December 22, 2023

Jiangsu Kangbao Medical Equipment Co., Ltd
Wenbin Fan
Deputy General Manager
78#, North Suzhong Road, Baoying
Yangzhou, Jiangsu 225800
China

Re: K232881
Trade/Device Name: Winged Infusion Set, Safety Winged Infusion Set, Blood Collection Set, Blood Collection Set with Holder, Safety Blood Collection Set, Safety Blood Collection Set with Holder, Needle Holder
Regulation Number: 21 CFR 862.1675
Regulation Name: Blood specimen collection device
Regulatory Class: Class II
Product Code: JKA, FMI, FPA
Dated: November 21, 2023
Received: November 22, 2023

Dear Wenbin Fan:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Porsche Bennett

Porsche Bennett
For David Wolloscheck, Ph.D.
Assistant Director

DHT3C: Division of Drug Delivery and
General Hospital Devices,
and Human Factors
OHT3: Office of Gastrorenal, ObGyn,
General Hospital, and Urology Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K232881

Device Name
Winged Infusion Set, Safety Winged Infusion Set, Blood Collection Set, Blood Collection Set with Holder, Safety Blood Collection Set, Safety Blood Collection Set with Holder, Needle Holder

Indications for Use *(Describe)*
Winged Infusion Set is indicated for the short-term infusion of intravenous fluids for 2 hours or less. It is to be used by appropriately trained healthcare professionals in accordance with the instructions.

Safety Winged Infusion Set is indicated for the short-term infusion of intravenous fluids for 2 hours or less. It is to be used by appropriately trained healthcare professionals in accordance with the instructions. The safety shield is intended to aid in the protection against accidental needle stick injury.

Blood Collection Set is indicated for venous blood collection. It is to be used by appropriately trained healthcare professionals in accordance with the instructions.

Blood Collection Set with Holder is indicated for venous blood collection. It is to be used by appropriately trained healthcare professionals in accordance with the instructions.

Safety Blood Collection Set is indicated for venous blood collection. It is to be used by appropriately trained healthcare professionals in accordance with the instructions. The safety shield is intended to aid in the protection against accidental needle stick injury.

Safety Blood Collection set with Holder is indicated for venous blood collection. It is to be used by appropriately trained healthcare professionals in accordance with the instructions. The safety shield is intended to aid in the protection against accidental needle stick injury.

Needle Holder is used for the collection of blood specimen into the blood collection tubes in routine venipuncture procedures. It is used with blood collection sets, needles and tubes. It is to be used by trained healthcare professional only.

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.

510(k) SUMMARY K232881

Preparation Date:	December 22, 2023
Manufacturer's Name and Address:	Jiangsu Kangbao Medical Equipment Co., Ltd 78#, North Suzhong Road Baoying, Yangzhou, Jiangsu, China 225800 Tel. +86-514-88223540 Fax +86-514-88232089
Corresponding Official:	Charles Mack
Telephone Number:	931-625-4938
Email Address:	charliemack@irc-us.com
Trade Name:	Winged Infusion Set, Safety Winged Infusion Set, Blood Collection Set, Blood Collection Set with Holder, Safety Blood Collection Set, Safety Blood Collection set with Holder, Needle Holder
Common Name(s):	Tubes, Vials, Systems, Serum Separators, Blood Collection
Regulation Name(s):	Blood specimen collection device
Regulation Number(s):	21 CFR 862.1675
Primary Product Code:	JKA
Subsequent Product Codes:	FMI, FPA
Device Class:	Class II

Primary Predicate Device:	K193074
Trade Name:	Bevel Up Holder
Common Name:	tubes, vials, systems, serum separators, blood collection
Regulation Number:	21 CFR 862.1675
Product Code:	JKA

Predicate Device:	K214075
Trade Name:	Safety Blood Collection / Infusion Set (with/without needle holder), Blood Collection / Infusion Set (with/without needle holder)
Common Name:	needle, hypodermic, single lumen
Regulation Number:	21 CFR 880.5570
Product Code:	FMI, FPA

Device Description:

The Blood Collection Set with Holder, Blood Collection Set, and Winged Infusion Set are single-use, sterile, winged needles bonded to flexible tubing with a Luer connector. The devices are individually wrapped and sterile with a luer port. The luer port can connect FDA-cleared accessories like luer adapter, holder, etc.

