August 10, 2022

Anhui Hongyu Wuzhou Medical Manufacturer Co., Ltd.
% Evan Hu
Marketing & Technical Manager
Shanghai Mind-link Consulting Co., Ltd.
1399 Jiangyue Road, Minhang
Shanghai, Shanghai 201114
China

Re: K220900
Trade/Device Name: Safety Blood Collection Needles with/without Needle Holder
Regulation Number: 21 CFR 862.1675
Regulation Name: Blood Specimen Collection Device
Regulatory Class: Class II
Product Code: JKA
Dated: June 10, 2022
Received: July 11, 2022

Dear Evan Hu:

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)*

K220900

Device Name

Safety Blood Collection Needles with/without Needle Holder

Indications for Use *(Describe)*

Safety blood collection needles with/without needle holder are intended to be used with vacuum blood collection tubes for multiple collections of venous blood. The safety shield is intended to aid in the protection against, accidental needle stick injuries.

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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K220900 510(k) SUMMARY

1. Preparation Date: 8/10/2022

2. Submitter

   Manufacturer: Anhui Hongyu Wuzhou Medical Manufacturer Co., Ltd.
   Address: No.2 Guanyin Road, Taihu Economic Development Zone, Anqing City, Anhui Province, 246400, China
   Contact person: Bingyi Xiang, +86-556 5129666, hwj1@hongyu-wuzhou.cn
   Submission correspondent: Evan Hu, 86-18616124827, Evan.hu@mind-link.net

3. Device

   Trading Name: Safety Blood Collection Needles with/without Needle Holder
   Common Name: Blood Collection Tubes, Vials, Systems, Serum Separators
   Regulation Name: Blood specimen collection device
   Regulation Number: 21 CFR 862.1675
   Classification: Class II
   Product code: JKA

4. Predicate device

   Primary predicate device: Safety Blood Collection Needle for Single Use / Safety Blood Collection Needle with Holder for Single Use – K212019

5. Device description

   The Safety blood collection needles with/without needle holder is used in routine venipuncture procedures. That is composed of a bottom sheath, rubber cap, needle hub, connecting base, safety shield, needle tube, upper sheath, and optional needle holder, which are made from PP, PE, ABS, rubber, and SUS materials. The proposed device has various configurations and sizes, differing in various colors for easy recognition by use.
   The threaded hub is one side that connects 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 is fitted with a rubber cap and a needle hub.
   The Safety blood collection needles with /without needle holder are manufactured from tubular stainless steel sharpened at both ends that are attached:

- The opposite end of the needle tube is ¾" ～1 ½" for blood collection and is fitted with a protective sleeve.
- The needle hub and protective cap protect the needle tube.

The self-locking mechanism is positioned within the center and the proximal end of the sheath. The hinge structure could let clinical personnel flexibly adjust the sheath to the designed position for use. The safety feature is easily operated by releasing 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.

Table. 1. Device specifications

Size (mm)	Gauge	Bevel		Wall thickness (mm)		Needle length (Inch and mm)					
		LB	SB	RW	TW	¾", 19mm	1", 25mm	1 ⅛", 28mm	1 ¼", 32mm	1 ⅜", 35mm	1 ½", 38mm
0.5	25G	√	√	0.18	0.23	√	√	√	√	√	√
0.55	24G	√	√	0.22	0.27	√	√	√	√	√	√
0.6	23G	√	√	0.25	0.29	√	√	√	√	√	√
0.7	22G	√	√	0.3	0.35	√	√	√	√	√	√
0.8	21G	√	√	0.4	0.42	√	√	√	√	√	√
0.9	20G	√	√	0.48	0.49	√	√	√	√	√	√
1.1	19G	√	√	0.58	0.6	√	√	√	√	√	√
1.2	18G	√	√	0.7	0.73	√	√	√	√	√	√

Note: "√" means that it is available to this configuration.

6. Indications for use/Intended use

Safety blood collection needles with/without needle holder are intended to be used with vacuum blood collection tubes for multiple collections of venous blood. The safety shield is intended to aid in the protection against, accidental needle stick injuries.

