U&U Medical Technology Co.,Ltd
Nick Wang
Project Director
Dongzhou Village, Hengshanqiao
Changzhou, China 213119 Jiangsu

Re: K181508
Trade/Device Name: U&U Blood Collection Sets
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: Class II
Product Code: FMI, JKA
Dated: January 8, 2019
Received: January 17, 2019

Dear Nick Wang:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

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,

Sarah B. Mollo -S

for 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)*
K181508

Device Name

U&U Blood Collection Sets

Indications for Use *(Describe)*

The U&U Blood Collection Sets is used in routine venipuncture procedures. It is used for blood collection. The safety shield is activated to cover the needle immediately following blood collection thus preventing 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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"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."

K181508 510(K) Summary

This summary of 510(k) information is being submitted in accordance with the requirements of SMDA and 21 CFR §807.92

1. Submitter Name and Address:

Name: U&U Medical Technology Co., Ltd
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US Agent:
Name: U&U Medical Inc.
Address: 1580 Boggs Rd, Suite 500, Duluth, GA 30096
TEL: 404 426 1248
Contact person: Ms. LI QIAN li@UU-Medicalus.com

Date Prepared: February 09, 2019

2. Submission Devices Information:

Trade/Proprietary Name:	U&U Blood Collection Sets
Common Name:	Blood Collection Needle
Regulation Name:	Hypodermic single lumen needle
Class:	II
Product codes:	FMI, JKA
Regulation Number:	21 CFR 880.5570

3. Predicate Devices Information:

Trade Name:	VACUETTE PREMIUM Safety Blood Collection Set
510(K) Number:	K102010
Regulation Number:	21 CFR 880.5570
Product codes:	FMI & JKA

4. Devices Description:

The U&U Blood Collection Set is a single use, individually wrapped, sterile winged blood collection needle with an integrated needle and safety shield bonded to a flexible tubing with a female luer adapter allowing the set to be used with a luer system. It is available with optional Luer Adapter and / or Luer Adapter + Holder. The device is not made with Latex.

5. Indications for Use

The U&U Blood Collection Sets is used in routine venipuncture procedures. It is used for blood collection. The safety shield is activated to cover the needle immediately following blood collection thus preventing accidental needle-stick injury.

6. Technological Characteristics:

The subject device has demonstrated substantial equivalence to the predicate device in device comparison technology, method of operation, intended use and through performance bench test results.

Comparison Table

Element of Comparison	Submission Device K181508	Predicate Device K102010
Indication for Use	The U&U Blood Collection Sets is used in routine venipuncture procedures. It is used for blood collection. The safety shield is activated to cover the needle immediately following blood collection thus preventing accidental needle-stick injury.	The VACUETTE PREMIUM Safety Blood Collection Set is used in routine venipuncture procedures. It is used for blood collection. The safety shield is activated to cover the needle immediately following blood collection thus preventing accidental needle-stick injury.
Regulation Number	880.5570	880.5570
Product codes	FMI & JKA	FMI & JKA
Principle of Operation	Manual	Manual
Needle gauges	19G to 27G	21G to 25G
Leakage	No Leakage	No Leakage
Tensile strength	Withstand a static tensile force of not less than 15N for 15s;	Withstand a static tensile force of not less than 15N for 15s;
Tubing	The tubing shall be transparent or sufficiently translucent so that the interface of air and water during the passage of air bubbles can be observed with normal or corrected vision.	The tubing shall be transparent or sufficiently translucent so that the interface of air and water during the passage of air bubbles can be observed with normal or corrected vision.
Materials	PVC HDPE ABS RUBBER SUS 304 PP	PVC HDPE ABS RUBBER SUS 304 PP
Sharps Injury Prevention Features force to attach connection force to activate number of activations to failure	 < 15N < 15N Tested 500, Failure 0 ≥100N	 < 15N < 15N Tested 100, Failure 0 ≥100N

force to deactivate	≥100N	≥100N
Sterilization Method	EtO Gas	EtO Gas
Method to retract needle	Pull back on tubing until needle is locked within the Safety Shield	Pull back on tubing until needle is locked within the Safety Shield
Performances	Conforms to ISO 9626, 23908, 594-2, ISO7864	Conforms to ISO 9626, 23908, 594-2, ISO7864
Biocompatibility	Conforms to ISO10993	Conforms to ISO10993
Shelf life	5 Years	3 Years
Labeling	Meet the requirements of 21 CFR Part 801	Meet the requirements of 21 CFR Part 801

7. Summary Non-Clinical Test:

The non-clinical testing consisted of evaluation studies of the U&U Blood Collection Set to verify its ability to meet its intended use requirements. This testing also included testing to the relevant product standards. When appropriate, predicate devices were tested using the exact same method and sample size, for direct comparison of results. The data obtained from bench testing, sterilization testing, and biocompatibility testing showed that the device is substantially equivalent to the predicated device.

Conform to ISO 7864

ISO 7864: Sterile hypodermic needles for single use -- Requirements and test methods.

Surface Finish and Cleanliness
Needle Freedom from Defects
Bond Between Hub and Needle Tube
Needle Tolerance on Length
Needle Patency of Lumen
Lubricant
Reducing (oxidizable) matter
Metal ions
Titration acidity or alkalinity
Residue on evaporation
UV absorption of extract solution
Pyrogenicity

Conform to ISO 9626

ISO 9626: Stainless steel needle tubing for medical devices.

Physical Performance - Resistance to breakage
Physical Performance – Stiffness

Physical Performance - Resistance to corrosion

Conform to ISO 23908

Sharps protection features for single-use hypodermic needles, introducers for catheters and needles used for blood sampling.

Activated the sharps injury prevention feature in 500samples of each gauge size with zero failures.

Conform to ISO 594-2

ISO 594-2, Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment - Part 2: Lock fittings.

Leakage with Positive and Negative Pressure

Conform to ISO 11607-1

ISO 11607-1, Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging.

Seal Strength
Visual Inspection
Dye Penetration
Bubble Emission

Conform to ISO 10993-1

ISO 10993-1, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process.

Acute Systemic Toxicity
Bacterial endotoxins(Gel-clot techniques)
Cyotoxicity
Haemolysis
Irritation
Skin Sensitization
Test for Pyrogenicity

Conform to ISO 10993-7

ISO 10993-7, Biological evaluation of medical devices. Ethylene oxide sterilization residuals.

Ethylene oxide & Ethylene Chlorohydrin Residues Test

8. Conclusion:

The subject device has demonstrated substantial equivalence to the predicate device in device comparison technology, method of operation, intended use and through performance bench test results.