

November 4, 2021

Jiangsu Micsafe Medical Technology Co., Ltd Tony Yang General Manager Xituan Industrial Park, Dafeng District Yancheng, Jiangsu 224125 China

Re: K212019

Trade/Device Name: Blood Collection Needle for Single Use & Blood Collection Needle with Holder

for Single Use, Safety Blood Collection Needle for Single Use, Safety Blood Collection Needle with Holder for Single Use, Blood Collection Set for Single Use & Safety Blood Collection Set with Holder for Single Use, Safety Blood Collection Set for Single Use & Blood Collection Set with Holder for Single

Regulation Number: 21 CFR 862.1675

Regulation Name: Blood Specimen Collection Device

Regulatory Class: Class II

Product Code: JKA

Dated: September 24, 2021 Received: October 6, 2021

Dear Tony Yang:

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 <u>Federal Register</u>.

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-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">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,

For Payal Patel
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

Expiration Date: 06/30/2023 See PRA Statement below.

510(k) Number (if known) K212019

Device Name

Blood Collection Needle for Single Use & Blood Collection Needle with Holder for Single Use, Safety Blood Collection Needle for Single Use, Safety Blood Collection Needle with Holder for Single Use, Blood Collection Set for Single Use & Safety Blood Collection Set with Holder for Single Use, Safety Blood Collection Set with Holder for Single Use, Safety Blood Collection Set with Holder for Single Use & Blood Collection Set with Holder for Single Use, Safety Blood Collection Set with Holder for Single Use & Blood Collection Set with Holder for Single Use, Safety Blood Collection Set with Holder for Single Use, Safety Blood Collection Set with Holder for Single Use, Safety Blood Collection Set with Holder for Single Use, Safety Blood Collection Set with Holder for Single Use, Safety Blood Collection Set with Holder for Single Use, Safety Blood Collection Set with Holder for Single Use, Safety Blood Collection Set with Holder for Single Use, Safety Blood Collection Set with Holder for Single Use, Safety Blood Collection Set with Holder for Single Use, Safety Blood Collection Set with Holder for Single Use & Blood Collection Set with Holder for Single Use & Blood Collection Set with Holder for Single Use & Blood Collection Set with Holder for Single Use & Blood Collection Set with Holder for Single Use & Blood Collection Set with Holder for Single Use & Blood Collection Set with Holder for Single Use & Blood Collection Set with Holder for Single Use & Blood Collection Set with Holder for Single Use & Blood Collection Set with Holder for Single Use & Blood Collection Set with Holder for Single Use & Blood Collection Set with Holder for Single Use & Blood Collection Set with Holder for Single Use & Blood Collection Set with Holder for Single Use & Blood Collection Set with Holder for Single Use & Blood Collection Set with Holder for Single Use & Blood Collection Set with Holder for Single Use & Blood Collection Set with Holder for Single Use & Blood Collection Set with Holder for Single Use & Blood Collection Set wit

Indications for Use (Describe)

(1) Blood Collection Needle for Single Use

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

(2) Safety Blood Collection Needle for Single Use

The Safety Blood Collection Needle for Single Use 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.

(3) Blood Collection Needle with Holder for Single Use

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

(4) Safety Blood Collection Needle with Holder for Single Use

The Safety Blood Collection Needle with Holder for Single Use 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.

(5) Blood Collection Set for Single Use

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

(6) Safety Blood Collection Set for Single Use

The Safety Blood Collection Set for Single Use 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.

(7) Blood Collection Set with Holder for Single Use

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

(8) Safety Blood Collection Set with Holder for Single Use

The Safety Blood Collection Set with Holder for Single Use 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.				

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510(k) Summary K212019

(As required by 21 CFR 807.92(a))

1. Submitter Information

• Company: Jiangsu Micsafe Medical Technology Co., Ltd

Address: Xituan Industrial Park, Dafeng District, Yancheng City,

Jiangsu Province, 224125, China

• Phone: 086-13651929266

• Contact: Tony Yang, General Manager

• Date: November 3, 2021

2. Device Information

Trade/Device Name: Blood Collection Needle for Single Use

Safety Blood Collection Needle for Single Use

Blood Collection Needle with Holder for Single Use

Safety Blood Collection Needle with Holder for Single Use

Blood Collection Set for Single Use

Safety Blood Collection Set for Single Use

Blood Collection Set with Holder for Single Use

Safety Blood Collection Set with Holder for Single Use

• Common Name: Blood Collection Tubes, Vials, Systems, Serum Separators

• Classification:

Regulation Name: Blood specimen collection device

Review Panel: Clinical Chemistry

Product Code: JKA

Submission Type: 510(k)

Regulation Number: 21 CFR 862.1675

Device Class: II

Type of Use: Prescription use only



3. Predicate Device Information

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

[510(k) Number: K172763; submitted by Zhejiang kindly medical devices Co., Ltd.]

