March 7, 2024

Jiangsu Caina Medical Co., Ltd.
Camel Zhou
Management Representative
No.23, Huanxi Road, Zhutang Town
Jiangyin, Jiangsu 214415
China

Re: K232781
Trade/Device Name: Safety Sliding Blood Collection Set
Regulation Number: 21 CFR 862.1675
Regulation Name: Blood Specimen Collection Device
Regulatory Class: Class II
Product Code: JKA
Dated: January 12, 2024
Received: February 5, 2024

Dear Camel Zhou:

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)*
K232781

Device Name
Safety Sliding Blood Collection Set

Indications for Use *(Describe)*
The Safety Sliding Blood Collection Set is intended to be used for insertion into a patient's vascular system for blood collection or short term (up to 2 hours) IV administration, by a trained medical professional. It aids in the prevention of accidental needle stick through the use of an active safety feature.

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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K232781- 510(k) Summary

This 510(k) Summary is being submitted in accordance with requirements of Title 21, CFR Section 807.92.

1. Date of Preparation: March 7, 2024

2. Sponsor Identification

Jiangsu Caina Medical Co., Ltd.
No.23, Huanxi Road, Zhutang Town, Jiangyin, Jiangsu, 214415, China

Establishment Registration Number: 3005670221

Contact Person: Jun Lu
Position: General Manager
Tel: +86-510-86205183
Fax: +86-510-86215183
Email: jun.lu@cainamed.com

3. Designated Submission Correspondent

Mr. Camel Zhou (Primary Contact Person)
Email: camel.zhou@cainamed.com
Ms. Tracy Gong (Alternative Contact Person)
Email: tracy.gong@cainamed.com
Tel: +86-510-86866666-8027
Fax: +86-510-86866666-8009

4. Identification of Subject Device

Trade Name: Safety Sliding Blood Collection Set
Common name: Blood Collection Set
Regulation Name: Blood specimen collection device
Device Class: Class II
Product Code: JKA
Regulation Number: 21 CFR 862.1675

5. Identification of Predicate Device

Predicate Device
510(k) Number: K980414
Product Name: VACUTAINER® Brand Blood Collection Set and Safety-Lok™ Blood Collection Set
Regulation Name: Blood specimen collection device
Device Class: Class II
Product Code: JKA
Regulation Number: 21 CFR 862.1675

6. Indications for Use Statement:

The Safety Sliding Blood Collection Set is intended to be used for insertion into a patient's vascular system for blood collection or short term (up to 2 hours) IV administration, by a trained medical professional. It aids in the prevention of accidental needle stick through the use of an active safety feature.

7. Device Description

Components of the subject device include: (1) Needle cap, (2) Butterfly wings, (3) Safety shield, (4) Needle, (5) Flexible tube, (6) Female luer (adapter), (7) Male luer hub, (8) Puncture needle, (9) Rubber sleeve, (10) Puncture needle protect cover, (11) Holder, (12) Protective cap.

The subject device has three configurations: without Holder, with Holder, without Male Adapter. Each configuration has all of the (1) - (6) components mentioned above. The difference between the three configurations is that they have only one or more of the (7) – (12) components mentioned above. The proposed device is available various needle size and flexible tube length. The range of needle size is from 25G (0.5mm) to 20G (0.9mm). The range of flexible tube length is from 10cm (4”) to 30cm (12”). Detailed information was listed as below:

Configuration	Needle gauge	Needle length	Flexible tube length	Male adapter	Holder
without Holder	25G(0.5mm); Thin-walled	1/2”(13mm)	4”(10cm)	Yes	No
		5/8”(16mm)	4”(10cm)		
		3/4”(20mm)	4”(10cm)		
		1/2”(13mm)	7”(18cm)		
		5/8”(16mm)	7”(18cm)		
		3/4”(20mm)	7”(18cm)		
		1/2”(13mm)	12”(30cm)		
		5/8”(16mm)	12”(30cm)		
		3/4”(20mm)	12”(30cm)		
	23G(0.6mm); Thin-walled	5/8”(16mm)	4”(10cm)		
		3/4”(20mm)	4”(10cm)		
		5/8”(16mm)	7”(18cm)		
		3/4”(20mm)	7”(18cm)		
		5/8”(16mm)	12”(30cm)		

