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

December 11, 2015

Jiangyin Caina Technology Co., Ltd.
c/o Ms. Diana Hong
General Manager
Mid-link Consulting Co., Ltd
P.O. Box 120-119
Shanghai, 200120
CHINA

Re: K151991
Trade/Device Name: Safelock Disposable Blood Collection Set, Disposable Blood Collection Set
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: FPA
Dated: November 10, 2015
Received: November 13, 2015

Dear Ms. Hong:

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,

for Erin I. Keith, M.S.
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)

K151991

Device Name
Safelock Disposable Blood Collection Set
Disposable Blood Collection Set

Indications for Use (Describe)
The Disposable blood collection sets are intended to be used with vacuum blood collection tube for venipuncture to collect blood specimens from patients.

The Safelock disposable blood collection sets are intended to be used with vacuum blood collection tube for venipuncture to collect blood specimens from patients, and the safety sheath is designed to aid in the reduction of accidental needlesticks.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Exhibit # 2 Summary

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

The assigned 510(k) Number: K151991

1. Date of Preparation: 12/11/2015

2. Sponsor Identification

Jiangyin Caina Technology Co., Ltd.
No.2, Taifu Road, Huashi Town, Jiangyin, Jiangsu, 214421, China

Establishment Registration Number: 3005670221

Contact Person: Jun Lu
Position: General Manager
Tel: +86-510-86205183
Fax: +86-510-86215183
Email: jun.lu@cainamedical.com

3. Designated Submission Correspondent

Ms. Diana Hong (Primary Contact Person)
Mr. Lee Fu (Alternative Contact Person)

Mid-Link Consulting Co., Ltd
P.O. Box 120-119, Shanghai, 200120, China

Tel: +86-21-22815850,
Fax: 240-238-7587
Email: info@mid-link.net

4. Identification of Proposed Device

Trade Name: Safelock disposable blood collection set
Disposable blood collection set

Common Name: blood collection set

Regulatory Information

Classification Name: Set, Administration, Intravascular
Classification: II
Product Code: FPA
Regulation Number: CFR 880.5440
Review Panel: General Hospital

Intended Use Statement:

The Disposable blood collection sets are intended to be used with vacuum blood collection tube for venipuncture to collect blood specimens from patients.

The Safelock disposable blood collection sets are intended to be used with vacuum blood collection tube for venipuncture to collect blood specimens from patients, and the safety sheath is designed to prevent accidental needlesticks.

Device Description

The proposed devices are provided sterile, single use. The proposed devices are intended to be used with vacuum blood collection tube for venipuncture to collect blood specimens from patients. It has two models, Safelock disposable blood collection set and Disposable blood collection set.

For disposable blood collection set, they consist nine pieces components: (1) needle protect cover (2) patient–end tube needle (3) double wing needle handle (4)flexing tube (5) connect A (6) non-patient needle hub (7) puncture needle (8) rubber sleeve (9) puncture needle protective cover.

For Safelock disposable blood collection sets, they consist twelve components: (1) needle protect cover (2) patient-end tube needle (3) safety needle handle (4) double wing (5) safety sheath (6) Locking joint (7) flexing tube (8) connect A (9) non-patient needle hub(10) puncture needle (11) rubber sleeve (12) puncture needle protect cover.

5. Identification of Predicate Device

Predicate Device 1
510(k) Number: K020533
Product Name: EXEL Vaculet Blood Collection Set

Regulation No.: CFR 880.5440
Product Code: FPA

Predicate Device 2
510(k) Number: K031279
Product Name: SURSHIELD™ Safety Winged Blood Collection Set
Regulation No.: CFR 880.5440
Product Code: FPA

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 tests provided in this submission include:

Physical, Mechanical and Chemical Tests performed on the proposed device

ISO 9626:1991 AMENDMENT 1 2001 Stainless steel needle tubing for the manufacturing of medical devices

Sterile Barrier Packaging Testing performed on the proposed device:

Seal strength	ASTM F88/F88-09
Internal pressure	ASTM F1140/F1140M-13
Dye penetration	ASTM F 1929-12

Sterilization and Shelf Life Testing performed on the proposed device:

EO/ECH residue	ISO 10993-7:2008
Bacteria Endotoxin Limit	USP 37-NF 32 <85>
Shelf Life Evaluation	Physical, Mechanical, Chemical, Package and Sterility Tests were performed on accelerated aging samples to verify the claimed shelf life of the device

Biocompatibility Testing:

The patient-contact materials of blood collection sets are identified and biocompatibility testing is performed, which include

Cytotoxicity	ISO 10993-5: 2009
Intracutaneous Reactivity	ISO 10993-10: 2010
Skin Sensitization	ISO 10993-10: 2010
Acute Systemic Toxicity	ISO 10993-11:2006

Simulated Clinical Study performed on the proposed device:

A simulated clinical study was performed according to FDA Guidance, Guidance for Industry and FDA Staff: Medical Device with Sharps Injury Prevention Feature, issued on August 9, 2005 to evaluate the safety mechanism of the proposed device. The results demonstrated that the proposed device met the pre-established criteria.

7. Clinical Test Conclusion

No clinical study is included in this submission.

8. Substantially Equivalent (SE) Comparison

Table 1 Comparison of between proposed device and predicate device

Item	**Proposed device**	**Predicate Device 1** K020533	**Predicate Device 2** K031279
Product	Disposable blood collection set Safelock disposable blood collection set	EXEL Vaculet Blood Collection Set	SURSHIELD™ Safety Winged Blood Collection Set
Regulation No.	880.5440	880.5440	880.5440
Product Code	FPA	FPA	FPA
Indication for Use	The Disposable blood collection sets are intended to be used with vacuum blood collection tube for venipuncture to collect blood specimens from patients. The Safelock disposable blood collection sets are intended to be used with vacuum blood collection tube for venipuncture to collect blood specimens from patients, and the safety sheath is designed to prevent accidental needlesticks.	This device is an integral part of blood collection (intravenously) used in connection with luer adapter for collection of whole blood into tubes	The TERUMO® SURSHIELD™ Safety Winged Blood Collection Set is a winged blood collection needle intended for venipuncture to collec blood specimens from patients. The TERUMO ® SURSHIELD™ Safety Winged Blood Collection Set is also indicated for intravenous administration of fluids after removing the attached luer adapter from the blood collection set connector and attaching a syringe, or other conipatible/appropriate device. This device may be used for any patient population with consideration given to patient size, appropriateness for the solution being infused, and duration of therapy. Additionally, after withdraw of the needle from the patient's vein, the attached needle

			safety shield can be manually activated to cover the needle immediately after use to minimize risk of accidental needlestick.
Intended Use	The disposable blood collection set and safelock disposable blood collection set are intended for collection of blood specimens from patients.	EXEL Vaculet Blood Collection Set is intended for collection of blood specimens from patients.	SURSHIELD™ Safety Winged Blood Collection Set is intended for collection of blood specimens from patients.
Feature	The needle is locked in safety sheath by withdraw safety needle handle backward	The device does not include safety feature	The safety shield can be manually activated to cover the needle after use.
Sterile	Sterilized by EO	Sterilized by EO	Sterilized by EO
Single Use	Single Use	Single Use	Single Use
Performance	Complied with ISO 9626:1991, AMENDMENT 1 2001	unknown	unknown
Biocompatibility	Conform with ISO 10993	Conform with ISO 10993	Conform with ISO 10993

9. Substantially Equivalent (SE) Conclusion

Based on the comparison and analysis above, the proposed devices are determined to be Substantially Equivalent (SE) to the predicate devices.