7. Comparison of technological characters between proposed and predicate devices

Table 2. Characters comparison

Characters	Proposed device K220900	Primary predicate device K212019	Remark
Product name	Safety Blood Collection Needles with /without Needle Holder	Safety Blood Collection Needle for Single Use Safety Blood Collection Needle with Holder for Single Use	-
Product code	JKA	JKA	Same
Regulation No.	21 CFR 862.1675	21 CFR 862.1675	Same

Class	II	II	Same
Intended use/Indications for use	Safety blood collection needles with/without needle holder are intended to be used with vacuum blood collection tubes for multiple collections of venous blood. The safety shield is intended to aid in the protection against, accidental needle stick injuries.	The Blood Collection Needle/ The Blood Collection Needle with Holder/ The Blood Collection Set/ The Blood Collection Set with Holder is intended to be used with vacuum blood collection tube for multiple collections of venous blood. The Safety Blood Collection Needle/ The Safety Blood Collection Needle with Holder/ The Safety Blood Collection Set/ The Safety Blood Collection Set with Holder 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.	#1
Configuration and Material	(1) Bottom sheath (PP) (2) Rubber cap (Isoprene rubber) (3) Needle hub (PP) (4) Connecting base (ABS) (5) Safety sheath (PP) (6) Needle tube (SUS 304) (7) Upper sheath (PE) (8) Needle holder (PP)	(1) Needle cover (PP) (2) Needle sleeve (Isoprene rubber) (3) Needle hub-Male (PP) (4) Needle hub-Female (ABS) (5) Safety shield (PP) (6) Needle tube (SUS 304) (7) Needle cap (PP) (8) Holder (PP)	#2
Needle gauge and length	18G,19G, 20G, 21G, 22G, 23G, 24G, 25G ¾", 1", 1 ⅛", 1 ¼", 1 ⅜", 1 ½",	18G, 20G, 21G, 22G, 23G,25G 1 ½", ¾"	#3
Sharps prevention function	Manually operated safety sheath Comply with ISO 23908	Manually operated safety sheath Comply with ISO 23908	Same
Performance	Comply with ISO 7864 and ISO 9626	Comply with ISO 7864 and ISO 9626	Same
Sterility method	Sterilized by EO SAL 10^{-6}	Sterilized by EO SAL 10^{-6}	Same
Biocompatibility	Comply with ISO 10993 serials	Comply with ISO 10993 serials	Same

Notes:

#1: Intended use/indication for use

The predicate device is a bundle of different devices that comprises (1)Blood Collection Needle for Single Use, (2)Safety Blood Collection Needle for Single Use, (3)Blood Collection Needle with Holder for Single Use, (4)Safety Blood Collection Needle with Holder for Single Use, (5)Blood Collection Set for Single Use, (6)Safety Blood Collection Set for Single Use,

(7)Blood Collection Set with Holder for Single Use, and (8)Safety Blood Collection Set with Holder for Single Use. The proposed device only compares with (2) and (4), included in the predicate device. Therefore, it does not affect the safety and effectiveness comparison that can be considered substantially equivalent.

#2: configuration and materials
Most of the materials used by the proposed device and the predicate device are the same, except for the upper sheath/needle cap. The proposed device uses PE, but the predicate device uses PP. However, the biocompatibility testing of the proposed device proves to be safe and complies with ISO 10993. Therefore, it does not affect the safety and effectiveness comparison that can be considered substantially equivalent.

#3: Needle gauge and length
The proposed device has a broader range of needle gauges and lengths than the predicate device. The performance testing of all specifications of the proposed device proves to be safe and effective and complies with ISO 9626 and ISO 7864. Therefore, it does not affect the safety and effectiveness comparison that can be considered substantially equivalent.

8. Non-clinical performance testing

The non-clinical tests of this proposed device are tested in conformance with the following standards.

(1) Physical performance testing:
(a) ISO 7864:2016, Sterile hypodermic needles for single use.
(b) ISO 9626:2016 Stainless Steel Needle Tubing for the Manufacture of Medical Device.
(c) ISO 6009:2016 Hypodermic needles for single use - Colour coding for identification
(d) ISO 23908:2011 SHARPS INJURY PROTECTION — REQUIREMENTS AND TEST METHODS — SHARPS PROTECT
(e) ISO 80369-7:2016 Small-bore connectors for liquids and gases in healthcare application- Part 7: Connectors for intravascular or hypodermic applications
(f) ISO 80369-20:2015 Small-bore connectors for liquids and gases in healthcare applications - Part 20: Common test methods
(g) Simulated Clinical Use Study was conducted per the Guidance for Industry and FDA Staff, *Medical Devices with Sharps Injury Prevention Features*