Regulation Name: Blood specimen collection device

Review Panel: Clinical Chemistry

Product Code: JKA

Submission Type: 510(k)

Regulation Number: 21 CFR 862.1675

Device Class: II

Type of Use: Prescription use only

4. Device Description

The subject devices are single use, EtO sterilized with a shelf-life of 5 years. Blood collection needles and holders are intended to be used with a 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.

(1) Blood Collection Needle for Single Use

This product use PP, Polyisoprene rubber and SUS304 as the main materials. It contains needle cap, needle hub, needle tube and needle sleeve.

Device Models:

	Specification of Needle	Length of Needle
	18G	1 1/2"
Blood Collection Needle	20G	1 1/2"
for Single Use	21G	1 1/2"
	22G	1 1/2"
	23G	1 1/2"



(2) Safety Blood Collection Needle for Single Use

This product use PP, Polyisoprene rubber and SUS304 as the main materials. It contains needle cap, needle hub with safety shield, needle tube, needle sleeve.

Device Models:

Cofety Dland Callection	Specification of Needle	Length of Needle
Safety Blood Collection	21G	1 1/2"
Needle for Single Use	22G	1 1/2"

(3) Blood Collection Needle with Holder for Single Use

This product use PP, Polyisoprene rubber and SUS304 as the main materials. It contains needle cap, needle hub, needle tube, needle sleeve, holder.

Device Models:

	Specification of Needle	Length of Needle
	18G	1 1/2"
Blood Collection Needle	20G	1 1/2"
with Holder for Single Use	21G	1 1/2"
	22G	1 1/2"
	23G	1 1/2"

(4) Safety Blood Collection Needle with Holder for Single Use

This product use PP, Polyisoprene rubber and SUS304 as the main materials. It contains needle cap, needle hub with safety shield, needle tube, needle sleeve, holder.

Device Models:

Safety Blood Collection	Specification of Needle	Length of Needle
Needle with Holder for	21G	1 1/2"
Single Use	22G	1 1/2"

(5) Blood Collection Set for Single Use

The products use PP, ABS, PVC, Polyisoprene rubber and SUS304 as the main materials. It contains needle cap, needle hub, needle tube, tubing, butterfly wings, needle sleeve.



Device Models:

	Specification of Needle	Length of Needle
	20G	3/4"
Blood Collection Set for	21G	3/4"
Single Use	22G	3/4"
	23G	3/4"
	25G	3/4"

(6) Safety Blood Collection Set for Single Use

The products use PP, ABS, PVC, Polyisoprene rubber and SUS304 as the main materials. It contains needle cap, safety shield, needle hub, needle tube, tubing, butterfly wings, needle sleeve.

Device Models:

	Specification of Needle	Length of Needle
	20G	3/4"
Safety Blood Collection	21G	3/4"
Set for Single Use	22G	3/4"
	23G	3/4"
	25G	3/4"

(7) Blood Collection Set with Holder for Single Use

The products use PP, ABS, PVC, Polyisoprene rubber and SUS304 as the main materials. It contains needle cap, needle hub, needle tube, tubing, butterfly wings, needle sleeve, holder.

Device Models:

	Specification of Needle	Length of Needle
	20G	3/4"
Blood Collection Set with	21G	3/4"
Holder for Single Use	22G	3/4"
	23G	3/4"
	25G	3/4"

(8) Safety Blood Collection Set with Holder for Single Use

The products use PP, ABS, PVC, Polyisoprene rubber and SUS304 as the main materials. It contains needle cap, needle hub, safety shield, needle tube, tubing, butterfly wings, needle sleeve,



holder.

