April 12, 2022

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

Re: K214075
Trade/Device Name: Safety Blood Collection / Infusion Set (with/without needle holder), Blood Collection / Infusion Set (with/without needle holder)
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: Class II
Product Code: FMI, FPA
Dated: March 18, 2022
Received: March 24, 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,

Gang Peng 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)*
K214075

Device Name
Safety Blood Collection / Infusion Set (with/without needle holder)
Blood Collection / Infusion Set (with/without needle holder)

Indications for Use *(Describe)*
The Safety Blood Collection / Infusion Set (with/without needle holder) is indicated for venous blood collection and/or the short-term infusion of intravenous fluids for 2 hours or less. It is to be used by appropriately trained healthcare professionals in accordance with the instructions. The safety shield is intended to aid in the protection against accidental needle stick injury.

The Blood Collection / Infusion Set (with/without needle holder) is indicated for venous blood collection and/or the short-term infusion of intravenous fluids for 2 hours or less. It is to be used by appropriately trained healthcare professionals in accordance with the instructions.

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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K214075
510(k) SUMMARY

Submitter Information:

Preparation Date:	April 3, 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 Mr. Bingyi Xiang General Manager Tel: +86-556 5129666 Fax: +86-556 4249999 birrell@hongyu-wuzhou.com
Submission Corresponding Official:	Charles Mack
Telephone Number:	931-625-4938
Email Address:	charliemack@irc-us.com
Trade Name:	Safety Blood Collection / Infusion Set (with/without needle holder) Blood Collection / Infusion Set (with/without needle holder)
Common Name(s):	Needle, hypodermic, single lumen Intravascular administration set
Regulation Name(s):	Needle, hypodermic, single lumen Intravascular administration set
Regulation Number(s):	21CFR 880.5570
Product Code:	FMI, FPA
Device Class:	Class II
Predicate Device:	K173757 VACUETTE EVOPROTECT Safety Blood Collection/Infusion Set Greiner Bio-One NA Inc

Device Description:

The Blood Collection / Infusion Set (with/without needle holder) is a single-use, sterile, winged needle bonded to flexible tubing with a Luer connector. The Blood Collection / Infusion Set (with/without a needle holder) is individually wrapped and sterile with a luer port. The luer port can connect FDA cleared accessories like luer adapter, holder, etc.

The Safety Blood Collection / Infusion Set (with/without needle holder) is a single-use, sterile, winged needle bonded to flexible tubing with a Luer connector and a safety mechanism. The winged needle is designed with a safety mechanism, which allows for activation, ensuring the needle is covered immediately following venipuncture to protect against accidental needlestick injury. The Safety Blood Collection / Infusion Set (with/without a needle holder) is individually wrapped and sterile with a luer port. The luer port can connect FDA cleared accessories like luer adapter, holder, etc.

The safety feature is easily operated by releasing a latch mechanism whereby the user slides a winged cover over the needle removed from the patient. Once the needle is covered, the safety cover locks in place. There is no ability to clean and reuse these devices because the safety feature cannot be deactivated without bending the needle and rendering it unusable.

The Blood Collection / Infusion Set (with/without needle holder) and Safety Blood Collection / Infusion Set (with/without needle holder) are used for venous blood collection and/or the short-term infusion of intravenous fluids. It can be used with an intravascular administration set or a syringe or other device to administer fluids. The product is to be used by appropriately trained healthcare professionals only in accordance with the manufacturer's instructions.

Blood Collection / Infusion Set	Individually wrapped and sterile, allowing set to be usedwith a luer system.
Blood Collection Set (without needle holder)	Individually wrapped and sterile with Luer Adapter (for use with e.g. Standard Needle holder).
Blood Collection Set (with needle holder)	Individually wrapped and sterile, ready to be used forblood collection.
Safety Blood Collection / Infusion Set	Individually wrapped and sterile, allowing set to be usedwith a luer system.
Safety Blood Collection Set (without needle holder)	Individually wrapped and sterile with Luer Adapter (for use with e.g. Standard Needle holder).
Safety Blood Collection Set (with needle holder)	Individually wrapped and sterile, ready to be used forblood collection.

The proposed device consists of the components defined below:

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
11. Protective cap

Indications for Use

The Safety Blood Collection / Infusion Set (with/without needle holder) is indicated for venous blood collection and/or the short-term infusion of intravenous fluids for 2 hours or less. It is to be used by appropriately trained healthcare professionals in accordance with the instructions. The safety shield is intended to aid in the protection against accidental needle stick injury.

The Blood Collection / Infusion Set (with/without needle holder) is indicated for venous blood collection and/or the short-term infusion of intravenous fluids for 2 hours or less. It is to be used by appropriately trained healthcare professionals in accordance with the instructions.

SE Comparison Table

Feature	Subject Device	Predicate Device	Discussion
Company	Anhui Hongyu Wuzhou Medical Manufacturer Co., Ltd.	Greiner Bio-One NA Inc	-
FDA510(K) Number	K214075	K173757	-
Device Name	Safety Blood Collection / Infusion Set (with/without needle holder); Blood Collection / Infusion Set (with/without needle holder)	VACUETTE EVOPROTECT Safety Blood Collection / Infusion Set	-
Product code	FMI, FPA	FMI, FPA	-
CFR	880.5570	880.5570	-
Indication for Use	The Safety Blood Collection / Infusion Set (with/without needle holder) is indicated for venous blood collection and/or the short-term infusion of intravenous fluids for 2 hours or less. It is to be used by appropriately trained healthcare professionals in accordance with the instructions. The safety shield is intended to aid in the protection against accidental needle stick injury. The Blood Collection / Infusion Set (with/without needle holder) is indicated for venous blood collection and/or the short-term infusion of intravenous fluids for 2 hours or less. It is to be used by appropriately trained healthcare professionals in accordance with the instructions.	The VACUETTE EVOPROTECT Safety Blood Collection/Infusion Set is indicated for venous blood collection and/or the short-term infusion of intravenous fluids. It is to be used by appropriately trained healthcare professionals in accordance with the instructions.	*Note 1*

