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

September 12, 2016

Guangzhou Improve Medical Instruments Co., Ltd.
% Dianna Hong
General Manager
Mid-Link Consulting Co., Ltd
P.O. Box 120-119
Shanghai, 200120 CHINA

Re: K153388
Trade/Device Name: IMPROSAFE® Blood Collection Set With Pre-attached Holder,
IMPROVACUTER® Blood Collection Set Pre-attached Holder,
IMPROSAFE® Blood Collection Set,
IMPROVACUTER® Blood Collection Set,
IMPROSAFE® Multi Sample Needle,
IMPROSAFE® Multi Sample Needle (flashback),
IMPROVACUTER® Multi Sample Needle
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: Class II
Product Code: FMI
Dated: November 3, 2015
Received: February 23, 2016

Dear Dianna Hong:

This letter corrects our substantially equivalent letter of June 7, 2016.

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 yours,

Michael J. Ryan -S

for Tina Kiang, PhD
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)*
K153388

Device Name
IMPROSAFE® Blood Collection Set with Pre-attached Holder

Indications for Use *(Describe)*
The IMPROSAFE® Blood Collection Sets with Pre-attached holder are intended to be used with evacuated blood collection tube for the collection of venous blood. The safety shield is intended to aid in the protection against accidental needle stick 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.

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)*
K153388

Device Name
IMPROSAFE® Multi Sample Needle

Indications for Use *(Describe)*
The IMPROSAFE® Multi-Sample Needles are intended to be used with evacuated blood collection tube for the collection of venous blood. The safety shield is intended to aid in the protection against accidental needle stick 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.

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)*
K153388

Device Name
IMPROVACUTER® Blood Collection Set

Indications for Use *(Describe)*
The IMPROVACUTER® Blood Collection Sets are intended to be used with evacuated 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.

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)*
K153388

Device Name
IMPROSAFE® Blood Collection Set

Indications for Use *(Describe)*
The IMPROSAFE® Blood Collection Sets are intended to be used with evacuated blood collection tube for the collection of venous blood. The safety shield is intended to aid in the protection against accidental needle stick 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.

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)*
K153388

Device Name
IMPROVACUTER® Blood Collection Set with Pre-attached Holder

Indications for Use *(Describe)*
The IMPROVACUTER® Blood Collection Sets with Pre-attached holder are intended to be used with evacuated 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)

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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)*
K153388

Device Name
IMPROSAFE® Multi Sample Needle (Flashback)

Indications for Use *(Describe)*
The IMPROSAFE® Multi-Sample Needles (Flashback) are intended to be used with evacuated blood collection tube for the collection of venous blood. The safety shield is intended to aid in the protection against accidental needle stick 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.

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)*
K153388

Device Name
IMPROVACUTER® Multi Sample Needle

Indications for Use *(Describe)*
The IMPROVACUTER® Multi-Sample Needles are used with holder and vacuum blood collection tube for the venous blood collection.

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.

510(k) Summary

This 510(k) Summary is being submitted in accordance with requirements of Title 21, CFR Section 807.92.

The assigned 510(k) Number: K153388
Date of Preparation: 08/15/2016

1. Sponsor Identification

Guangzhou Improve Medical Instruments Co., Ltd.
No.102, Kaiyuan Avenue, Science City,
Guangzhou Economic & Technological Development District,
Guangzhou, 510530, CHINA

Establishment Registration Number: 3008449424

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2. Identification of Proposed Device

Trade Name: IMPROSAFE® Blood Collection Set with Pre-attached Holder
IMPROVACUTER® Blood Collection Set with Pre-attached Holder
IMPROVACUTER® Blood Collection Set
IMPROSAFE® Blood Collection Set
IMPROSAFE® Multi Sample Needle
IMPROVACUTER® Multi Sample Needle
IMPROSAFE® Multi Sample Needle (Flashback)
Common Name: Blood Collection Set
Classification Name: Needle, Hypodermic, Single Lumen
Classification: II
Product Code: FMI
Regulation Number: 21CFR 880.5570
Review Panel: General Hospital

3. Identification of Predicate Devices

Proposed Device	Predicate Device
IMPROSAFE® Blood Collection Set with Pre-attached holder	510(k) Number: K980414 Product Name: VACUTAINER® Brand Blood Collection Set and Safety-Lok™ Blood Collection Set
IMPROSAFE® Blood Collection Set	510(k) Number: K980414 Product Name: VACUTAINER® Brand Blood Collection Set and Safety-Lok™ Blood Collection Set
IMPROVACUTER® Blood Collection Set with Pre-attached Holder	510(k) Number: K980414 Product Name: VACUTAINER® Brand Blood Collection Set and Safety-Lok™ Blood Collection Set
IMPROVACUTER® Blood Collection Set	510(k) Number: K980414 Product Name: VACUTAINER® Brand Blood Collection Set and Safety-Lok™ Blood Collection Set
IMPROSAFE® Multi Sample Needle	510(k) Number: K982541 Product Name: VACUTAINER® Brand ECLIPSE™ Blood Collection Needle
IMPROSAFE® Multi Sample Needle (Flashback)	510(k) Number: K982541 Product Name: VACUTAINER® Brand ECLIPSE™ Blood Collection Needle
IMPROVACUTER® Multi Sample Needle	510(k) Number: K090426 Product Name: VAKU-8™ Blood Collection Needle

