August 26, 2020

Zhejiang Kindly Medical Devices Co.,Ltd
% Diana Hong
General Manager
Mid-Link Consulting Co.,Ltd
P.O.Box 120-119
Shanghai, Zhejiang 325025
China

Re: K172763
Trade/Device Name: Blood Collecting Needle, Safety Blood Collecting Needle, Blood Collecting Needle with Holder, Safety Blood Collecting Needle with Holder, Blood Collecting Set, Safety Blood Collecting Set, Blood Collecting Set with Holder, Safety Blood Collecting Set with Holder
Regulation Number: 21 CFR 862.1675
Regulation Name: Blood specimen collection device
Regulatory Class: Class II
Product Code: JKA

Dear Diana Hong:

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 June 4, 2018. Specifically, FDA is updating this SE Letter to update the product code to better categorize your device technology.

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

Sincerely,

Sapana Patel -S

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

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

Office of Product Evaluation and Quality
Center for Devices and Radiological Health

June 4, 2018

Zhejiang kindly medical devices Co., Ltd
℅ Diana Hong
Mid-Link Consulting Co., Ltd
P.O. Box 120-119
Shanghai, 200120
CHINA

Re: K172763
Trade/Device Name: Blood Collecting Needle, Safety Blood Collecting Needle, Blood Collecting Needle with Holder, Safety Blood Collecting Needle with Holder, Blood Collecting Set, Safety Blood Collecting Set, Blood Collecting Set with Holder, Safety Blood Collecting Set with Holder
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: Class II
Product Code: FMI
Dated: April 28, 2018
Received: May 4, 2018

Dear Diana 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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K172763

Device Name
Blood Collecting Needle, Safety Blood Collecting Needle, Blood Collecting Needle with Holder, Safety Blood Collecting Needle with Holder, Blood Collecting Set, Safety Blood Collecting Set, Blood Collecting Set with Holder, Safety Blood Collecting Set with Holder

Indications for Use *(Describe)*
The Blood Collecting Needle is intended to be used with vacuum blood collection tube for multiple collections of venous blood.

The Safety Blood Collecting Needle is intended to be used with vacuum blood collection tube for multiple collections of venous blood. The safety shield is intended to aid in the protection against accidental needle stick injury.

The Blood Collecting Needle with Holder is intended to be used with vacuum blood collection tube for multiple collections of venous blood.

The Safety Blood Collecting Needle with Holder is intended to be used with vacuum blood collection tube for multiple collections of venous blood. The safety shield is intended to aid in the protection against accidental needle stick injury.

The Blood Collecting Set is intended to be used with vacuum blood collection tube for multiple collections of venous blood.

The Safety Blood Collecting Set is intended to be used with vacuum blood collection tube for multiple collections of venous blood. The safety shield is intended to aid in the protection against accidental needle stick injury.

The Blood Collecting Set with Holder is intended to be used with vacuum blood collection tube for multiple collections of venous blood.

The Safety Blood Collecting Set with Holder is intended to be used with vacuum blood collection tube for multiple collections 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.

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.

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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 #2 510(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: K172763

1. Date of Preparation: 04/28/2018

2. Sponsor Identification

Zhejiang kindly medical devices Co., Ltd.
No.758, 5th Binhai Road, Binhai Industrial Park, Longwan District, 325025 Wenzhou,
Zhejiang Province, PRC.

Establishment Registration Number: Not yet registered

Contact Person: Yong Zhang
Position: General Manager
Tel: +86-577-86960616
Fax: +86-577-86374972
Email: zjkdl@kdlchina.com

3. Designated Submission Correspondent

Ms. Diana Hong (Primary Contact Person)
Ms. Ying Xu (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: Blood Collecting Needle
Safety Blood Collecting Needle
Blood Collecting Needle with Holder
Safety Blood Collecting Needle with Holder
Blood Collecting Set
Safety Blood Collecting Set
Blood Collecting Set with Holder
Safety Blood Collecting Set with Holder

Common Name: Blood Collecting Needle and Set

Regulatory Information

Classification Name: Needle, Hypodermic, Single Lumen
Classification: II;
Product Code: FMI;
Regulation Number: 21 CFR 880.5570
Review Panel: General Hospital;

Indications for Use:

The Blood Collecting Needle is intended to be used with vacuum blood collection tube for multiple collections of venous blood.

The Safety Blood Collecting Needle is intended to be used with vacuum blood collection tube for multiple collections of venous blood. The safety shield is intended to aid in the protection against accidental needle stick injury.

The Blood Collecting Needle with Holder is intended to be used with vacuum blood collection tube for multiple collections of venous blood.

The Safety Blood Collecting Needle with Holder is intended to be used with vacuum blood collection tube for multiple collections of venous blood. The safety shield is intended to aid in the protection against accidental needle stick injury.

The Blood Collecting Set is intended to be used with vacuum blood collection tube for multiple collections of venous blood.