The Safety Blood Collection Set with Holder, Safety Blood Collection Set, and Safety Winged Infusion Set are single-use, sterile, winged needles bonded to flexible tubing with a Luer connector and a safety mechanism. The winged needle is designed with a safety mechanism, which allows for activation and ensures the needle is covered immediately following venipuncture to protect against accidental needlestick injury. The Safety Blood Collection / Infusion Set (with/without needle holder) is individually wrapped sterile with a luer port. The luer port can connect FDA-cleared accessories like luer adapter, holder, etc.

The safety feature is operated by releasing a latch mechanism whereby the user slides a winged cover over the needle as it is removed from the patient. Once the needle is covered, the safety cover locks in place. There is no ability to clean and reuse these devices because the safety feature cannot be deactivated without bending the needle and rendering it unusable.

The devices are used for venous blood collection and/or the short-term infusion of intravenous fluids. The product is to be used by appropriately trained healthcare professionals only in accordance with the manufacturer's instructions. It can be used with an intravascular administration set, syringe, or other device to administer fluids.

Indications for Use

Winged Infusion Set is indicated for the short-term infusion of intravenous fluids for 2 hours or less. It is to be used by appropriately trained healthcare professionals in accordance with the instructions.

Safety Winged Infusion Set is indicated for the short-term infusion of intravenous fluids for 2 hours or less. It is to be used by appropriately trained healthcare professionals in accordance with the instructions. The safety shield is intended to aid in the protection against accidental needle stick injury.

Blood Collection Set is indicated for venous blood collection. It is to be used by appropriately trained healthcare professionals in accordance with the instructions.

Blood Collection Set with Holder is indicated for venous blood collection. It is to be used by appropriately trained healthcare professionals in accordance with the instructions.

Safety Blood Collection Set is indicated for venous blood collection. It is to be used by appropriately trained healthcare professionals in accordance with the instructions. The safety shield is intended to aid in the protection against accidental needle stick injury.

Safety Blood Collection set with Holder is indicated for venous blood collection. It is to be used by appropriately trained healthcare professionals in accordance with the instructions. The safety shield is intended to aid in the protection against accidental needle stick injury.

Needle Holder is used for the collection of blood specimen into the blood collection tubes in routine venipuncture procedures. It is used with blood collection sets, needles, and tubes. It is to be used by trained healthcare professional only.

Needle Holder

Feature	Subject Device	Predicate Device	Discussion
510(K)	K232881	K193074	-
Device Name	Needle Holder	BEVEL UP HOLDER	-
Indication for Use	The Needle Holder is used for the collection of blood specimen into the blood collection tubes in routine venipuncture procedures. It is used with blood collection sets, needles, and tubes. It is to be used by trained healthcare professional only.	The Bevel Up Holder is used for the collection of blood into blood collection tubes in routine venipuncture procedures. It is used with blood collection sets, needles, and tubes. The device is to be used by trained healthcare professional only.	Identical
Product Configuration	Clear plastic holder	Clear plastic holder	Identical
Material	Polypropylene	Polypropylene	Identical
Sterility	They are not sterilized when provided alone. Sterilized when provided attached to the blood collection set	Not sterilized	*Note 1*
Packaging	Bulk pack in poly bag or Blister packaging	Bulk pack in poly bag	*Note 2*
Use	Single use	Single use	Identical
Biocompatibility	Complies with ISO 10993-1	Complies with ISO 10993-1	Identical
Shelf Life	Complies with ASTM F1980 5 years	3 years	*Note 3*

Note 1

When the needle holder of the subject device is provided alone for sale, it is not sterilized the same as the predicate device.

When the needle holder of the subject device is provided and attached to the blood collection set, it undergoes sterilization as part of the system conforming to the applicable standards. The needle holder when provided attached to the blood collection set is EO sterilized in accordance with ISO11135-1: Second edition 2014. Therefore, the difference does not raise new questions about the safety and effectiveness of the subject device.

Note 2

More packaging types of the subject device are available than the predicate device, but they conform to the same applicable performance standards. Therefore, this difference does not raise new or different questions of safety and effectiveness.

Note 2

The subject device has a shelf life longer than the predicate device. However, the subject device was tested to applicable performance standards and

the design outputs met the design inputs over the proposed 5 year shelf life. Therefore, the difference does not raise new or different questions of safety and effectiveness.