(2) Sterility, Shipping and Shelf-Life:
(a) ISO 10993-7:2008/AMD 1:2019 Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals - Amendment 1: Applicability of allowable limits for neonates and infants.
(b) ASTM D4169-16 Standard Practice for Performance Testing of Shipping Containers and Systems

(c) ASTM F1140: 2020, Standard Test Methods for Internal Pressurization Failure Resistance of Unrestrained Packages
(d) ASTM F88: 2015, Standard Test Method for Seal Strength of Flexible Barrier Materials
(e) ASTM D3078-2: 2013, Standard Test Method for Determination of Leaks in Flexible Packaging by Bubble Emission
(f) ASTM F1929: 2015, Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration
(g) ASTM F1980-16, Standard guide for accelerated aging of sterile barrier systems for medical devices
(h) ASTM F1886/F1886M-16, Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection
(i) 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.
(j) Shelf life of 5 years is validated per ASTM F1980-16, Standard Guidance for Accelerated Aging of Sterile Barrier Systems for Medical Devices

(3) Biocompatibility testing:
(a) ISO10993-1:2018, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process.
(b) ISO 10993-4:2017 Biological evaluation of medical devices Part 4: Selection of tests for interactions with blood.
(c) ISO 10993-5:2009, Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity.
(d) ISO 10993-10:2010, Biological evaluation on medical device Part 10: Test for irritation and Skin Sensitization.
(e) ISO 10993-11:2017, Biological evaluation of medical devices Part 11: Tests for systemic toxicity.
(f) USP 40, <85> Bacterial Endotoxins Test
(g) USP 40, <71> Sterility Test
(h) USP 40, <788>Particulate matter in injection

Briefly, performance testing summary as shown in table 3
Table 3. A summary of the performance/biocompatibility testing results

Standard/Test description	Acceptance criteria	Results
ISO 7864, needle performance testing	Refer to ISO 7864 clause 4	Meet performance requirements
ISO 9626, needle tube performance testing	Refer to ISO 9626 clause 5	Meet performance requirements
ISO 6009, needle hub color	Refer to ISO 6009 clause 3	Meet color code requirements
ASTM F88, packaging sealing strength testing	Sealing strength >1.5N/15mm	Pass, round 1.8N/15mm

ASTM D3078-2, package leakage bubble emission	No bubbles observed attributable to leaks, and no test fluid attributable to a leak is inside a specimen	Pass, no bubbles or fluid observed
ASTM F1929, dye penetration testing	No dye penetrates into packaging	Pass, no dye penetrated into package
ISO 11737-1/-2, USP <71>, sterility testing – microbiological method	Negative result of micros culture	Negative
ISO 10993-7, EO/ECH residual testing	EO <4mg/day ECH <9mg/day	EO pass ECH undetectable
ISO 10993-4, in-vitro hemolytic testing	No hemolysis	No hemolysis
ISO 10993-5, in-vitro cytotoxicity testing	No cytotoxicity	No cytotoxicity
ISO 10993-10, irritation and skin sensitization testing	No irritation and no skin sensitization	No irritation and no skin sensitization
ISO 10993-11, acute systemic toxicity testing	No acute systemic toxicity	No acute systemic toxicity
ISO 10993-11, pyrogens testing	No pyrogens	No evidence of pyrogens
USP <85>, endotoxin testing	<20EU/device	Pass
USP <788>, residual particles testing	The average number of particles present in the units tested should not exceed 6000 per container equal to or greater than 1 0 mm and should not exceed 600 per container equal to or greater than 25 mm.	Pass
ISO 23908 sharp injury protection – activation and safe mode	Testing items with vary criteria Refer to ISO 23908 Clause 4.2 and Clause 4.3	Pass
USP 41 <1207> rigid package integrity evaluation	Testing items with vary criteria Refer to USP <1207.2>	Pass
Simulated clinical study	<1% failures under 95% CL	0% failures.
ISO 80369, luer connector	Vary criteria refer to ISO 80369	Pass

9. Clinical Tests
   Not Applicable

10. Conclusion
    The differences between the predicate and the subject device do not raise any new or different questions of safety or effectiveness. The subject device is substantially equivalent to the predicate device with respect to indications for use and technological characteristics.