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 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,

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
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 for Single Use & Blood Collection Set with Holder for Single

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
Blood Collection Needle for Single Use	18G	1 1/2"
	20G	1 1/2"
	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:

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

	Specification of Needle	Length of Needle
Safety Blood Collection Needle with Holder for Single Use	21G	1 1/2"
	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
Blood Collection Set for Single Use	20G	3/4"
	21G	3/4"
	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
Safety Blood Collection Set for Single Use	20G	3/4"
	21G	3/4"
	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
Blood Collection Set with Holder for Single Use	20G	3/4"
	21G	3/4"
	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 Class: II	Product Code: JKA Class: II	Same
Indications for Use	The Blood Collection Needle/ The Blood Collection Needle with Holder/ The Blood Collection Set/ 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.	The Blood Collection Needle/ The Blood Collection Needle with Holder/ The Blood Collection Set/ The Blood Collection Set with Holder is intended to be used with vacuum blood collection tube for multiple collections of venous blood.	Same
	The Safety Blood Collection Needle/ The Safety Blood Collection Needle with Holder/ The	The Safety Blood Collection Needle/ The Safety Blood Collection Needle with Holder/ The	Same

Comparison Item	Subjective Device	Predicate Device (K172763)	Remark
	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.	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.	
Materials of Different Device Parts	Needle Cap (PP)	Protective cover of Patient-end Needle/ Protective cover of Non-Patient-end Needle (PP)	Same
	Needle Sleeve (Polyisoprene Rubber)	Rubber Sleeve (Natural Rubber)	Different (Comment #1)
	Needle Hub (PP)	Patient-end Needle Hub/ Non-Patient end Hub (PP)	Same
	Needle Tube (SUS304)	Patient-end Needle/ Non-Patient end Needle (Stainless Steel)	Same
	Needle Hub with Safety-Shield (PP)	Safety-Shield (PP)	Same
	Holder (PP)	Needle Holder (PP)	Same
	Butterfly Wings (PVC)	Double Wing (PVC)	Same
	Tubing (PVC)	Flexible Tube (PVC)	Same
	Needle Hub-Female (ABS)	Conical Fitting Connector (ABS)	Same
	Needle Hub-Male (PP)	Conical Fitting (ABS)	Different (Comment #2)
	Needle Cover (PP)	Protective Cover (PP)	Same
	Safety Shield (PP)	Safety Shield (PP)	Same
Gauge Size and Needle Length	18G, 20G, 21G, 22G, 23G, 25G Needle Length: 1 1/2”, 3/4”	18G~23G, 25G Needle Length: 5/8”, 3/4”, 1”, 1 1/4”, 1 1/2”, 1 3/4”, 2”	Different (Comment #3)
Operate Mode	Manual	Manual	Same
Sterile Method	EO sterilized	EO sterilized	Same

Comparison Item	Subjective Device	Predicate Device (K172763)	Remark
SAL	10^{-6}	10^{-6}	Same
Single Use	Yes	Yes	Same
[redacted]			
Biocompatibility	Conforms to the requirement of ISO 10993 series Standards	Conforms to the requirement of ISO 10993 series Standards	Same
	No cytotoxicity	No cytotoxicity	Same
	No irritation to skin	No irritation to skin	Same
	No significant evidence of sterilization	No significant evidence of sterilization	Same
	No systemic toxicity	No systemic toxicity	Same
	No hemolysis	No hemolysis	Same
	No pyrogen	No pyrogen	Same
Performance Safety & Effectiveness	Conforms with the requirements of ISO 7864 and ISO 9626	Conforms with the requirements of ISO 7864 and ISO 9626	Same

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.