



February 23, 2021

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

Re: K202188
Trade/Device Name: Safety Blood Collection Sets for Single Use
Regulation Number: 21 CFR 862.1675
Regulation Name: Blood Specimen Collection Device
Regulatory Class: Class II
Product Code: JKA, FMI

Dear Charles Mack:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated February 19, 2021. Specifically, FDA is updating this SE Letter to include the secondary product code (FMI) as an administrative correction.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Payal Patel, OHT3: Office of GastroRenal, ObGyn, General Hospital and Urology Devices, 240-402-6029, Payal.Patel@fda.hhs.gov.

Sincerely,

**James M. Simpson Jr -
S7**

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



February 19, 2021

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Principal Engineer
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Re: K202188

Trade/Device Name: Safety Blood Collection Sets for Single Use
Regulation Number: 21 CFR 862.1675
Regulation Name: Blood Specimen Collection Device
Regulatory Class: Class II
Product Code: JKA
Dated: January 8, 2021
Received: January 19, 2021

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,

James M. Simpson Jr -
S7 

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
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Enclosure

Indications for Use

510(k) Number (if known)

K202188

Device Name

Safety Blood Collection Sets for Single Use

Indications for Use (Describe)

The Safety Blood Collection Sets for Single Use and blood collection tube/syringe are used together for the collection of venous blood. The winged needle is designed with a safety shield which can be activated to cover the needle immediately following blood collection to aid in the protection against accidental needlestick 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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K202188 510(k) SUMMARY

Preparation Date: February 23, 2021

Manufacturer's Name and Address: Anhui Hongyu Wuzhou Medical
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PRINCIPAL ENGINEER
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931-625-4938

Telephone Number:

Email Address: charliemack@irc-us.com

Trade Name: Safety Blood Collection Sets for Single-
Use

Common Name(s): Blood collection

Regulation Name(s): Blood specimen collection device

Regulation Number(s): 21CFR862.1675

Product Code: JKA (Primary)
FMI (Secondary)

Device Class: Class II

Predicate Device: Innovative Medical Technologies, Inc.
Improsafe Blood Collection Set
K123987

Device Description:

The Safety Blood Collection Sets for Single Use are used in routine venipuncture procedures. The winged needle is designed with a safety shield, which can be activated to cover the needle immediately the following venipuncture to aid in the protection against accidental needlestick injury. The Safety Blood Collect Sets is compatible for use with a tube and syringe. The product is to be used by appropriately trained healthcare professionals, only following the product instructions.

The Blood Collection needle is manufactured from tubular stainless steel sharpened at both ends that is attached to the hub.

- The hub is threaded on one side to connect to the needle holder, which is used to guide the needle into an evacuated blood collection tube. This end of the needle is the shorter end and is fitted with a protective rubber cap and a needle holder.
- The opposite end of the needle is 3/4" long for withdrawing blood and is fitted with a needle sheath.

The needle holder and needle sheath protect the needle.

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

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

The proposed device consists of ten components:

1. needle holder
2. rubber sleeve
3. puncture needle
4. needle hub (male luer lock connector)
5. connect base (female luer lock connector)
6. flexing tube
7. safety shield
8. wings
9. patient-end tube needle
10. needle sheath

The subject device is classified as externally communicating devices, contact circulating blood for limited contact (<24 h) duration according to ISO10993-1 Fourth edition 2009-10-15 Annex A Table A.1-Evaluation tests for consideration.

Intended Use / Indications for Use

The Safety Blood Collection Sets for Single Use and blood collection tube/syringe are used together for the collection of venous blood. The winged needle is designed with a safety shield which can be activated to cover the needle immediately following blood collection to aid in the protection against accidental needle stick injury.

Comparison of Technological Characteristics with the Predicate Device

Feature	Subject Device	Predicate Device	Discussion /Comment
Company	Anhui Hongyu Wuzhou Medical Manufacturer Co., Ltd.	Innovative Medical Technologies, Incorporated	N/A
FDA510(K) Number	K202188	K123987	N/A
Device Name	Safety Blood Collection Set for Single-Use	Improsafe Blood Collection Set	N/A
Primary product code	21CFR862.1675, JKA	21CFR862.1675, JKA	N/A
Secondary product code	21CFR880.5570, FMI		
Indication for Use	<p>The Safety Blood Collection Set for Single Use and blood collection tube/syringe are used together for the collection of venous blood. The winged needle is designed with a safety shield which can be activated to cover the needle immediately following blood collection to aid in the protection against accidental needle stick injury.</p>	<p>Improve Blood Collection Set and Improsafe Blood Collection Set are winged blood collection needles with flexible tubing and a female luer adapter intended for venipuncture to obtain blood samples from patients. Some reorder numbers are provided with a male luer adapter. The male luer adapter contains a non-patient needle end for puncturing the stopper of an evacuated blood collection tube. Those without a male luer adapter are provided with a protective cap on the end of the female luer adapter. The Improsafe Blood Collection Set is provided with an attached safety shield for covering the used needle prior to disposal. After withdrawal of the needle from the patient's vein, the attached safety shield can be manually activated to cover the needle immediately after use to minimize risk of accidental needle stick.</p> <p>The Improve Blood Collection Set and Improsafe Blood Collection Set is also indicated for short-term (up to 2 hours) intravenous administration of fluids and may be used for any patient population with consideration given to patient size, appropriateness for the solution being infused and duration of therapy. For devices that include the male luer adapter: after removing the attached male luer adapter from the blood collection set, connect the female luer adapter to a syringe or other compatible/appropriate device.</p>	<p>The indications for use of venipuncture to obtain blood samples from patients are the same between the subject device and the predicate device.</p> <p>The predicate device can be provided without a male luer adapter, where this is not available in the subject devices.</p> <p>The predicate device is indicated for short-term (up to 2 hours) intravenous administration of fluids, while subject device is not indicated for intravenous administration of fluids.</p>