The Safety Blood Collecting Set is intended to be used with vacuum blood collection tube for multiple collections of venous blood. The safety shield is intended to aid in the protection against accidental needle stick injury.

The Blood Collecting Set with Holder is intended to be used with vacuum blood collection tube for multiple collections of venous blood.

The Safety Blood Collecting Set with Holder is intended to be used with vacuum blood collection tube for multiple collections of venous blood. The safety shield is intended to aid in the protection against accidental needle stick injury.

Device Description

The proposed devices are blood collection devices form a channel between patient's vein and the vacuum blood collection tube. The patient-end needle is punctured into vein, and non-patient end needle will penetrate into vacuum blood collection tube, blood will flow into blood collection tube under the action of differential pressure. The proposed devices are divided into several types and available in different specifications, see following table

Device Name	Ref No.	Needle Gauge	Needle Length
Blood Collecting Needle	04-11	18G~23G	1", 1 1/4", 1 1/2"
	04-13	18G~23G	1", 1 1/4", 1 1/2"
	04-31	19G, 25G	5/8", 3/4", 1", 1 1/4", 1 1/2", 1 3/4", 2"
Safety Blood Collecting Needle	04-12	18G~23G	1", 1 1/4", 1 1/2"
	04-32	19G, 25G	5/8", 3/4", 1", 1 1/4", 1 1/2", 1 3/4", 2"
Blood Collecting Needle with Holder	04-14	18G~23G	1", 1 1/4", 1 1/2"
	04-16	18G~23G	1", 1 1/4", 1 1/2"
	04-33	19G, 25G	5/8", 3/4", 1", 1 1/4", 1 1/2", 1 3/4", 2"
Safety Blood Collecting Needle with Holder	04-15	18G~23G	1", 1 1/4", 1 1/2"
	04-34	19G, 25G	5/8", 3/4", 1", 1 1/4", 1 1/2", 1 3/4", 2"
Blood Collecting Set	04-21	19G, 25G	5/8", 3/4", 1"
Safety Blood Collecting Set	04-22	19G, 25G	5/8", 3/4", 1"
Blood Collecting Set with Holder	04-23	19G, 25G	5/8", 3/4", 1"
Safety Blood Collecting Set with Holder	04-24	19G, 25G	5/8", 3/4", 1"

5. Identification of Predicate Devices

Predicate Device 1
510(k) Number: K982541
Product Name: VACUTAINER® Brand ECLIPSE™ Blood Collection Needle

Predicate Device 2
510(k) Number: K965202
Product Name: VACUTAINER® Brand Safety-Lok Blood Collection Set

6. Technological Characteristics

Table 1 Comparison of Technology Characteristics

ITEM	Proposed Device	Predicate Device 1 K982541	Predicate Device 2 K965202
Class	II	II	II
Indications for Use	The Blood Collecting Needle is intended to be used with vacuum blood collection tube for multiple collections of venous blood. The Safety Blood Collecting Needle is intended to be used with vacuum blood collection tube for multiple collections of venous blood. The safety shield is intended to aid in the protection against accidental needle stick injury. The Blood Collecting Needle with Holder is intended to be used with vacuum blood collection tube for multiple collections of venous blood. The Safety Blood Collecting Needle with Holder is intended to be used with vacuum blood collection tube for multiple collections of venous blood. The safety shield is intended to aid in the protection against accidental needle stick injury. The Blood Collecting Set is intended to be used with vacuum blood collection tube for multiple collections of venous blood. The Safety Blood Collecting Set is intended to be used with vacuum blood collection tube for multiple collections of venous blood. The safety	The VACUTAINER® Brand ECLIPSE™ Blood Collection Needle is a sterile, multiple sample, single-use device for blood collection. The needle is designed with an attached safety shield, which can be activated to cover the needle immediately after venipuncture to provide protection from accidental needle sticks.	The VACUTAINER® Brand Safety-Lok™ Blood Collection Set is a winged blood collection needle and flexible tubing for venipuncture to collect blood specimens from patients. The Safety-Lok™ Blood Collection Set also contains a needle safety shield which minimizes the possibility of needlesticks if manually activated following blood collection. The VACUTAINER® Brand Safety-Lok™ Blood Collection Set is also recommended for use in patients with small veins