		3/4”(20mm)	12”(30cm)		
	22G(0.7mm); Thin-walled	5/8”(16mm)	4”(10cm)		
		3/4”(20mm)	4”(10cm)		
		5/8”(16mm)	7”(18cm)		
		3/4”(20mm)	7”(18cm)		
		5/8”(16mm)	12”(30cm)		
		3/4”(20mm)	12”(30cm)		
	21G(0.8mm); Thin-walled	5/8”(16mm)	4”(10cm)		
		3/4”(20mm)	4”(10cm)		
		5/8”(16mm)	7”(18cm)		
		3/4”(20mm)	7”(18cm)		
		5/8”(16mm)	12”(30cm)		
		3/4”(20mm)	12”(30cm)		
	20G(0.9mm); Thin-walled	5/8”(16mm)	4”(10cm)		
		3/4”(20mm)	4”(10cm)		
		5/8”(16mm)	7”(18cm)		
		3/4”(20mm)	7”(18cm)		
		5/8”(16mm)	12”(30cm)		
		3/4”(20mm)	12”(30cm)		
with Holder	25G(0.5mm); Thin-walled	1/2”(13mm)	4”(10cm)	Yes	Yes
		5/8”(16mm)	4”(10cm)		
		3/4”(20mm)	4”(10cm)		
		1/2”(13mm)	7”(18cm)		
		5/8”(16mm)	7”(18cm)		
		3/4”(20mm)	7”(18cm)		
		1/2”(13mm)	12”(30cm)		
		5/8”(16mm)	12”(30cm)		
		3/4”(20mm)	12”(30cm)		
	23G(0.6mm); Thin-walled	5/8”(16mm)	4”(10cm)		
		3/4”(20mm)	4”(10cm)		
		5/8”(16mm)	7”(18cm)		
		3/4”(20mm)	7”(18cm)		
		5/8”(16mm)	12”(30cm)		
		3/4”(20mm)	12”(30cm)		
	22G(0.7mm); Thin-walled	5/8”(16mm)	4”(10cm)		
		3/4”(20mm)	4”(10cm)		
		5/8”(16mm)	7”(18cm)		
		3/4”(20mm)	7”(18cm)		
		5/8”(16mm)	12”(30cm)		
		3/4”(20mm)	12”(30cm)		
	21G(0.8mm);	5/8”(16mm)	4”(10cm)		

	Thin-walled	3/4”(20mm)	4”(10cm)		
		5/8”(16mm)	7”(18cm)		
		3/4”(20mm)	7”(18cm)		
		5/8”(16mm)	12”(30cm)		
		3/4”(20mm)	12”(30cm)		
	20G(0.9mm); Thin-walled	5/8”(16mm)	4”(10cm)		
		3/4”(20mm)	4”(10cm)		
		5/8”(16mm)	7”(18cm)		
		3/4”(20mm)	7”(18cm)		
		5/8”(16mm)	12”(30cm)		
		3/4”(20mm)	12”(30cm)		
without Male Adapter	25G(0.5mm); Thin-walled	1/2”(13mm)	4”(10cm)	No	No
		5/8”(16mm)	4”(10cm)		
		3/4”(20mm)	4”(10cm)		
		1/2”(13mm)	7”(18cm)		
		5/8”(16mm)	7”(18cm)		
		3/4”(20mm)	7”(18cm)		
		1/2”(13mm)	12”(30cm)		
		5/8”(16mm)	12”(30cm)		
		3/4”(20mm)	12”(30cm)		
	23G(0.6mm); Thin-walled	5/8”(16mm)	4”(10cm)		
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		5/8”(16mm)	7”(18cm)		
		3/4”(20mm)	7”(18cm)		
		5/8”(16mm)	12”(30cm)		
		3/4”(20mm)	12”(30cm)		
	22G(0.7mm); Thin-walled	5/8”(16mm)	4”(10cm)		
		3/4”(20mm)	4”(10cm)		
		5/8”(16mm)	7”(18cm)		
		3/4”(20mm)	7”(18cm)		
		5/8”(16mm)	12”(30cm)		
		3/4”(20mm)	12”(30cm)		
	21G(0.8mm); Thin-walled	5/8”(16mm)	4”(10cm)		
		3/4”(20mm)	4”(10cm)		
		5/8”(16mm)	7”(18cm)		
		3/4”(20mm)	7”(18cm)		
		5/8”(16mm)	12”(30cm)		
		3/4”(20mm)	12”(30cm)		
	20G(0.9mm); Thin-walled	5/8”(16mm)	4”(10cm)		
		3/4”(20mm)	4”(10cm)		
		5/8”(16mm)	7”(18cm)		

