September 9, 2020

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

Re: K200027
Trade/Device Name: Blood Collection Needle with/without Holder, Safety Blood Collection Needle with/without Holder, Luer Access Device-holder with Preattached Multiple Sample Adapter
Regulation Number: 21 CFR 862.1675
Regulation Name: Blood specimen collection device
Regulatory Class: Class II
Product Code: JKA
Dated: July 24, 2020
Received: August 10, 2020

Dear Diana Hong:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K200027

Device Name
Blood Collection Needle with/without Holder
Safety Blood Collection Needle with/without Holder
Luer Access Device-holder with Preattached Multiple Sample Adapter

Indications for Use *(Describe)*
The Blood Collection Needle with/without holder is intended to be used with vacuum blood collection tube for the collection of venous blood.

The Safety Blood Collection Needle with/without holder is intended to be used with vacuum blood collection tube for the collection of venous blood. The safety shield is intended to aid in the protection against accidental needle stick injury.

The Luer access device- holder with preattached multiple sample adapter is a sterile, non-invasive device used to connect devices with male or female luer connectors to blood collection tubes for the collection of blood.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Exhibit # 2 510(k) Summary

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

The assigned 510(k) Number: K200027

1. Date of Preparation: 9/9/2020

2. Sponsor Identification

Jiangsu Caina Medical Co., Ltd.
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3. Designated Submission Correspondent

Ms. Diana Hong (Primary Contact Person)
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4. Identification of Proposed Device

Trade Name:
Blood Collection Needle with/without Holder
Safety Blood Collection Needle with/without Holder
Luer Access Device-holder with Preattached Multiple Sample Adapter

Common Name:
Blood specimen collection device

Regulatory Information

Primary product code
Regulation Name: Blood specimen collection device
Classification: II
Primary Product Code: JKA
Regulation Number: 21 CFR 862.1675

Indications for Use:

The Blood Collection Needle with/without holder is intended to be used with vacuum blood collection tube for the collection of venous blood.

The Safety Blood Collection Needle with/without holder is intended to be used with vacuum blood collection tube for the collection of venous blood. The safety shield is intended to aid in the protection against accidental needle stick injury.

The Luer access device- holder with preattached multiple sample adapter is a sterile, non-invasive device used to connect devices with male or female luer connectors to blood collection tubes for the collection of blood.

Device Description

The proposed devices are blood collection devices form a channel between patient's vein and the evacuated blood collection tube intended for collection of blood.

The Blood Collection Needle with/without Holder is intended for single use only, which consists of a non-patient needle cap or holder, non-patient needle, rubber sleeve, patient needle cap, patient needle, hub. They are available in different configurations.

The Safety Blood Collection Needle with/without Holder is intended for single use only, which consists

of a non-patient needle cap or holder, non-patient needle, rubber sleeve, patient needle cap, patient needle, hub, safety shield. They are available in different configurations. The safety shield will be manually activated to cover the needle immediately after use to minimize risk of accidental needle sticks.

In addition, the proposed devices are available in different specifications of needle gauge(27G-18G) and length (1”-1.5”).

The Luer Access Device- holder with Pre-attached Multiple Sample Adapter is intended for single use only, which consists of a holder, non-patient needle, rubber sleeve, and a male (or female) luer lock hub which mates the female (or male) connector of other medical devices. The luer hub is permanent assembled with holder. It can be used to establish a channel to connect with medical vacuum tubes and transfer fluids.

5. Identification of Predicate Devices

Predicate Device 1
510(k) Number: K172763
Product Name:
Blood Collecting Needle, Safety Blood Collecting Needle, Blood Collecting Needle with Holder, Safety Blood Collecting Needle with Holder, Blood Collecting Set, Safety Blood Collecting Set, Blood Collecting Set with Holder, Safety Blood Collecting Set with Holder
Regulation number: 862.1675
Product Code: JKA

Predicate Device 2
510(k) Number: K991088
Product Name: VACUTAINER® Brand Multiple Sample Luer Adapter
Regulation Number: 862.1675
Product Code: JKA

6. Comparison of Technological Characteristics

Table 1 Comparison of Technology Characteristics for Blood Collecting Needle with/without Holder and Safety Blood Collection Needle with/without Holder

ITEM	Proposed Device	Predicate Device K172763	Remark
Product Code	JKA	JKA	SE
Regulation Number	21CFR 862.1675	21CFR 862.1675	

