October 21, 2022

Anhui Hongyu Wuzhou Medical Manufacturer Co., Ltd.
% Charles Mack
Principal Engineer
IRC
2950 E Lindrick Drive
Chandler, Arizona 85249

Re: K222141
Trade/Device Name: Safety Blood Collection Needle (Without Needle Holder)
Regulation Number: 21 CFR 862.1675
Regulation Name: Blood Specimen Collection Device
Regulatory Class: Class II
Product Code: JKA, FMI
Dated: July 22, 2022
Received: July 25, 2022

Dear Charles Mack:

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,

David Wolloscheck, Ph.D.
For Payal Patel
Assistant Director
DHT3C: Division of Drug Delivery and
General Hospital Devices,
and Human Factors
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

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)*
K222141

Device Name
Safety Blood Collection Needle (Without Needle Holder)

Indications for Use *(Describe)*
The safety blood collection needle without a needle holder is intended to be used with a vacuum blood collection tube to collect venous blood. The safety shield is intended to protect against accidental 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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安徽宏宇五洲医疗器械股份有限公司
ANHUI HONGYU WUZHOU MEDICAL MANUFACTURER CO., LTD

510(k) SUMMARY

K222141

1. Submitter Information

Preparation Date:	October 21, 2022
Manufacturer's Name and Address:	Anhui Hongyu Wuzhou Medical Manufacturer Co., Ltd. No. 2 Guanyin Road, Economic Development Zone, Taihu, Anqing City, Anhui Province, China 246400 Tel: +86- 0556 5129666
Corresponding Official:	Charles Mack
Telephone Number:	931-625-4938
Email Address:	charliemack@irc-us.com

2. Device

Trade Name:	Safety Blood Collection Needle (Without Needle Holder)
Common Name:	Blood Collection Tubes, Vials, Systems, Serum Separators
Regulation Name:	Blood specimen collection device
Regulation Number:	21 CFR 862.1675
Primary Product Code:	JKA
Secondary Product Code:	FMI
Device Class:	Class II
Predicate Device:	K200027 Safety Blood Collection Needle without Holder

3. Device Description:

The proposed device is a blood collection device to form a channel between the patient's vein and the evacuated blood collection tube intended for blood collection. The Pipe plug piercing needle is designed with a rubber cap, which can be activated to cover the needle immediately following venipuncture to aid in the protection against accidental needle stick injury. The product is to be used by appropriately trained healthcare professionals only in accordance with these instructions.
The Safety blood collection needles without needle holders are manufactured from tubular stainless steel sharpened at both ends that are attached as follows:

- The threaded hub has one side that is to connect with the needle holder, which is used to guide the needle into a vacuum blood collection tube. This end of the needle is shorter and fitted with a rubber cap and a needle hub.
- The opposite end of the needle tube is 3/4"-1 1/2" for blood collection and is fitted with a protective sleeve.

The needle hub and protective cap protect the needle tube.

The safety feature is easily operated through the release of a latch mechanism whereby the user slides a safety shield over the needle as it is removed from the patient. Once the needle is covered, the safety shield locks in place. This mechanism is substantially equivalent to that of the predicate device.

The devices are packaged as sterile, single-use, and single-patient use only.

The proposed device is comprised of the components listed below:

1. Bottom sheath
2. Rubber cap
3. Needle hub
4. Connecting base
5. Safety shield
6. Needle tube
7. Upper sheath

4. Indications for Use

The safety blood collection needle without a needle holder is intended to be used with a vacuum blood collection tube to collect venous blood. The safety shield is intended to protect against accidental needle stick injury.

5. Comparison of Technological Characteristics with the Predicate Device

Feature	Proposed Device	Predicate Device	Discussion
510(K)	K222141	K200027	N/A
Device Name	Safety Blood Collection Needle (Without Needle Holder)	Safety Blood Collection Needle without Holder	N/A
Product Code	JKA, FMI	JKA, FMI	Identical
Indication for Use	The safety blood collection needle without needle 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 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 Collection Needle with/without holder is intended to be used with vacuum blood collection tube for the collection of venous blood. 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.	*Note 1*
Operating mode	Manual	Manual	Identical
Safety Mechanism	The safety shield is intended to prevent needle sticks.	The safety shield is intended in order to avoid needle sticks.	Identical
Sterile	Yes	Yes	Identical