		3/4”(20mm)	7”(18cm)		
		5/8”(16mm)	12”(30cm)		
		3/4”(20mm)	12”(30cm)		

The subject device has sharps injury protection features. It aids in the prevention of accidental needle stick through the use of an active safety feature.

The subject device is a sterile, single use device. It is sterilized by Ethylene Oxide Gas (EtO) to achieve a SAL of 10^{-6} and supplied sterility maintenance package which could maintain the sterility of the device during the shelf life of three years.

No DEHP, BPA and Natural Rubber Latex are added in the proposed device.

8. Substantially Equivalent (SE) Comparison

Table 1 Comparison of Technology Characteristics

Characteristic	Subject Device, K232781	Predicate Device, K980414	SE Discussion
Indications for use	The Safety Sliding Blood Collection Set is intended to be used for insertion into a patient's vascular system for blood collection or short term (up to 2 hours) IV administration, by a trained medical professional. It aids in the prevention of accidental needle stick through the use of an active safety feature	The Vacutainer Brand Blood Collection Set and Safety-Lok Blood Collection Set is a winged blood collection needle and flexible tubing for venipuncture to collect blood specimen from patients or monitoring blood pressure. The Safety-Lok Blood Collection Set also contains a needle safety shield which minimizes the possibility of a needlesticks if manually activated following blood collection. The Vacutainer Brand Blood Collection Set and Safety-Lok Blood Collection Set is also recommended for use in patients with small veins. The Vacutainer Brand Blood Collection Sets and Safety-Lok Blood is also indicated for the intravenous administration of fluids and may be used for any patient population with	Similar See Comment 1

		consideration given to patient size, appropriateness for the solution being infused and duration of therapy.	
Components	Needle cap Butterfly wings Safety shield Needle Flexible tube Female luer (adapter) Male luer hub Puncture needle Rubber sleeve Puncture needle protect cover Holder Protective cap	Needle cap Butterfly wings Safety shield Needle Flexible tube Female luer (adapter) Male luer hub Puncture needle Rubber sleeve Holder Protective cap	Different See Comment 2
Patient contact material	Stainless steel SUS304; Polyvinyl chloride (PVC); Acrylonitrile butadiene styrene plastics(ABS); Methyl methacrylate acrylonitrile butadiene styrene plastics(MABS); Isoprene Rubber; Polydimethysiloxane; Color additive.	unknown	Different See Comment 3
Conditions of Use	Used in a health care facility by trained medical professional.	Used in a health care facility by trained medical professional.	Same
Needle size	Needle gauge 20G, 21G, 22G, 23G, 25G Needle length 1/2", 5/8", 3/4"	Needle gauge 21G,23G, 25G Needle length 3/4"	Different See Comment 4
Tube length	10cm(4"), 18cm(7"), 30cm(12")	12"	Different See Comment 4
Colors of safety shield	Translucent yellow	Translucent yellow	same
Biocompatibility	ISO 10993-1	ISO 10993-1	Same
Sterile	Yes	Yes	Same
Sterilization Method	EO	EO	Same
Sterility Assurance Level	10^{-6}	10^{-6}	Same
Non Pyrogenic	Yes	Yes	Same

Shelf life	3 years	3 years	Same
Single use	Yes	Yes	Same
Prescription Only or OTC	Prescription only	Prescription only	Same
Principles of operation	When vacuum blood collection tube is used, blood flows into the blood collection tube via the device under the action of differential pressure.	When vacuum blood collection tube is used, blood flows into the blood collection tube via the device under the action of differential pressure.	Same
Safety feature	Manual, active safety feature, an audible click indicate activation of safety feature	Manual, active safety feature, an audible click indicate activation of safety feature	Same

Comment 1

The subject device indications for use are similar to the predicate device indications for use. Both the subject and predicate devices are indicated for blood collection and IV administration. The difference is the subject device indication for use includes the maximum time for which the device can be used for IV administration, which is 2 hours. The difference does not raise different questions of safety and effectiveness.