Feature	Subject Device	Predicate Device	*Discussion*
Safe Feature	For the Safety Blood Collection / Infusion Set (with/without needle holder), the needle is locked in the safety sheath after using the safety shield by pulling the tubing backward until an audible click is heard. There is no safety mechanism for the Blood Collection / Infusion Set (with/without needle holder).	The needle is completely retracted and locked by sliding the safety shield forward and pulling the tubing backward until an audible click is heard.	*Note 2*
Material			
Needle tube	SUS304	SUS304	Identical
Flexing tube	PVC	PVC	Identical
Luer adapter	ABS	ABS	Identical
Needle sheath	HDPE	PP	*Note 3*
Safety shield	Polypropylene	PC	
Rub sleeve	Gather Isoprene Rubber	Unknown	
Lubricate	Silicone oil	Unknown	
Adhesive	Epoxy Resin	UV cured adhesive	
Needle Gauge	18G, 19G, 20G, 21G, 22G, 23G, 24G, 25G, 26G, 27G;	21G, 23G, 25G	*Note 4*
Needle Length	1/2'' - 1 1/8''	3/4'	
Flexing tubing Length	7½"; 12"	4"; 7½"; 12"	*Note 5*
Hub/Needle bond strength	Complies with ISO7864	Complies with ISO7864	Identical
Biocompatibility	Complies with ISO10993-1	Complies with ISO10993-1	Identical
Performance	Complies with ISO 9626 ISO 7864 ISO 80369-7 ISO 80369-20 ISO 23908 ISO 6009 ISO 8536-4	Complies with ISO 9626 ISO 7864 ISO 80369-7 ISO 80369-20 ISO 23908 ISO 6009 ISO 8536-4	Identical
Sterilization	EO	Rx	*Note 6*
Sterile	Yes	Yes	Identical
SAL	10^{-6}	10^{-6}	Identical
Disposable	Yes	Yes	Identical
Single Patient Use	Yes	Yes	Identical

Note 1
The subject devices include two configurations, with the safety mechanism and without safety mechanism, but the predicate device only includes one configuration with a safety mechanism. Although the configuration is different, the indication for use is the same, and both can be used for blood collection and infusion. Therefore, the difference is not determined to affect substantially equivalence on safety and effectiveness.

Note 2
For the Safety Blood Collection / Infusion Set (with/without needle holder), the safety mechanism is the same as predicate device;
There is no safety mechanism for the Blood Collection / Infusion Set (with/without needle holder).
Whether there is a safety mechanism will not affect the indication for the use of the devices; both can be used for blood collection and infusion. Therefore, the difference is not determined to affect substantially equivalence on safety and effectiveness.

Note 3
Although the material of these components of subject devices are different from predicate devices (or some unknown for predicate device), they conform to the same ISO10993-1 biocompatibility standards; Therefore, the difference does not raise new questions on the safety and effectiveness of the proposed method device.

Note 4
The subject devices' needle gauge and needle length are available in more sizes than the predicate device, but they conform to the same applicable performance standards as the predicate device; Therefore, the difference does not raise new questions on the safety and effectiveness of the proposed method device.

Note 5
The subject device has two sizes, same as the predicate device, but the predicate device has an additional one size;
They conform to the same applicable performance standards. Therefore, this difference is not considered to affect safety and effectiveness substantially.

Note 6
The sterilization method is different; The subject device’s sterilization is validated per ISO11135 and achieves the same SAL of 10^{-6} as the predicate device. The difference will not affect the Substantial Equivalence (SE) between the proposed and predicate device

Performance Testing

Performance testing was provided in support of the substantial equivalence determination and to validate and verify that the Safety Blood Collection / Infusion Set (with/without needle holder) and Blood Collection/Infusion set (with/without needle holder) met all requirements of related international standards, including biocompatibility, sterility, and product specifications. These tests demonstrate compliance with the requirements of the consensus standards noted below.

Non-clinical Testing

Performance Testing

- ISO 8536-4-2019 Infusion equipment for medical use —Part 4: Infusion sets for single-use, gravity feed
- 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 - 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)]
- USP 788 Particulate Matter in Injections
- Flowrate and Priming volume of tubing

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)
- Coagulation (ISO10993-4:2017)
- Complement Activity Test (ISO10993-4: 2017)
- Hemolytic Properties Test (ISO10993-4: 2017, ASTM F756-17)
- Ames Test (ISO10993-3:2014)
- Mammalian Chromosome Aberration Test (ISO10993-3:2014)
- Mammalian Erythrocyte Micronucleus Test (ISO10993-3:2014)

All of the pre-determined acceptance criteria were met.

Sterility Information

The devices are EO sterilized. The sterilization validation was 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.
- ISO10993-7 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 standards noted below:

- 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:

- Accelerated Aging Test
- Simulated shipping distribution testing
- Visual inspection
- Performance Inspection
- Sterile Test
- Vacuum Leak Test
- Dye penetration test
- Agar Contact-Attack Test
- Tensile Seal Strength 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 / Infusion Set (with/without needle holder) and Blood Collection/Infusion set (with/without needle holder) are substantially equivalent to the Greiner Bio-One NA Inc VACUETTE EVOPROTECT Safety Blood Collection / Infusion Set cleared under K173757 with respect to the indications for use, target populations, treatment method, and technological characteristics.

END