Device Models:

	Specification of Needle	Length of Needle
Safety Blood Collection Set with Holder for Single Use	20G	3/4"
	21G	3/4"
	22G	3/4"
	23G	3/4"
	25G	3/4"

5. Indications for Use

(1) Blood Collection Needle for Single Use

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

(2) Safety Blood Collection Needle for Single Use

The Safety Blood Collection Needle for Single Use 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.

(3) Blood Collection Needle with Holder for Single Use

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

(4) Safety Blood Collection Needle with Holder for Single Use

The Safety Blood Collection Needle with Holder for Single Use 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.

(5) Blood Collection Set for Single Use

The Blood Collection Set for Single Use is intended to be used with vacuum blood collection tube



for multiple collections of venous blood.

(6) Safety Blood Collection Set for Single Use

The Safety Blood Collection Set for Single Use 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.

(7) Blood Collection Set with Holder for Single Use

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

(8) Safety Blood Collection Set with Holder for Single Use

The Safety Blood Collection Set with Holder for Single Use 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.

6. Comparison of Technological Characteristics with the Predicate Device

Comparison Item	Subjective Device	Predicate Device (K172763)	Remark
Classification	Product Code: JKA	Product Code: JKA	Same
Classification	Class: II	Class: II	Same
	The Blood Collection	The Blood Collection	
	Needle/ The Blood	Needle/ The Blood	
	Collection Needle with	Collection Needle with	
	Holder/ The Blood	Holder/ The Blood	
	Collection Set/ The Blood	Collection Set/ The Blood	
	Collection Set with Holder	Collection Set with Holder	Same
Indications for	for Single Use is intended	is intended to be used with	
Use	to be used with vacuum	vacuum blood collection	
Use	blood collection tube for	tube for multiple collections	
	multiple collections of	of venous blood.	
	venous blood.		
	The Safety Blood	The Safety Blood	
	Collection Needle/ The	Collection Needle/ The	Same
	Safety Blood Collection	Safety Blood Collection	Same
	Needle with Holder/ The	Needle with Holder/ The	



Subjective Device Safety Blood Collection Set The Safety Blood Collection Set with Holder for Single Use 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. Protective cover of Patient-end Needle (PP) Needle Cap (PP) Needle Sleeve (Polyisoprene Rubber) Materials of Different Device Parts Medle Tube (SUS304) Needle Hub With Safety-Shield (PP) Needle Hub with Safety-Shield (PP) Same Needle Hub Wings (PVC) Tubing (PVC) Needle Hub-Female (ABS) Needle Hub-Male (PP) Needle Cover (PP) Redle Cover (PP) Needle Cover (PP) Redle Cover (PP) Needle Cover (PP) Same Needle Hub-Male (PP) Same Safety Shield (PP) Same Remark Safety Blood Collection Set '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. Protective cover of Patient-end Needle (PP) Non-Patient-end Needle (PP) Non-Patient end Needle Hub/ Non-Patient end Needle (Stainless Steel) Needle Hub with Safety-Shield (PP) Same Safety-Shield (PP) Same Needle Hub-Female (ABS) Needle Hub-Female (ABS) Needle Hub-Male (PP) Conical Fitting Connector (ABS) Different (Comment #2) Needle Hub-Male (PP) Same Safety Shield (PP) Same Safety Shield (PP) Same Gauge Size and Needle Length: 11/2", 3/4" Needle Length: 58", 3/4", 1", 11/4", 1 (Comment #3)	C			
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Comparison Item	Subjective Device	Predicate Device (K172763)	Remark
SAL	10-6	10 ⁻⁶	Same
Single Use	Yes	Yes	Same
	Conforms to the	Conforms to the	
	requirement of ISO 10993	requirement of ISO 10993	Same
	series Standards	series Standards	
	No cytotoxicity	No cytotoxicity	Same
D: 4:1-:1:4	No irritation to skin	No irritation to skin	Same
Biocompatibility	No significant evidence of	No significant evidence of	Same
	sterilization	sterilization	Same
	No systemic toxicity	No systemic toxicity	Same
	No hemolysis	No hemolysis	Same
	No pyrogen	No pyrogen	Same
Performance	Conforms with the	Conforms with the	
Safety &	requirements of ISO 7864	requirements of ISO 7864	Same
Effectiveness	and ISO 9626	and ISO 9626	

Discussion

The subject devices are similar to the predicate device K172763 in design, indications for use, sterilization, method of operation and technological characteristics. The biocompatibility of both devices has been ensured by relevant ISO 10993 standards, which ensures that the subject device will be as safe for use as the predicate device.