4. Indications for Use

The IMPROSAFE® Blood Collection Sets with Pre-attached holder are intended to be used with evacuated 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 IMPROVACUTER® Blood Collection Sets with Pre-attached holder are intended to be used with evacuated blood collection tube for the collection of venous blood.

The IMPROVACUTER® Blood Collection Sets are intended to be used with evacuated blood collection tube for the collection of venous blood.

The IMPROSAFE® Blood Collection Sets are intended to be used with evacuated 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 IMPROSAFE® Multi-Sample Needles are intended to be used with evacuated 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 IMPROVACUTER® Multi-Sample Needles are used with holder and vacuum blood collection tube for the venous blood collection.

The IMPROSAFE® Multi-Sample Needles (Flashback) are intended to be used with evacuated blood collection tube for the collection of venous blood. The safety shield is intended to aid in the protection against accidental needle stick injury.

Indication for Use Statement:

The proposed device IMPROSAFE® Blood Collection Set with Pre-attached Holder, IMPROVACUTER® Blood Collection Set with Pre-attached Holder, IMPROVACUTER® Blood Collection Set, IMPROSAFE® Blood Collection Set are not indicated for intravenous administration of fluids compared to predicate device. However, both proposed devices and predicate device are indicated for collection of venous blood. Therefore, this difference does not affect safety and effectiveness.

The indication for use of proposed devices IMPROSAFE® Multi Sample Needle, IMPROVACUTER® Multi Sample Needle, IMPROSAFE® Multi Sample Needle (Flashback) are identical to predicate device .

5. Device Description

The proposed devices are blood collection sets form a channel between patient's vein and the evacuated blood collection tube intended for collection of blood. They are available in different configurations as follows:

Model	Patient-End Needle	Non-Patient End Needle	Flexible Tubing	Pre-attached Holder	Safety Mechanism	Visible Flash Back
MPROSAFE® Blood Collection Set with Pre-attached holder	X	X	X	X	X	X
IMPROSAFE® Blood Collection Set	X	X	X	N.A.	X	X
IMPROVACUTER® Blood Collection Set with Pre-attached Holder	X	X	X	X	N.A.	X
IMPROVACUTER® Blood Collection Set	X	X	X	N.A.	N.A.	X
IMPROSAFE® Multi Sample Needle	X	X	N.A.	X	X	N.A.

IMPROSAFE® Multi Sample Needle (Flashback)	X	X	N.A.	X	X	X
IMPROVACUTER® Multi Sample Needle	X	X	N.A.	N.A.	N.A.	N.A.

Model	Needle Gauge	Needle Length
MPROSAFE® Blood Collection Set with Pre-attached holder	21G, 23G, 25G, 27G	3/4″, 2/5″
IMPROSAFE® Blood Collection Set	21G, 23G, 25G, 27G	3/4″, 2/5″
IMPROVACUTER® Blood Collection Set with Pre-attached Holder	21G, 23G, 25G, 27G	3/4″, 2/5″
IMPROVACUTER® Blood Collection Set	21G, 23G, 25G, 27G	3/4″, 2/5″
IMPROSAFE® Multi Sample Needle	21G, 22G	1″, 1 1/2″
IMPROSAFE® Multi Sample Needle (Flashback)	21G, 22G	1″, 1 1/4″
IMPROVACUTER® Multi Sample Needle	21G, 22G	1″, 1 1/2″

6. Non-Clinical Test Conclusion

Non clinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

- ISO 9626:1991+AMENDMENT 1 2001 Stainless steel needle tubing for the manufacture of medical devices;
- ISO 7864: 1993 Sterile hypodermic needles for single use
- ISO 10993-7:2008 Biological evaluation of medical devices- Part 7: Ethylene oxide sterilization residuals;
- ASTM F 88/F88M-09 Standard test method for seal strength of flexible barrier materials;
- ASTM F1929-12 Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration;
- USP38-NF33 <85> Bacterial Endotoxins Limit.
- ISO 10993-5:2009 Biological evaluation of medical devices-Part 5: Tests for in vitro cytotoxicity.
- ISO 10993-10:2010 Biological evaluation of medical devices- Part 10: Test for irritation and delayed-type hypersensitivity
- ISO 10993-11:2006 Biological evaluation of medical devices- Part 11: Tests for systemic toxicity
- ASTM F 756-13 Standard practice for assessment of hemolytic properties of materials
- Guidance for Industry and FDA Staff: Medical Devices with Sharps Injury Prevention Features

7. Clinical Test Conclusion

No clinical study is included in this submission.

