March 24, 2023

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

Re: K223323
Trade/Device Name: Blood Collection Needle (with/without Needle Holder)
Regulation Number: 21 CFR 862.1675
Regulation Name: Blood Specimen Collection Device
Regulatory Class: Class II
Product Code: JKA, FMI
Dated: February 21, 2023
Received: February 22, 2023

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.

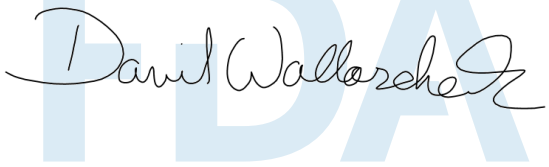
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal

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.
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)*
K223323

Device Name
Blood Collection Needle (with/without Needle Holder)

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

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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

K223323 - 510(k) SUMMARY

Preparation Date:	March 24, 2023
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- 556 5129666
Corresponding Official:	Charles Mack
Telephone Number:	931-625-4938
Email Address:	charliemack@irc-us.com
Trade Name:	Blood Collection Needle (with/without Needle Holder)
Common Name:	Blood Collection Tubes, Vials, Systems, Serum Separators
Regulation Name:	Blood specimen collection device
Regulation Number:	21CFR862.1675
Primary Product Code:	JKA
Secondary Product Code:	FMI
Device Class:	Class II
Predicate Device:	
510K Number:	K200027
Product Name:	Blood Collection Needle with/without Holder
Regulation Number(s):	21CFR862.1675
Product Code:	JKA

Device Description:

The subject devices are blood collection devices used in routine venipuncture procedures, which form a channel between the patient's vein and the evacuated blood collection tube intended to collect blood.

The Blood Collection Needle (with/without Needle Holder) is intended for single use only and consists of a bottom sheath or needle holder, needle tube, rubber cap, upper sheath, and hub. They are available in different configurations.

The product is to be used by appropriately trained healthcare professionals only in accordance with these instructions.

It is manufactured from tubular stainless steel sharpened at both ends and is attached to the hub:

- The subject devices are available with a pre-attached needle holder or without a needle holder; the hub is threaded on one side to connect with the needle holder, which is used to guide the needle into an evacuated blood collection tube. This needle's end is shorter and fitted with a protective rubber cap and a needle holder.
- The opposite end of the needle is longer for withdrawing blood and is fitted with a needle sheath.

The subject devices are available in different specifications of needle gauge (25G-18G) and length (3/4"-1 1/2").
The proposed devices are only packaged as sterile, disposable, and single-patient use.

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

Indications for Use

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

Feature	Subject Device	Predicate Device	Remark
FDA510(K)	Pending	K200027	N/A
Device Name	Blood Collection Needle (with/without Needle Holder)	Blood Collection Needle with/without Holder; Safety Blood Collection Needle with/without Holder; Luer Access Device-holder with Preattached Multiple Sample Adapter	*Note 1*
Product code	JKA	JKA	Identical
Subsequent product code:	FMI	FMI	Identical
Indication for Use	The Blood Collection Needle (with/without Needle Holder) is intended to be used with a vacuum blood collection tube for the collection of venous blood.	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.	*Note 1*
Needle gauge	25G, 24G, 23G, 22G, 21G, 20G, 19G, 18G	27G, 25G, 23G, 22G, 21G, 20G, 18G	*Note 2*
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 3*
Needle wall thickness	Regular Wall and Thin Wall	Regular Wall and Thin Wall	Identical

Feature	Subject Device	Predicate Device	Remark
Configuration and material	*Bottom Sheath (PP)* *Upper Sheath (PE)* *Non- patient Needle Tube* (Stainless Steel) *Patient Needle Tube* (Stainless Steel) *Rubber Sleeve* *Needle Hub (ABS)* *Lubricant* (Polydimethysiloxane) *Holder* (PP)	*Non-patient Needle Cap*(PP) *Patient Needle Cap* (PP) *Non- patient Needle Tube* (Stainless Steel) *Patient Needle Tube* (Stainless Steel) *Rubber Sleeve* (Case Gather Isoprene Rubber) *Needle Hub* (PP or MABS) *Lubricant* (Polydimethysiloxane) *Holder* (PP)	*Note 4*
Biocompatibility	Complies with ISO10993-1 *In Vitro Cytotoxicity* *Skin Sensitization* *Intracutaneous Reactivity* *Acute Systemic Toxicity* *Hemocompatibility*	Complies with ISO10993-1 *In Vitro Cytotoxicity* *Skin Sensitization* *Intracutaneous Reactivity* *Acute Systemic Toxicity* *Hemocompatibility*	Identical
Performance	Complies with ISO 7864 ISO 9626 ISO 11135:2014 ISO 80369-7 ISO 80369-20 USP788	Complies with ISO 7864 ISO 9626 ISO 11135:2014 ISO 80369-7 ISO 80369-20 USP788	Identical
Label/labeling	Conform with 21 CFR Part 801	Conform with 21 CFR Part 801	Identical
Sterilization	EO	EO	Identical
Sterile	Yes	Yes	Identical
SAL	10^{-6}	10^{-6}	Identical
For Single use	Yes	Yes	Identical
Single Patient Use	Yes	Yes	Identical

Note 1: Predicate Device and IFU statement

The predicate device included three devices; We only chose one "Blood Collection Needle with/without Needle Holder" as the predicate device;

The subject device's Indication for Use is precisely the same as the selected predicate device "Blood Collection Needle with/without Needle Holder" in K200027; it doesn't raise new questions on the safety and effectiveness of the subject device.

Note 2: Needle Gauge

The needle gauge of the subject devices differs from 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 3: Needle Length

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

Note 4: Material

Although the materials of these components of subject devices are different from predicate devices, they conform to the same ISO10993-1 biocompatibility standards;

Performance Testing

To establish substantial equivalence to the identified predicate devices, we performed the tests noted below on the subject devices. The testing results proved that the 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 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: standard test methods. (General I (QS/RM))
- ISO 6009 Fourth edition 2016-08-01 Hypodermic needles for single use - Colour coding for identification

Biocompatibility

The subject device is classified as an external communication device → Circulating Blood → Limited Contact Duration (≤24h).

- 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:

Applicable Standards:

- 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
- USP 41 <1207> Package Integrity Evaluation – Sterile Products; <1207.1> Package Integrity Testing in the Product Life Cycle – Test Method Selection and Validation; <1207.2> Package Integrity Leak Test Technologies.

The package integrity test 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
- Container Closure Integrity Test

Clinical Data

No clinical data was submitted in this submission.

Conclusions:

Based on the verification test results, the subject devices conform to the exact standards requirements, such as performance and biocompatibility as the predicate devices. The subject device uses the same fundamental scientific technology, the same indications for use, sterilization methods, and the same shelf life and packaging. The different technological characteristics do not raise new or different questions about the safety and effectiveness of the proposed device.

END