Feature	Subject Device	Predicate Device	Discussion /Comment
Safe Feature	The needle is locked in a safety sheath by slide the safety shield forward with pulling the tubing backward until an audible click is heard.	The needle is wholly retracted and locked by slide the safety shield forward by pulling the tubing backward until an audible click is heard.	Both devices have the same operation.
Material			
Needle sheath	HDPE	HDPE	Same material
Needle tube	SUS304	SUS304	Same material
Needle holder	Polypropylene	None.	The subject device is available with a needle holder, while the predicate is not.
Safety shield	Polypropylene	Polypropylene	Same material
Flexing tube	PVC	PVC	Same material
Rub sleeve	Gather Isoprene Rubber	Rubber (Synthetic)	Although the rub sleeve material is different between subject device and the predicate device, both conform to the same ISO10993-1 standards requirement.
Luer adapter	ABS	ABS	Same Material
Lubricant	Silicone oil	Unknown	Although the predicate device's lubricant material is unknown, both conform to the same ISO10993-1 standards requirement.
Adhesive	Epoxy Resin	Unknown	Although the predicate device's adhesive material is unknown, both conform to the same ISO10993-1 standards requirement.
Colors of wing	Green	Green	Same color, no difference.
Colors of the safety shield	Translucent blue	Translucent yellow	The color of the safety shield is different. The subject device is translucent blue, while the predicate device is translucent yellow. Both conform to the same ISO 10993-1 standard.
Length	3/4" x 12"(needle length x tube length)	3/4" x 12"(needle length x tube length)	No differences.
Gauge	21G	21G, 23G, 25G	The predicate has two additional sizes. There is no difference in the 21G.
Hub/Needle bond strength	Complies with ISO7864: 21G>44N	Complies with ISO7864: 21G>44N 23G>34N 25G>22N	Both comply with ISO7864.
Biocompatibility	Complies with ISO10993-1	Complies with ISO10993-1	There is no difference, as both comply with ISO10993-1
Performance	Complies with ISO 9626 ISO 7864 ISO 80369-7 ISO 80369-20 ISO 23908 ISO 6009	Complies with ISO 9626 ISO 7864 ISO 594-1 ISO 594-2 ISO 23908:2011 ISO 10555-1 ASTM F2132- Needle penetration	Both devices demonstrate compliance with ISO standards showing safe and effective use per the Indications for use.
Sterilization	EO	EO	Same sterilization method, no differences.
Sterile	Yes	Yes	Subject and predicate are delivered sterile.
SAL	10 ⁻⁶	10 ⁻⁶	Subject and predicate have the same SAL.
Disposable	Yes	Yes	Subject and predicate are disposable.
Single Patient Use	Yes	Yes	Subject and predicate are for single patient use.

Note 1:

Although the material of proposed and the predicate device is not available, the patient-contact material of the proposed device material conforms to the ISO 10993 series of standards the same as predicate device. Therefore, this difference will not affect the Substantial Equivalence (SE) between the proposed and predicate device.

Note 2:

Both devices conform to the same performance standards.

Performance Testing

Performance testing was provided in support of the substantial equivalence determination and to validate and verify that the safety blood collection sets for single use met all requirements of related international standards, including biocompatibility, sterility, and product specifications. The results of these tests demonstrate compliance with the requirements of the consensus standards noted below.

Non-clinical Testing

Performance Testing

- 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: common test methods. (General I (QS/RM))
- 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 - Color coding for identification

Biocompatibility

The new device complies with the biocompatibility requirement defined in ISO10993-1. Patient contact classification: externally communicating devices, contact circulating blood for limited contact (<24 h) duration. The verification test shows that the new devices comply with the biocompatibility requirement defined in ISO10993-1, the same as the predicate device.

- In Vitro Cytotoxicity (ISO10993-5: 2009)
- Skin Sensitization (ISO10993-10: 2010)

- Intracutaneous Reactivity Test (ISO10993-10: 2010)
- Acute Systemic toxicity (ISO10993-11:2006)
- Hemocompatibility
- Pyrogenicity

All of the pre-determined acceptance criteria were met.

Sterility Information

The devices are EO sterilized. The sterilization validation conducted according to the following standards:

- 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.
- ANSI/AAMI ST72 Bacterial endotoxins - Test methods, routine monitoring, and alternatives to batch testing.

All of the pre-determined acceptance criteria were met.

Package and Shelf Life:

We conducted the below package and shelf life verification test to support the shelf life claim according to the below 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/ISO11737-2:2009 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 F1929-98 (2004) Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration

- ASTM F1980-07 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices

- ASTM D3078-02 (2008), Standard Test Method for Determination of Leaks in Flexible Packaging by Bubble Emission. (Sterility)

- ASTM F88/F88M-09 Standard Test Method for Seal Strength of Flexible Barrier Materials

The tests were conducted as noted below:

- Product Performance Inspection (Chemical performance and Physical performance)
- Sterile Test
- Vacuum Leak Test
- Dye penetration test
- Agar Contact-Attack Test
- Tensile Seal Strength Test
- Accelerated Aging Test

The test result supports the shelf life claim for the subject device from the sterilization date.

All of the pre-determined acceptance criteria were met.

Clinical Test:

No clinical study is included 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 Sets for Single Use is substantially equivalent to the Innovative Medical Technologies, Inc. Improsafe Blood Collection Set cleared under K123987 with respect to the indications for use, target populations, treatment method, and technological characteristics.