8. Substantially Equivalent (SE) Comparison

Table 1 Comparison of Technology Characteristics

ITEM	Proposed Device	Predicate Device K982541	Reference Device 1 K980414	Reference Device 2 K090426
Class	II	II	II	II
Intended Use	The IMPROSAFE® Blood Collection Sets with Pre-attached holder are intended to be used with evacuated 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 IMPROVACUTER® Blood Collection Sets with Pre-attached holder are intended to be used with evacuated blood collection tube for the collection of venous blood. The IMPROVACUTER® Blood Collection Sets are intended to be used with evacuated blood collection tube for the collection of venous blood. The IMPROSAFE® Blood Collection Sets are intended to be used with evacuated blood collection tube for the collection of venous blood. The safety shield is intended to aid in the	VACUTAINER® Brand ECLIPSE™ Blood Collection Needle is designed for use with VACUTAINER® Brand Blood Collection Needle Holders in performing venipuncture to obtain blood samples. After venipuncture, the safety shied is activated with thumb pressure. The hinged safety shield pivots up and over the needle, locking into place. In the activated position, the safety shield protects against accidental needle stick during normal handling and disposal.	The VACUTAINER® Brand Blood Collection Set and Safety-Lok™ 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 or monitoring blood pressure. The Safety-Lok™ Blood Collection Set is provided with a safety shield for covering the used needle prior to disposal. 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 VACUTAINER ® Brand Blood Collection Set and Safety-Lok™ Blood Collection Set is also indicated for the intravenous administration of fluids and may be used for any patient population with	VAKU-8™ Blood Collection Needles are designed for routine blood collection by q qualified practitioner.

	protection against accidental needle stick injury. The IMPROSAFE® Multi-Sample Needles are intended to be used with evacuated 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 IMPROVACUTER® Multi-Sample Needles are used with holder and vacuum blood collection tube for the venous blood collection. The IMPROSAFE® Multi-Sample Needles (Flashback) are intended to be used with evacuated blood collection tube for the collection of venous blood. The safety shield is intended to aid in the protection against accidental needle stick injury.		consideration given to patient size, appropriateness for the solution being infused and duration of therapy.	
Configuration	Protective Cover of Patient end Needle Patient end Needle Double Wing Needle Handle Flexible Tubing Conical Fitting Connector Conical Fitting Rubber Sleeve	Protective Cover of Patient end Needle Needle Needle Hub Rubber Sleeve Safety Shield	Protective Cover of Patient end Needle Patient end Needle Double Wing Needle Handle Flexible Tubing Conical Fitting Connector Conical Fitting Rubber Sleeve	Top Cover Needle Button Cover Needle Hub Rubber Sleeve

	Non-patient end Needle Safety Shield Needle Holder		Non-patient End Needle Safety Shield	
Performance	Conform with ISO 9626:1991 AMD 2001 and ISO 7864: 1993	Conform with ISO 9626:1991 AMD 2001 and ISO 7864: 1993	Conform with ISO 9626:1991 AMD 2001 and ISO 7864: 1993	Conform with ISO 9626:1991 AMD 2001 and ISO 7864: 1993
Specification	21G, 22G, 23G, 25G, 27G 3/4″, 2/5″, 1″, 1 1/4″ and 1 1/2″	21G, 22G 1.25″	21G, 23G, 25G 0.75″	21G, 22G, 23G 1″ and 1.5″
Sterile	EO sterilized	EO sterilized	EO sterilized	EO sterilized
Single Use	Single Use	Single Use	Single Use	Single Use
Biocompatibility	Conform with ISO 10993	Conform with ISO 10993	Conform with ISO 10993	Conform with ISO 10993
Label/Labeling	Conform with 21 CFR Part 801	Conform with 21 CFR Part 801	Conform with 21 CFR Part 801	Conform with 21 CFR Part 801

The intended use of proposed device IMPROSAFE® Blood Collection Set with Pre-attached Holder, IMPROVACUTER® Blood Collection Set with Pre-attached Holder, IMPROVACUTER® Blood Collection Set, IMPROSAFE® Blood Collection Set are similar in that they are sterile single use needle with/without holder for the collection of venous blood. Although the indication for use are not identical to that of the predicate devices, it does not change the intended use because they are both single use devices intended for collection of venous blood.

9. Substantially Equivalent (SE) Conclusion

Comparison results demonstrate that the specifications and performance of the device are substantially equivalent to the legally marketed predicate device. Therefore, it is concluded that IMPROSAFE® Multi Sample Needle, IMPROVACUTER® Multi Sample Needle, IMPROSAFE® Multi Sample Needle (Flashback) are substantially equivalent to the legally marketed predicate devices.