Class	II	II	SE
Indications for Use	The Blood Collection Needle with/without holder is intended to be used with vacuum blood collection tube for the collection of venous blood. The Safety Blood Collection Needle with/without Holder is intended to be used with vacuum blood collection tube for the collection of venous blood. The safety shield is intended to aid in the protection against accidental needle stick injury.	The Blood Collecting Needle is intended to be used with vacuum blood collection tube for multiple collection of venous blood. The Safety Blood Collecting Needle is intended to be used with vacuum blood collection tube for multiple collections of venous blood. The safety shield is intended to aid in the protection against accidental needle stick injury.	SE
Configuration and material	Non-patient Needle Cap(PP) Patient Needle Cap(PP) Holder(PP) Rubber Sleeve (Case Gather Isoprene Rubber) Non- patient Needle Tube (Stainless Steel) Patient Needle Tube (Stainless Steel) Needle Tube (Stainless Steel) Luer Lock Male Hub(MABS) Luer Slip Male Hub(MABS) Needle Hub (PP or MABS) Safety Shield(PP) – only on the Safety Blood Collection Needle configuration Lubricant- Polydimethysiloxane	Protective Cover of Patient-end Needle (PP) Protective Cover of Non-patient end Needle(PP) Needle Holder (PP) Rubber Sleeve (Natural Rubber) Non-patient end Needle (Stainless Steel) Patient-end Needle (Stainless Steel) Patient-end Needle Hub (PP) Non-patient end Needle Hub (ABS) Conical fitting Lubricant: Epoxy Resin	SE Analysis 1
Operate mode	Manual	Manual	SE
Flashback Feature	Visible	Visible	SE
Safety Mechanism	The safety shield is intended to prevent needle sticks. Only on the Safety Blood Collection Needle configuration	The safety shield is intended to prevent needle sticks.	SE
Label/	Conform with 21 CFR Part 801	Conform with 21 CFR Part 801	SE

Labeling			
Needle Gauge and Length	Gauge: 20G~23G Length: 1",1.25",1.5"	Gauge: 18G~23G Length: 1", 1 1/4", 1 1/2"	SE Analysis 2
	Gauge: 27G, 25G, 23G, 22G, 21G, 20G, 18G Length: 1",1.25",1.5"	Gauge: 19G, 25G Length: 5/8", 3/4", 1", 1 1/4", 1 1/2", 1 3/4", 2"	
Performance	Comply with ISO 9626 ISO 7864	Comply with ISO 9626 ISO 7864	SE
Biocompatibility			
In Vitro Cytotoxicity	Testing leveraged from reference device K172938	Conform with ISO 10993 Standards	SE Analysis 3
Skin Sensitization			
Intracutaneous Reactivity			
Acute Systemic Toxicity			
Hemocompatibility			
Sterilization			
Method	EO sterilized	EO sterilized	SE
SAL	10^{-6}	10^{-6}	
Endotoxin Limit	20 EU per device	20 EU per device	

SE Analysis 1 –Configuration and material

The configuration difference between proposed device and predicate device is only the description of component. They have same configuration. The difference in the description of component does not affect the safety or effectiveness. This was evaluated through the performance testing.

In addition, the materials of rubber sleeve and hub from proposed device are different with predicate device. However, the biocompatibility test for proposed device has been tested and the results comply with the requirements of ISO 10993. Therefore, this difference is not determined to affect substantial equivalence on safety and effectiveness.

SE Analysis 2- Needle Gauge and Length

The needle gauge and length of between the proposed device and predicate device is different. However, this difference is just in dimension. Different gauge and length device will be selected by the end user. This difference does not affect raise new or different questions of safety or effectiveness

SE Analysis 3- Biocompatibility

The patient-contact materials of proposed device are different with the patient-contact materials of predicate device.

The patient contact material and manufacturing process for the proposed device is same as the reference device K172938. Therefore, new biocompatibility tests were not performed on the proposed device. And were leveraged from the reference device (K172938). Therefore, the proposed device will not raise any safety issues and is substantially equivalent to the predicate device.

The differences in technological characteristics were evaluated through performance testing.

Table 2 Comparison of Technology Characteristics for Luer Access Device-holder with Preattached Multiple Sample Adapter

ITEM	Proposed Device	Predicate Device K991088	Remark
Product Code	JKA	JKA	SE
Regulation Number	21CFR 862.1675	21CFR 862.1675	SE
Class	II	II	SE
Number of Uses	Single-use	Single-use	SE
Indications for Use	The Luer access device- holder with preattached multiple sample adapter is a sterile, non-invasive device used to connect devices with male or female luer connectors to blood collection tubes for the collection of blood.	The VACUTAINER® Brand Luer Adapter is a sterile, non-invasive device used to connect venous access devices such as needles, blood collection sets, and infusion sets to blood collection tubes. They are also used in connection with non-needle devices for collection of blood from catheters. The VACUTAINER® Brand Luer Adapter is sold by itself and as a component of other VACUTAINER Brand devices.	SE Analysis 4
Material	Luer Lock Male Hub(MABS) Non-patient Needle Tube(Stainless Steel) Rubber Sleeve (Isoprene Rubber) Holder(PP)	Hub(Polystyrene) Cannula(Stainless Steel) Sheath(Isoprene Rubber) Holder(Polypropylene (PP))	SE Analysis 5
Label/Labeling	Conform with 21 CFR Part 801	Conform with 21 CFR Part 801	SE