Comment 2

The subject device provides an additional puncture needle protection cover compared to the predicate device. The puncture needle protect cover is made of PP, which is designed to prevent from needle stick injuries. The difference does not raise different questions of safety and effectiveness.

Comment 3

The patient contact materials for the subject device are different from predicate device. According to FDA guidance, Use of International Standard ISO 10993-1 "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process", the subject device is an externally communicating device of Blood path, indirect and limited contact. The Cytotoxicity test, Sensitization test, Intracutaneous reactivity test, Acute systemic toxicity test, Pyrogen test, Hemolysis test have been performed for subject device and adequately demonstrated biocompatibility. Therefore, this material difference does not affect substantially equivalence on safety and effectiveness.

Comment 4

The needle size and flexible tube length is different between subject device and predicate device. The subject device includes additional device configurations that include additional needle gauges and lengths and flexible tubing lengths. These additional devices configurations have been verified according to ISO 9626, ISO 7864, ISO 8536-4. The differences do not raise different questions of safety and effectiveness.

9. Non-Clinical Testing

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 subject device complies with the following standards:

- ISO 10993-7:2008 AMD.1:2019 Biological evaluation of medical devices- Part 7: Ethylene Oxide Sterilization Residuals
- ISO 10993-5:2009 Biological evaluation of medical devices- Part 5: Test for in vitro cytotoxicity
- ISO 10993-10:2021 Biological evaluation of medical devices - Part 10: Tests for skin sensitization
- ISO 10993-23:2021 Biological evaluation of medical devices - Part 23: Tests for irritation
- ISO 10993-11:2017 Biological evaluation of medical devices -- Part 11: Tests for systemic toxicity
- USP <151> Pyrogen Test
- ASTM F756-17 Standard Practice for Assessment of Hemolytic Properties of Materials
- ASTM F1929-15 Standard test method for detecting seal leaks in porous medical packaging by dye penetration.
- ASTM F88/F88M-21 standard method for seal strength of flexible barrier materials
- ASTM F1886/F1886M-16, Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection
- USP <85> Bacterial Endotoxins Test
- ISO 80369-7:2021 Small-bore connectors for liquids and gases in healthcare applications -Part 7: Connectors for intravascular or hypodermic applications
- ISO 80369-20:2015 Small-bore connectors for liquids and gases in healthcare applications - Part 20: Common test methods
- ISO 8536-4:2019 Infusion equipment for medical use - Part 4: Infusion sets for single use, gravity feed
- ISO 9626:2016 Stainless steel needle tubing for the manufacture of medical devices – Requirements and test methods
- ISO 7864:2016 Sterile hypodermic needles for single use - Requirements and test methods
- USP <788> Particulate Matter in Injections
- ISTA 3A:2018 Packaged-Products for Parcel Delivery System Shipment 70 kg (150 lb) or Less

In addition, the following verification or testing is performed to meet the stated performance requirements:

- Extraction force testing in simulation using
- Simulated Clinical Study for safety feature
- Sharps injury protection testing in accordance with ISO 23908:2011 Sharps injury protection - Requirements and test methods - Sharps protection features for single-use hypodermic needles, introducers for catheters and needles used for blood sampling

10. Clinical Test Conclusion

Clinical studies are not required to demonstrate substantial equivalence to the predicate device.

11. Substantial Equivalence Conclusion

Based on the comparison and analysis above, the subject device, Safety Sliding Blood Collection Set is determined to be Substantially Equivalent (SE) to the predicate device, cleared under K980414 in intended use, principles of operation, technology, design, materials and performance.