DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

March 14, 2017

Jiangsu Shenli Medical Production Co., Ltd
% Charles Mack
Principal Engineer
IRC
7808 Rush Creek Drive
Pasco, Washington 99301

Re: K163093
Trade/Device Name: Safety Blood Collection Set
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: Class II
Product Code: FMI
Dated: February 8, 2017
Received: February 22, 2017

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Tina Kiang -S

Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K163093

Device Name
Safety Blood Collection Set

Indications for Use *(Describe)*

The Safety Blood Collection Set 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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

K163093

510(k) Summary (21 CFR §807.92)

Submitter Information	Submitter Name:	Jiangsu Shenli Medical Production Co., Ltd.
	Address:	No 20, Changzheng Road, Zhenglu, Changzhou City, Jiangsu Province, China 213111
	Contact Person:	Ms. Tina Cai General Manager charliemack@irc-us.com 931-625-4938
	Date of Preparation:	March 13, 2017

Subject Device	Trade Name:	Safety Blood Collection Set
	Common Name:	Hypodermic single lumen needle
	Regulation Number:	21 CFR §880.5570
	Regulation Name:	Hypodermic single lumen needle
	Regulatory Class:	II
	Product Code:	FMI
	Classification Panel:	General Hospital

Predicate Device	Trade Name:	Improve Blood Collection Set and Improsafe Blood Collection Set
	510(k) Reference:	K123987
	Common Name:	Hypodermic single lumen needle
	Regulation Number:	21 CFR §880.5570
	Regulation Name:	Hypodermic single lumen needle
	Regulatory Class:	II
	Product Code:	FMI
	Classification Panel:	General Hospital

Purpose of Submission

This is a new submission of a Safety Blood Collection set. There have been no previous submissions of this product.

Indications for Use

Safety Blood Collection Set 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.

Device Description

The Safety Blood Collection Set is used in routine venipuncture procedures. The winged needle is designed with a safety shield, which can be activated to cover the needle immediately following venipuncture to aid in the protection against accidental needlestick injury. The product is to be used by appropriately trained healthcare professionals.

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 with 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 sleeve and a hard plastic needle cap. The opposite end of the needle is ¾" for withdrawing blood and is fitted with a color coded hard plastic needle cap. The two needle caps protect the needle and maintain the sterility. The seal between the two needle caps is covered with a perforated paper label that permits identification and acts as a seal integrity.

The Safety Blood Collection Set is delivered sterile and is intended for single use only.

Technological Characteristics

Feature	Proposed Device	Predicate Device
Company	Jiangsu Shenli Medical Production Co., Ltd	Innovative Medical Technologies, Incorporated
FDA510(K) Number	K163093	K123987
Device Name	Safety Blood Collection Set	Improsafe Blood Collection Set
FDA Classification	Same	21CFR880.5570, Product code- FMI
Indication for Use	Safety Blood Collection Set 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.	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. 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 liter 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.
Feature	The needle is locked in safety sheath by slide the translucent yellow safety shield forward with pulling the tubing backward until an audible click is heard.	The needle is completely retracted and locked by slide the translucent yellow safety shield forward with pulling the tubing backward until an audible click is heard.
Material:		
Needle sheath	PE	HDPE

Needle tube	SUS304	SUS304
Needle holder	Ethylene/propylene copolymer	Polypropylene
Safety shield	Polypropylene	Polypropylene
Flexing tube	PVC	PVC
Rub sleeve	Polyisoprene	Rubber (Synthetic)
Luer adapter	ABS	ABS
Lubricate	Medical Highly Activated Silicone	Unknown
Colors:		
21G	Green	Green
Length	3/4'' x 12''(needle length x tube length)	3/4'' x 12''(needle length x tube length)
Gauge	21G	21G, 23G, 25G
Hub/Needle bond strength	Complying with ISO7864: 21G>44N	Complying with ISO7864: 21G>44N 23G>34N
Biocompatibility	Complying with ISO10993-1 In Vitro Cytotoxicity Test (ISO10993-5) Skin Sensitization Test (ISO10993-10) Intracutaneous Reactivity Test (ISO10993-10) Acute Systemic Toxicity Test (ISO10993-11) Haemocompatibility: -In Vitro Hemolytic Properties Test (ASTM F756-13) -Coagulation Test (ISO10993-4) -Complement Activity (ISO10993-4)	Complying with ISO10993-1
Sterilization	EO	EO
Sterile	Yes	Yes
SAL	10-6	10-6
Disposable	Yes	Yes
Single Patient Use	Yes	Yes

The predicate device (K123987) has two devices types cleared for marking; Improsafe and Improve. The subject device is claiming substantial equivalence to the Improsafe device. The indications for use between the predicate device and subject device are similar as both used in routine venipunture. However, the subject device is not intended for intravenous medication adminstration. The minor differences in indications for use between subject and predicate device do not raise different questions of safety or effectiveness. All the labeling and characteristics of the submitted Safety Blood Collection Set is the same as the predicate devices and most typical Safety Blood Collection Sets currently on the market. The basic design of the submitted device specifications is substantially the same as the predicate, with differences in the plastic material. Though the plastic material is different, biocompatibility characteristics of the subject and predicate devices are equivalent.

Summary of Performance Tests

The following performance testing was performed to demonstrate substantial equivalence of the subject device Safety Blood Collection Set, and applicable standards:

- Sterility
- Toxin in bacteria
- Reducing Substance
- Metal Ion
- pH Value
- Residue after evaporation
- Ultraviolet absorbency degree
- EO gas residue
- ECH gas residue
- Particle pollution
- Connection firmness
- Needle Tube
- Lubricant
- Needle Handle
- Rubber Sleeve
- Leakage
- Flow Rate
- Length of needle tube
- Needle tip
- Needle base to connection base
- Flexing tube
- Protective safety sheath

All of the pre-determined acceptance criteria were met.

Summary of Substantial Equivalence

Based on the indications for use, technological characteristics, and performance testing, the subject Safety Blood Collection Set has demonstrated to be substantially equivalent to the predicate IMPROSAFE Blood Collection Set.