Blood Collection/Infusion Set

Feature	Subject Device	Predicate Device	Discussion
510(K)	K232881	K214075	-
Device Name	Winged Infusion Set, Safety Winged Infusion Set, Blood Collection Set, Blood Collection Set with Holder, Safety Blood Collection Set, Safety Blood Collection Set with Holder, Needle Holder	Safety Blood Collection / Infusion Set (with/without needle holder). Blood Collection / Infusion Set (with/without needle holder)	-
Indication for Use	**Winged Infusion Set** is indicated for the short-term infusion of intravenous fluids for 2 hours or less. It is to be used by appropriately trained healthcare professionals in accordance with the instructions. **Safety Winged Infusion Set** is indicated for the short-term infusion of intravenous fluids for 2 hours or less. It is to be used by appropriately trained healthcare professionals in accordance with the instructions. The safety shield is intended to aid in the protection against accidental needle stick injury. **Blood Collection Set** is indicated for venous blood collection. It is to be used by appropriately trained healthcare professionals in accordance with the instructions. **Blood Collection Set with Holder** is indicated for venous blood collection. It is to be used by appropriately trained healthcare professionals in accordance with the instructions.	**The Safety Blood Collection / Infusion Set (with/without needle holder)** is indicated for venous blood collection and/or the short-term infusion of intravenous fluids for 2 hours or less. It is to be used by appropriately trained healthcare professionals in accordance with the instructions. The safety shield is intended to aid in the protection against accidental needle stick injury. **The Blood Collection / Infusion Set (with/without needle holder)** is indicated for venous blood collection and/or the short-term infusion of intravenous fluids for 2 hours or less. It is to be used by appropriately trained healthcare professionals in accordance with the instructions.	Similar Note 1

Feature	Subject Device	Predicate Device	Discussion
510(K)	K232881	K214075	-
	Safety Blood Collection Set is indicated for venous blood collection. It is to be used by appropriately trained healthcare professionals in accordance with the instructions. The safety shield is intended to aid in the protection against accidental needle stick injury. **Safety Blood Collection set with Holder** is indicated for venous blood collection. It is to be used by appropriately trained healthcare professionals in accordance with the instructions. The safety shield is intended to aid in the protection against accidental needle stick injury. **Needle Holder** is used for the collection of blood specimen into the blood collection tubes in routine venipuncture procedures. It is used with blood collection sets, needles and tubes. It is to be used by trained healthcare professional only.		
Safety Feature	The needle is locked in safety sheath after use for the Safety Blood Collection / Winged Infusion Set (with/without needle holder). Slide the safety shield forward and pull the tubing backward until an audible click is heard. There is no safety mechanism for the Blood Collection Set / Winged Infusion Set (with/without needle holder).	For the Safety Blood Collection / Infusion Set (with/without needle holder), the needle is locked in safety sheath after use by sliding the safety shield forward with pulling the tubing backward until an audible click is heard. For the Blood Collection / Infusion Set (with/without needle holder), no safety mechanism.	Identical
Material			
Needle tube	SUS304	SUS304	Identical
Flexing tube	PVC	PVC	
Luer adapter	ABS	ABS	
Needle sheath	HDPE	HDPE	
Safety shield	Polypropylene	Polypropylene	
Rub sleeve	Gather Isoprene Rubber	Gather Isoprene Rubber	

Feature	Subject Device	Predicate Device	Discussion
510(K)	K232881	K214075	-
Lubricate	Silicone oil	Silicone oil	
Adhesive	Epoxy Resin	Epoxy Resin	
Needle Gauge	18G, 19G, 20G, 21G, 22G, 23G,	18G, 19G, 20G, 21G, 22G,	Identical
	24G, 25G, 26G, 27G	23G, 24G, 25G, 26G, 27G;	
Needle Length	1/2'' - 1 1/8''	1/2'' - 1 1/8''	Identical
Flexing tubing Length	4"; 7½"; 12"	7½"; 12"	Note 2
Hub/Needle bond strength	Complies with ISO7864	Complies with ISO7864	Identical
Biocompatibility	Complies with ISO10993-1	Complies with ISO10993-1	Identical
Performance	Complies with ISO 9626	Complies with ISO 9626	Identical
	ISO 7864	ISO 7864	
	ISO 80369-7	ISO 80369-7	
	ISO 80369-20	ISO 80369-20	
	ISO 23908	ISO 23908	
	ISO 6009	ISO 6009	
	ISO 8536-4	ISO 8536-4	
Sterilization	EO	EO	Identical
Sterile	Yes	Yes	Identical
SAL	10-6	10-6	Identical
Disposable	Yes	Yes	Identical
Single Patient Use	Yes	Yes	Identical
Shelf life	ASTMF 1980 5 years	ASTMF 1980 5 years	Identical

Note 1

The indication for use of subject devices is similar to the predicate device. The wording is slightly different; each subject device's IFU is listed individually for explicit identification (blood collection or infusion use; needle holder listed for sales individually). It does not raise new questions of safety or effectiveness.

