | Needle Hub<br>Protective Cap   |           |
| Operate mode  | Manual                                | Manual   | Same      |
| Safety Mechanism  | Yes                                   | Yes  | Same      |
| Label/Labeling  | Conform with Part 801                 | Conform with Part 801  | Same      |
| <p>Different-Configuration</p> <p>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.</p>   |                                       |  |           |
| Needle gauge and length   | 21G<br>3/4"                           | 19G, 21G, 23G, 25G<br>3/4"   | Different |
| Flexible tube length  | 300±5mm                               | 19G: 300mm<br>21G: 300mm<br>23G: 180mm or 300mm<br>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                       |  |           |
| <p>Different-Needle gauge</p> <p>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.</p> <p>Different-Flexible tube length</p> <p>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.</p> |                                       |  |           |

|   |                              |                                    |      |
|---|------------------------------|------------------------------------|------|
| 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<br>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<br>Thromboresistance  | No                           |                                    |      |
| Complement Activation   | No                           |                                    |      |
| Sterilization   |                              |                                    |      |
| Method  | EO sterilized                | EO sterilized                      | Same |
| SAL   | 10 <sup>-6</sup>             | 10 <sup>-6</sup>                   | 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.<br>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.<br>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<br>Needle Tube<br>Double Wing<br>Safety Sheath<br>Flexible tube   | Protective Cover of Patient-end Needle<br>Needle Tube<br>Double Wing<br>Safety Sheath<br>Flexible Tube   | Different |

|   |   |  |           |
|---|---|--|-----------|
|   | Needle Hub<br>Non-patient end Needle<br>Needle Holder | Needle Hub<br>Protective Cap   |           |
| Operate mode  | Manual  | Manual   | Same      |
| Safety Mechanism  | Yes   | Yes  | Same      |
| Label/Labeling  | Conform with Part 801                                 | Conform with Part 801  | Same      |
| <p>Different-Configuration</p> <p>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.</p>  |   |  |           |
| Needle gauge and length   | 21G<br>3/4"   | 19G, 21G, 23G, 25G<br>3/4"   | Different |
| Flexible tube length  | 300±5mm   | 19G: 300mm<br>21G: 300mm<br>23G: 180mm or 300mm<br>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                                       |  |           |
| <p>Different-Needle gauge</p> <p>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.</p> <p>Different-Flexible tube length</p> <p>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.</p> |   |  |           |

|  |                              |                                    |      |
|--|------------------------------|------------------------------------|------|
| 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 <sup>-6</sup>             | 10 <sup>-6</sup>                   | 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.