Design Feature	Length:60.8±0.2mm	Length: 64.3 mm	SE Analysis 6
Performance	Comply with ISO 80369-7	Comply with ISO 80369-7	SE
Biocompatibility			
In Vitro Cytotoxicity	Conform with ISO 10993 Standards	Conform with ISO 10993 Standards	SE
Skin Sensitization			
Intracutaneous Reactivity			
Acute Systemic Toxicity			
Hemocompatibility			
Sterilization			
Method	EO sterilized	EO sterilized	SE
SAL	10^{-6}	10^{-6}	
Endotoxin Limit	20 EU per device	20 EU per device	

SE Analysis 4 – Indications for Use

The proposed device and the predicate device is used to connect devices to blood collection tubes used for sampling. The differences in indications for use does not change the intended use of the device, which is to collect blood and connect to blood collection tubes for sampling.

SE Analysis 5- Material

The materials of hub from proposed device are different with predicate device. However, the biocompatibility test for proposed device has been tested and the results comply with the requirements of ISO 10993. Therefore, this difference is not determined to affect substantially equivalence on safety and effectiveness.

SE Analysis 6- Design Feature

The length of between the proposed device and predicate device is different. However, this difference is just in dimension. Different length device will be selected by physician per patient's condition. This difference does not affect intended use. Therefore, this difference does not affect substantially equivalence on safety and effectiveness.

The differences between proposed device and predicated device include Material of product and Length. These differences do not raise any question regarding its safety and effectiveness. The differences in technological characteristics may be evaluated through performance testing.

7. Non-Clinical Test Summary for the Subject Devices

Non clinical tests were conducted to verify that the proposed devices met all design specifications as

was Substantially Equivalent (SE) to the predicate device. For full titles of the standards and guidances used, see below. The tests performed on the relevant device configurations include:

Biocompatibility test

Biocompatibility tests was leveraged from our own reference device Disposable Sterile Needle (K172938) for the Blood Collecting Needle with/without Holder and Safety Blood Collection Needle with/without Holder, include in vitro cytotoxicity test (ISO 10993-5), skin sensitization test (ISO 10993-10), irritation sensitivity (ISO 10993-10), Acute Toxicity Test (ISO 10993-11), pyrogen test (ISO 10993-11) and Hemocompatibility Test (ASTM F756-17).

Biocompatibility tests was conducted on the Luer Access Device-holder with Preattached Multiple Sample Adapter, include in vitro cytotoxicity test (ISO 10993-5), skin sensitization test (ISO 10993-10), irritation sensitivity (ISO 10993-10), Acute Toxicity Test (ISO 10993-11), pyrogen test (ISO 10993-11) and Hemocompatibility Test (ASTM F756-17).

Extraction Force Test

The extraction force test was performed on proposed device. The test result demonstrated that the proposed device is able to successfully extract blood from a patient and fill blood tubes. This test is an internal test.

The test results demonstrated that the proposed devices comply with the following standards and guidance. The following tests were conducted as applicable to the subject devices:

- ISO 7864:2016 Sterile hypodermic needles for single use - Requirements and test methods
- ISO 9626:2016 Stainless steel needle tubing for the manufacture of medical devices - Requirements and test methods
- ISO 10993-5:2009 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
- ISO 10993-7:2008 Biological evaluation of medical devices - 7: Ethylene oxide sterilization residuals [Including: Technical Corrigendum 1 (2009)]
- ISO 10993-10:2010 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
- ISO 10993-11:2017 Biological evaluation of medical devices - Part 11: Tests for systemic toxicity
- 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 [Including: Amendment 1 (2018)]
- 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
- ISO 80369-7:2016 Small-bore connectors for liquids and gases in healthcare applications - Part 7: Connectors for intravascular or hypodermic applications

- ISO 80369-20:2015 Small-bore connectors for liquids and gases in healthcare applications - Part 20: Common test methods
- ASTM F756-17: Standard Practice for Assessment of Hemolytic Properties of Materials
- USP 41-NF 36:2018 <85> Bacterial Endotoxins Test
- Simulated Use Study Sharps Injury Prevention Feature FDA Guidance, Guidance for Industry and FDA Staff: Medical Device with Sharps Injury Prevention Feature, issued on August 9, 2005
- USP <788> Particular Matter in Injections

8. Clinical Test Conclusion

No clinical study is included in this submission.

9. Substantially Equivalent (SE) Conclusion

Based on the comparison and analysis above and the performance testing conducted, the proposed devices are determined to be Substantially Equivalent (SE) to the predicate devices.