Feature	Proposed Device	Predicate Device	Discussion
Sterilization	EO	EO	Identical
Sterility (SAL)	10^{-6}	10^{-6}	Identical
Configuration and material	Bottom sheath (Non-patient Needle Cap) (PP) The upper sheath (Patient Needle Cap) (PE) Holder (N/A) Rubber Cap/Sleeve (Isoprene Rubber) Non- patient Needle Tube (Stainless Steel) Patient Needle Tube (Stainless Steel) Needle hub (ABS) Safety shield (PP) Lubricant- Silicone-based oils	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 Hub (PP or MABS) Safety Shield(PP) Lubricant- Silicone-based oils	*Different Note 2*
Needle gauge	25G, 24G, 23G, 22G, 21G, 20G, 19G, 18G	27G, 25G, 23G, 22G, 21G, 20G, 18G	*Note 3*
Needle Length	3/4”, 1”, 1 1/8”, 1 1/4”,1 2/5”, 1 1/2”	1”, 1 1/4”, 1 1/2”	*Note 4*
Performance	Complies with ISO7864, ISO9626, ISO 23908	Complies with ISO7864, ISO9626, ISO 23908	Identical
Biocompatibility	Complies with ISO10993-1	Complies with ISO10993-1	Identical
Single Patient Use	Yes	Yes	Identical

Discussion:

Note 1: IFU

The predicate device included three devices: Blood Collection Needle with/without holder; Safety Blood Collection Needle with/without holder and Luer access device-holder with preattached multiple sample adapter; We only choose "Safety Blood Collection Needle with/without holder" as the predicate device, and the difference is that the subject device doesn't include needle holder, but the intended use is exactly same as the predicate device. The difference doesn't raise new questions on the safety and effectiveness of the subject device.

Note 2: Material

Although the material of the subject device is not fully exactly the same as predicate device, they conform to the same ISO10993-1 biocompatibility standards.

Note 3: Needle Gauge

The needle gauge of the subject devices is not fully exactly the same as the predicate device, but they still conform to the same applicable performance standards of ISO 9626. Therefore, the difference does not raise new questions about the safety and effectiveness of the proposed device.

Note 4: Needle Length

The needle length of the subject devices is available more in size than the predicate device, but they conform to the same applicable performance standards per ISO 7864. Therefore, the difference does not raise new questions about the safety and effectiveness of the proposed device.

6. Performance Testing

To establish substantial equivalence to the identified predicate device, we performed the tests noted below on the subject devices. The testing results proved that the subject device complies with the applicable standards requirement and is substantially equivalent to the predicate devices.

Non-Clinical Performance Testing

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

Performance:

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 Corrected version 2016-12-01 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

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

ISO 6009 Fourth edition 2016-08-01 Hypodermic needles for single use - Colour coding for identification

ISO 2859-1 Second edition 1999-11-15 Sampling procedures for inspection by attributes - Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection [Including: Technical Corrigendum 1 (2001), Amendment 1 (2011)]

Biocompatibility

ISO 10993-5: 2009 In Vitro Cytotoxicity

ISO 10993-10: 2010 Skin Sensitization

ISO 10993-10: 2010 Intracutaneous Reactivity

ISO 10993-11: 2017 Acute Systemic Toxicity

ISO 10993-4: 2017 & ASTM F756-17: Hemolytic Properties

ISO 10993-4: 2017 Complement activity

ISO 10993-4:2017 Coagulation - PPT Test

ISO10993-11: 2017 USP 43-NF38 <151> Pyrogen Test

Sterilization Validation:

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.
ISO 10993-7: Biological evaluation of medical devices - Part 7: Test of Ethylene Oxide Residuals.
AAMI / ANSI ST72: Bacterial endotoxins - Test methods, routine monitoring, and alternatives to batch testing.

Package and Shelf Life:
AAMI/ANSI/ISO 11137-1:2006/(R) 2010 Sterilization of health care products - Radiation - Part 1: Requirements for development, validation, and routine control of a sterilization process for medical devices
AAMI/ANSI/ISO 11737-2:2009 Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation, and maintenance of a sterilization process
AAMI/ANSI/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)
DIN58953-6: 2016 Sterilization - Sterile supply - Part 6: Microbial barrier testing of packaging materials for medical devices which are to be sterilized.
ASTM F88/F88M-15 Standard Test Method for Seal Strength of Flexible Barrier Materials

The package integrity test, as noted below, was conducted for the sterilization package of the subject devices by accelerated aging testing followed by simulated shipping distribution testing:
Accelerated Aging Test
Simulated shipping distribution testing
Visual inspection
Performance Inspection (Chemical performance and Physical performance)
Sterile Test
Vacuum Leak Test

Dye penetration test
Agar Contact-Attack Test
Tensile Seal Strength Test

Clinical Performance Data

No clinical data was submitted in this submission.

Conclusions:

The differences between the predicate and the subject device do not raise any new or different questions of safety or effectiveness. The Safety Blood Collection Needle (Without Needle Holder) is substantially equivalent to the predicate cleared under K200027 concerning the indications for use, target populations, treatment method, and technological characteristics.