July 7, 2023

Yangzhou Medline Industry Co., Ltd.
℅ Diana Hong
General Manager
Mid-Link Consulting Co.,Ltd.
P.O. Box 120-119
Shanghai, 200120
China

Re: K230080
Trade/Device Name: Blood Collection Set, Blood Collection Set with Holder, Safety Blood Collection Set, Safety Blood Collection Set with Holder, Blood Collection Needle, Blood Collection Needle with Holder, Safety Blood Collection Needle, Safety Blood Collection Needle with Holder, Luer Adapter with Holder
Regulation Number: 21 CFR 862.1675
Regulation Name: Blood Specimen Collection Device
Regulatory Class: Class II
Product Code: JKA
Dated: June 7, 2023
Received: June 7, 2023

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. 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,

David Wolloscheck, Ph.D.
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)*

K230080

Device Name

Blood Collection Set, Blood Collection Set with Holder, Safety Blood Collection Set, Safety Blood Collection Set with Holder, Blood Collection Needle, Blood Collection Needle with Holder, Safety Blood Collection Needle, Safety Blood Collection Needle with Holder, Luer Adapter with Holder

Indications for Use *(Describe)*

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

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

The Safety Blood Collection 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 Safety Blood Collection 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.

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

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

The Safety Blood Collection 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 Safety Blood Collection 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 Luer adapter with Holder is intended to be used with vein puncture needle and vacuum blood collection tube for multiple collections 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.

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510(k) Summary K230080

1. Sponsor Identification

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Establishment Registration Number: 3017180772

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2. Designated Submission Correspondent

Ms. Diana Hong (Primary Contact Person)
Ms. Xingqi Wang (Alternative Contact Person)

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Tel: +86-21-22815850
Fax: 360-925-3199
Email: info@mid-link.net

3. Date of Preparation: 07/07/2023

4. Subject Device

Trade Name: Blood Collection Set,
Blood Collection Set with Holder,
Safety Blood Collection Set,
Safety Blood Collection Set with Holder,
Blood Collection Needle,
Blood Collection Needle with Holder,
Safety Blood Collection Needle,
Safety Blood Collection Needle with Holder,
Luer Adapter with Holder

Common Name: Blood Collection Systems

Regulatory Information

Classification Name: Blood specimen collection device
Classification: Class II
Product Code: JKA
Regulation Number: 21CFR 862.1675

5. Identification of Predicate Devices

Predicate Device
510(k) Number: K172763
Product 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: 862.1675
Product Code: JKA

6. Device Description

The proposed devices are blood collection devices form a channel between patient's vein and the evacuated blood collection tube intended for collection of blood.

The Blood Collection Set with/without Holder is intended to be used with vacuum blood collection tube for

multiple collections of venous blood. It is provided sterile and single use. The proposed devices are composed of Needle cap, Needle cannula, Needle handle, Flexible tube, Connector Luer adapter and Holder.

The Safety Blood Collection Set with/without 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. It is provided sterile and single use. The proposed devices are composed of Needle cap, Needle cannula, Needle handle, Safety sheath, Flexible tube, Connector, Luer adapter and Holder.

The Blood Collection Needle with/without Holder is intended to be used with vacuum blood collection tube for multiple collections of venous blood. It is provided sterile and single use. The proposed devices are composed of Needle cap, Needle cannula, Needle hub, Luer adapter and Holder.

The Safety Blood Collection Needle with/without Holder is intended to be used with vacuum blood collection tube for multiple collections of venous blood. It is provided sterile and single use. The proposed devices are composed of Needle cap, Needle cannula, Safety sheath, Needle hub, Luer adapter and Holder.

The Luer adapter with Holder is intended to be used with vein puncture needle and vacuum blood collection tube for multiple collections of venous blood. The Pre-attached Holder is designed to aid in protection against accidental non-patient needle injury and blood splatter. It is provided sterile and single use. The proposed devices are composed of Needle cap, Needle cannula, Safety sheath, Needle hub, Luer adapter and Holder.

7. Indication for Use:

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

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

The Safety Blood Collection 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 Safety Blood Collection 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.

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

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

The Safety Blood Collection 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 Safety Blood Collection 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 Luer adapter with Holder is intended to be used with vein puncture needle and vacuum blood collection tube for multiple collections of venous blood.

8. Comparison of Technological Characteristics

Table 1 Comparison of Technology Characteristics

ITEM	Proposed Device	Predicate Device K172763	Remark
Product Code	JKA	JKA	Same
Regulation Number	21CFR 862.1675	21CFR 862.1675	Same
Classification	II	II	Same
Indications for Use	The Blood Collection Needle is intended to be used with vacuum blood collection tube for multiple collections of venous blood. The Safety Blood Collection 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 Collection Needle with Holder is intended to be used with vacuum blood collection tube for multiple collections of venous blood. The Safety Blood Collection 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 Collection Set is intended to be used with vacuum	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	Analysis 1

	blood collection tube for multiple collections of venous blood. The Safety Blood Collection 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 Collection Set with Holder is intended to be used with vacuum blood collection tube for multiple collections of venous blood. The Safety Blood Collection 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. The Luer adapter with Holder is intended to be used with vein puncture needle and vacuum blood collection tube for multiple collections of venous blood.	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.	