	shield is intended to aid in the protection against accidental needle stick injury. The Blood Collecting Set with Holder is intended to be used with vacuum blood collection tube for multiple collections of venous blood. The Safety Blood Collecting Set with Holder is intended to be used with vacuum blood collection tube for multiple collections of venous blood. The safety shield is intended to aid in the protection against accidental needle stick injury.		
Configuration and material	Patient-end Needle (Stainless Steel) Protective Cover of Patient-end Needle (PP) Patient-end Needle Hub (PP) Non-patient end Needle Hub (ABS) Non-patient end Needle (Stainless Steel) Rubber Sleeve (Natural Rubber) Protective Cover of Non-patient end Needle (PP) Double Wing (PVC) Flexible Tube (PVC) Conical Fitting Connector (ABS) Conical Fitting (ABS) Safety Shield (PP) Needle Holder (PP)	Protective Cover of Needle Needle Needle Hub Rubber Sleeve Safety Shield	Protective Cover of Patient-end Needle Patient-end Needle Needle Handle Double Wing Flexible Tube Conical Fitting Connector Conical Fitting Non-patient end Needle Rubber Sleeve Protective Cover of Non Patient end Needle Safety Shield
Operate mode	Manual	Same	Same
Specification	18G, 19G, 20G, 21G, 22G, 23G, 25G 5/8", 3/4", 1", 1 1/4", 1 1/2", 1 3/4", 2"	Similar	Similar
Safety Mechanism	The safety shield is intended to prevent needle sticks	Same	Same

Label/Labeling	Conform with Part 801	Same	Same
Sterilization	EO sterilized	Same	Same
	SAL: 10^{-6}		
	Endotoxin Limit: 20 EU per device		
Single Use	Single Use	Same	Same
Biocompatibility	In Vitro Cytotoxicity	Conform with ISO 10993 Standards	Conform with ISO 10993 Standard
	Skin Sensitization		
	Intracutaneous Reactivity		
	Acute Systemic Toxicity		
	Hemolytic Properties		
	Pyrogen		

The proposed devices Blood Collecting Needle, Safety Blood Collecting Needle, Blood Collecting Needle with Holder, Safety Blood Collecting Needle with Holder are similar to the predicate device K982541 in device design, Indications for use, sterilization, method of operation and technological characteristics. The proposed devices Blood Collecting Set, Safety Blood Collecting Set, Blood Collecting Set with Holder, Safety Blood Collecting Set with Holder are similar to the predicate device K965202 in device design, Indications for use, sterilization, method of operation and technological characteristics. The difference in configuration between proposed devices and predicate devices is that the proposed devices have the additional configuration of the needle holder. In addition, the proposed devices are available in a series of specification. Different specification will be selected by physician per patients' condition. These two differences do not affect intended use, therefore, the proposed devices can be determined substantially equivalence to predicate devices.

7. Non-Clinical Test Conclusion

Non clinical tests were conducted to verify that the proposed devices met all design specifications. The test include following items

Physical, Mechanical, Chemical testing performed on the proposed device:

Cleanliness	Clause 4.3 of ISO 7864:2016
Limits for acidity or alkalinity	Clause 4.4 of ISO 7864:2016
Limits for extractable metals	Clause 4.5 of ISO 7864:2016
Size designation	Clause 4.6 of ISO 7864:2016
Colour coding	Clause 4.7 of ISO 7864:2016
Needle hub	Clause 4.8 of ISO 7864:2016
Needle Cap	Clause 4.9 of ISO 7864:2016
Needle tube	Clause 4.10 of ISO 7864:2016
Needle point	Clause 4.11 of ISO 7864:2016
Bond between hub and needle tube	Clause 4.12 of ISO 7864:2016
Patency of lumen	Clause 4.13 of ISO 7864:2016

Surface finish	Clause 5.2 of ISO 9626:2016
Cleanliness	Clause 5.3 of ISO 9626:2016
Limits for acidity and alkalinity	Clause 5.4 of ISO 9626:2016
Size designation	Clause 5.5 of ISO 9626:2016
Dimensions	Clause 5.6 of ISO 9626:2016
Stiffness	Clause 5.8 of ISO 9626:2016
Resistance to breakage	Clause 5.9 of ISO 9626:2016
Resistance to corrosion	Clause 5.10 of ISO 9626:2016

Sterile Barrier Packaging Testing performed on the proposed device:

Seal strength	ASTM F88/F88-15
Dye penetration	ASTM F1929-15

Sterilization and Shelf Life Testing performed on the proposed device:

EO residue	ISO 10993-7:2008
ECH residue	ISO 10993-7:2008
Bacteria Endotoxin Limit	USP 38-NF 33 <85>
Shelf Life Evaluation	Physical, Mechanical, Chemical, Package Tests

were performed on aging samples to verify the claimed shelf life of the device

Biocompatibility testing include in vitro cytotoxicity test (ISO 10993-5), skin sensitization test (ISO 10993-10), irritation sensitivity (ISO 10993-10), Acute Toxicity Test (ISO 10993-11), pyrogen test (ISO 10993-11) and Hemolysis Test (ASTM F756-17).

Simulated Clinical Study

A simulated clinical study was performed on proposed device 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 devices. The results demonstrated that the proposed device met the pre-established criteria.

Safety Feature Test

The safety feature test was performed on both proposed device and predicate device to determine safety feature. The results demonstrated that the proposed devices did not show a significant difference from predicate devices.

8. Clinical Test Conclusion

No clinical study is included in this submission.

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.