Comment #1

The difference between subject device and predicate device is the materials of rubber sleeve. However, the biocompatibility test for the subject device has been tested and the results comply with the requirements of ISO 10993. Therefore, this difference is not determined to affect substantial equivalence on safety and effectiveness.

Comment #2

The difference between subject device and predicate device is the materials of needle hub-male. However, the biocompatibility test for the subject device has been tested and the results comply with the requirements of ISO 10993. Therefore, this difference is not determined to affect



substantial equivalence on safety and effectiveness.

Comment #3

In addition, the needle gauge and length of between the subjective device and predicate device is different. However, the difference is just in dimension. Different gauge and length device will be selected by the end user. This difference does not affect raise new or different questions of safety or effectiveness. Both the subject and the predicate device were tested to the same performance standards (ISO 7864 and ISO 9626).

7. Discussion of Test Performed

7.1. Clinical Tests

Clinical testing was not performed for the subject device as part of the submission.

7.2. Non-Clinical Tests

The subject device was tested/analyzed according to the following standards in order to ensure its effectiveness and safety:

(1) Biocompatibility

The products are considered blood path, indirect for a duration of less than 24 hours, the biocompatibility is according to:

- ISO 10993-4: Third Edition 2017-04. Biological Evaluation Of Medical Devices Part 4:
 Selection Of Tests For Interactions With Blood;
- ANSI AAMI ISO 10993-5:2009/(R)2014, Biological Evaluation Of Medical Devices Part 5:
 Tests For In Vitro Cytotoxicity;
- ANSI AAMI ISO 10993-10:2010/(R)2014, Biological Evaluation Of Medical Devices Part
 10: Tests For Irritation And Skin Sensitization;
- ISO 10993-11: Third Edition 2017-09, Biological Evaluation Of Medical Devices Part 11:
 Tests For Systemic Toxicity;
- (2) Physical, Mechanical, Chemical testing performed on the subjective device: Performance safety and effectiveness according to ISO 7864 Fourth Edition 2016-08-01,



Sterile Hypodermic Needles For Single Use Requirements And Test Methods:

- Cleanliness
- Limits for acidity or alkalinity
- Limits for extractable metals
- Size designation
- Colour coding
- Needle hub
- Needle cap
- Needle tube
- Needle point
- Bond between hub and needle tube
- Patency of lumen

Performance safety and effectiveness according to ISO 9626 Second Edition 2016-08-01, Stainless Steel Needle Tubing For The Manufacture Of Medical Devices - Requirements And Test Methods:

- Limits for acidity or alkalinity
- Surface finish and visual appearance
- Cleanliness
- Size designation
- Dimensions
- Stiffness
- Resistance to breakage
- Resistance to corrosion

Performance safety and effectiveness according to ISO 80369-7 First Edition 2016-10-15,

Small-Bore Connectors For Liquids And Gases In Healthcare Applications - Part 7:

Connectors For Intravascular Or Hypodermic Applications:

- Leakage by pressure decay
- Positive pressure liquid leakage



- Sub-atmospheric pressure air leakage
- Stress cracking
- Resistance to separation from axial load
- Resistance to separation from unscrewing
- Resistance to overriding
- (3) Additional performance safety and effectiveness for the Blood Collection Needle for Single Use/ Safety Blood Collection Needle for Single Use/ Blood Collection Needle with Holder for Single Use/ Safety Blood Collection Needle with Holder for Single Use/ Blood Collection Set for Single Use/ Safety Blood Collection Set for Single Use/ Blood Collection Set with Holder for Single Use/ Safety Blood Collection Set with Holder for Single Use:
- Risk Management Report to ISO 14971: 2019
- Sharps Injury Protection Test Report to ISO 23908: 2011

7.3. Simulated Clinical Use Study

A simulated clinical use 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 device. The results demonstrated that the proposed device met the pre-established criteria.

8. Conclusion

The differences between the predicate and the subject device do not raise any new or different questions of safety or effectiveness. Based on the comparison above and the non-clinical bench testing conducted, the subject device is determined to be Substantiality Equivalent (SE) to the predicate devices cleared under K172763 with respect to the indications for use, target populations, treatment method, and technological characteristics.