Configuration and material	Blood Collection Needle with/without Holder, Safety Blood Collection Needle with/without Holder: Needle cap (PP) Needle tube (Stainless Steel SUS304) Needle Hub (PP) Needle Holder (PP) Non-patient end needle tube (Stainless Steel SUS304) Connector base (ABS) Rubber sleeve (Gather Isoprene Rubber) Safety Sheath(PP) Non-patient end needle cap (PP)	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)	Analysis 2
	Blood Collection Set with/without Holder, Safety Blood Collection Set with/without Holder: Needle cap (PVC) Needle tube (Stainless Steel SUS304) Needle Wing (PVC) Flexible Tube (PVC) Needle Hub (ABS) Connect base (ABS) Non-patient end needle tube (Stainless Steel SUS304) Rubber sleeve (Gather Isoprene Rubber) Non-patient end needle cap (PP) Safety Sheath(PP) Needle Holder (PP)		

	Luer adapter with Holder Connect base (ABS) Non-patient end needle tube (Stainless Steel SUS304) Rubber sleeve (Gather Isoprene Rubber) Needle Holder (PP)		
Operate mode	Manual	Manual	Same
Needle Gauge and Length	21G, 22G, 23G, 25G 5/8", 3/4", 1/2", 1", 1 1/4", 1 1/2"	18G, 19G, 20G, 21G, 22G, 23G, 25G 5/8", 3/4", 1", 1 1/4", 1 1/2", 1 3/4", 2"	Analysis 3
Safety Mechanism	The safety shield is intended to prevent needle sticks	The safety shield is intended to prevent needle sticks	Same
Label/ Labeling	Conform with 21 CFR Part 801	Conform with 21 CFR Part 801	Same
Sterilization	EO sterilized	EO sterilized	Same
	SAL: 10^{-6}	SAL: 10^{-6}	
	Endotoxin Limit: 20 EU per device	Endotoxin Limit: 20 EU per device	
Single Use	Single Use	Single Use	Same
Biocompatibility	In Vitro Cytotoxicity	In Vitro Cytotoxicity	Same
	Skin Sensitization	Skin Sensitization	
	Intracutaneous Reactivity	Intracutaneous Reactivity	
	Acute Systemic Toxicity	Acute Systemic Toxicity	
	Hemolytic Properties	Hemolytic Properties	
	Pyrogen	Pyrogen	

Analysis 1- Indications for Use

The Indications for Use between proposed device and predicate device is similar. Because the needle holder is used as part of the predicate device, the proposed device is an independent needle holder, the Luer adapter with Holder, but the Indications for Use are the same. Therefore, this difference is not determined to affect substantially equivalence on safety and effectiveness.

Analysis 2 -Configuration and material

The configuration difference between proposed device and predicate device is only the description of component. They have same configuration. The difference in the description of component does not affect the indications for use. In addition, the material of rubber sleeve from proposed device is different with predicate device. However, the biocompatibility test for proposed device has been tested and the results

comply with the requirements of ISO 10993. Therefore, this difference is not determined to affect substantially equivalence on safety and effectiveness.

Analysis 3 -Needle Gauge and Length

The needle gauge and length of between the proposed device and predicate device is different. However, this difference is just in dimension. Different gauge and length device will be selected by the end user. In addition, needles were tested according to ISO 7864:2016 and ISO 9626:2016 standards, and the results met the requirements of the standards. Therefore, this difference does not affect raise new or different questions of safety or effectiveness

9. Non-Clinical Test Conclusion

The test results demonstrated that the proposed device complies with the following standards and guidance. The following tests were conducted as applicable to the subject devices:

Bench Test

- ISO 7864:2016 Sterile hypodermic needles for single use - Requirements and test methods
- ISO 9626:2016 Stainless steel needle tubing for the manufacture of medical devices - Requirements and test methods
- ISO 10993-7:2008 Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals [Including: Technical Corrigendum 1 (2009), AMENDMENT 1: Applicability of allowable limits for neonates and infants (2019)]
- ISO 11135:2014 Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices [Including: Amendment 1 (2018)]
- ISO 23908:2011 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 80369-7:2016 Small-bore connectors for liquids and gases in healthcare applications - Part 7: Connectors for intravascular or hypodermic applications
- ISO 80369-20:2015 Small-bore connectors for liquids and gases in healthcare applications – Part 20: Common test methods
- ASTM F88/F88M-15: Standard Test Method for Seal Strength of Flexible Barrier Materials
- ASTM F756-17: Standard Practice for Assessment of Hemolytic Properties of Materials
- ASTM F1929-15: Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration
- USP 41-NF 36:2018 <85> Bacterial Endotoxins Test
- Simulated Use Study Sharps Injury Prevention Feature FDA Guidance, Guidance for Industry and FDA Staff: Medical Device with Sharps Injury Prevention Feature, issued on August 9, 2005
- USP <788> Particular Matter in Injections

Biocompatibility

The subject device is classified as externally communicating medical device with circulating blood contact for limited exposure.

Biocompatibility tests was conducted on the subject device, include in vitro cytotoxicity test (ISO 10993-5), skin sensitization test (ISO 10993-10), and irritation sensitivity (ISO 10993-10), Acute Systemic Toxicity (ISO 10993-11), Pyrogen (USP <151>), Hemolysis Test (ASTM F756-2017), Complement Activation Test (ISO 10993-4), Partial Thromboplastin Time Study (ISO 10993-4) and Platelet Leukocyte Count Study (ISO 10993-4).

10. Clinical Test Conclusion

No clinical study is included in this submission as the device does not require clinical studies to determine substantial equivalence with the predicate device

11. Conclusion

It can be concluded that the differences between the subject devices, Blood collection Set with/without holder, Safety Blood Collection set with/without holder, Blood Collection Needle with/without Holder, Safety Blood Collection Needle with/without holder and Luer Adapter with Holder, and the predicate devices, 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 and Safety Blood Collecting Set, do not raise any new or different questions of safety or effectiveness. The subject devices are substantially equivalent to the predicate devices cleared under K172763 with respect to the indications for use, target population, treatment method, and technological characteristics.