Note 2

The flexing tubing length of the subject devices is available in more sizes than the predicates, but they conform to the same applicable performance standards. Therefore, this difference does not raise new questions of safety or effectiveness.

Non-Clinical Performance Testing

Testing was performed to evaluate the functional performance and safety of the subject device with the following standards:

Performance

- ISO 8536-4-2019 Infusion equipment for medical use —Part 4: Infusion sets for single use, gravity feed
- ISO 9626 Second edition 2016-08-01 Stainless steel needle tubing for the manufacture of medical devices - Requirements and test methods
- ISO 7864 Fourth edition 2016-08-01 Sterile hypodermic needles for single use - Requirements and test methods
- ISO 80369-7 First edition 2016-10-15 Small-bore connectors for liquids and gases in healthcare applications - Part 7: Connectors for intravascular or hypodermic applications
- ISO 80369-20 First edition 2015-05-15, small-bore connectors for liquids and gases in healthcare applications part 20: common test methods. (General I (QS/RM))
- ISO 23908 First edition 2011-06-11 Sharps injury protection - Requirements and test methods - Sharps protection features for single-use hypodermic needles, introducers for catheters, and needles used for blood sampling

Biocompatibility

The subject device is classified as external communication device and contact circulating blood for limited contact (duration $\leqslant$ 24 h).

- ISO10993-5: 2009 In Vitro Cytotoxicity
- ISO10993-10: 2021 Skin Sensitization
- ISO10993-23: 2021 Intracutaneous Reactivity Test
- ISO10993-11: 2017 Acute Systemic Toxicity
- ISO10993-4:2017 Coagulation test
- ISO10993-4: 2017 Complement activity (SC5b-9) Test
- ISO10993-4: 2017 Hemolytic Properties Test
- ISO10993-3 Ames Test
- ISO10993-3 Mammalian Chromosome Aberration Test

Sterilization:

The devices are EO sterilized. The sterilization validation was conducted according to the following standards:

- ISO11135-1 Sterilization of health care products - ethylene oxide - part 1: requirements for the development, validation, and routine control of a sterilization process for medical devices.
- ISO11737-1 Sterilization of medical devices-Microbiological Methods-Part 1: Determination of the population of microorganisms on the product.
- ISO11737-2 Sterilization of medical devices -- Microbiological methods – Part 2: Tests of sterility performed in the validation of a sterilization process.
- ISO10993-7 Biological evaluation of medical devices - Part 7: Test of Ethylene Oxide Residuals.
- ANSI/AAMI ST72 Bacterial endotoxins - Test methods, routine monitoring, and alternatives to batch testing.

Packaging and Shelf Life:

- ISO 11607-1:2006/(R) 2010 Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems, 3ed.
- ASTM F1929-15 Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration
- ASTM F1980-16 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
- ASTM D3078-02 (2021), Standard Test Method for Determination of Leaks in Flexible Packaging by Bubble Emission. (Sterility)
- ASTM F88/F88M-15 Standard Test Method for Seal Strength of Flexible Barrier Materials

The tests were conducted as noted below:

- Accelerated Aging Test
- Simulated shipping distribution testing
- Visual inspection
- Performance Inspection (Chemical performance and Physical performance)
- Sterile Test
- Vacuum Leak Test
- Dye penetration test
- Tensile Seal Strength Test

All the pre-determined acceptance criteria were met.

Clinical Data:
No clinical study is included in this submission.

Conclusions:
Based on the verification test results, the subject device, Jiangsu Kangbao Medical Equipment Co., Ltd, Winged Infusion Set, Safety Winged Infusion Set, Blood Collection Set, Blood Collection Set with Holder, Safety Blood Collection Set
Safety Blood Collection set with Holder and Needle Holder conforms to the requirements of the exact standard, such as performance and biocompatibility, as the predicate devices. The subject device uses the same fundamental scientific technology and indications for use and functionality. The differences do not raise new questions about the safety and effectiveness of the proposed device.