January 5, 2023

Jiangsu Caina Medical Co.,Ltd
Jianwei Pan
Regulatory Affairs
No.23, Huanxi Rd, Zhutang Town
Jiangyin, Jiangsu 214415
China

Re: K222834
Trade/Device Name: Safety Push Button Blood Collection Set
Regulation Number: 21 CFR 862.1675
Regulation Name: Blood Specimen Collection Device
Regulatory Class: Class II
Product Code: JKA, FPA
Dated: November 28, 2022
Received: December 5, 2022

Dear Jianwei Pan:

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.
For Joyce M. Whang, Ph.D.
Acting 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K222834

Device Name
Safety Push Button Blood Collection Set

Indications for Use *(Describe)*

The Safety Push Button Blood Collection Set is intended to be used for insertion into a patient's vascular system for blood specimens. When used without the male adapter, the device allows the clinician to obtain blood sampling from the female hub with a syringe, if necessary, or can be used for short-term (up to 2 hours), single infusions with consideration given to patient size and appropriateness for the solution being infused. The device is not to be left in place and remain under the direct supervision of a clinician.
It aids in the prevention of accidental needle stick through the use of an active safety feature.
The device is a sterile, multiple sample, single-use.

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.

K222834 - 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: K222834

1. Date of Preparation: Jan. 03, 2023

2. Sponsor Identification

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4. Identification of Proposed Device

Trade Name: Safety Push Button Blood Collection Set

Common name: Blood Collection Set

Regulatory Information
Classification Name: Blood specimen collection device

Class: II

Regulation Number: 21 CFR 862.1675
Product Code: JKA and FPA
Review Panel: General Hospital

Indications for Use Statement:

The Safety Push Button Blood Collection Set is intended to be used for insertion into a patient's vascular system for blood specimens. When used without the male adapter, the device allows the clinician to obtain blood sampling from the female hub with a syringe, if necessary, or can be used for short-term (up to 2 hours), single infusions with consideration given to patient size and appropriateness for the solution being infused. The device is not to be left in place and remain under the direct supervision of a clinician.

It aids in the prevention of accidental needle stick through the use of an active safety feature.

The device is a sterile, multiple sample, single-use.

5. Device Description

The proposed device consists of these components: (1) Needle cap, (2) Needle, (3) Spring, (4) Butterfly wings, (5) Hub, (6) Safety sheath, (7) Flexible tube, (8) Female luer, (9) Male luer hub, (10) Puncture needle, (11) Rubber sleeve, (12) Puncture needle protect cover or holder, (13) Safety push button protect cover.

The proposed device have three configurations: Without holder, With holder, Without male adapter. For without male adapter, there is a a protective cap to cover female luer. The proposed device is available various needle size and tube length. The range of needle size is from 25G(0.5mm) to 20G(0.9mm). The range of tube length is from 10cm(4") to 30cm(12").

The proposed device have sharps injury protection features. It aids in the prevention of accidental needle stick through the use of an active safety feature.

The proposed device is a sterile, single use device. It is sterilized by Ethylene Oxide Gas (EtO) to achieve a SAL of 10^{-6} and supplied sterility maintenance package which could maintain the sterility of the device during the shelf life of three years.

No DEHP, BPA and Natural Rubber Latex are added in the proposed device.

6. Identification of Predicate Device

Predicate Device

510(k) Number: K153309

Product Name: BD Vacutainer UltraTouch Push Button Blood Collection Set

7. Substantially Equivalent (SE) Comparison

Table 1 Comparison of Technology Characteristics with K153309

ITEM	Proposed Device	Predicate Device K153309	Comment
Product code	JKA and FPA	JKA and FPA	Same

Regulation No.	21 CFR 862.1675	21 CFR 862.1675	Same
Regulation Name	Blood specimen collection device	Blood specimen collection device	Same
Class	II	II	Same
Indications for use	The Safety Push Button Blood Collection Set is intended to be used for insertion into a patient's vascular system for blood specimens. When used without the male adapter, the device allows the clinician to obtain blood sampling from the female hub with a syringe, if necessary, or can be used for short-term (up to 2 hours), single infusions with consideration given to patient size and appropriateness for the solution being infused. The device is not to be left in place and remain under the direct supervision of a clinician. It aids in the prevention of accidental needle stick through the use of an active safety feature. The device is a sterile, multiple sample, single-use.	The BD Vacutainer® UltraTouch™ Push Button Blood Collection Set is a sterile, multiple sample, single-use fixed winged blood collection set intended for venipuncture to obtain blood specimens from patients. When used without the male adapter, the device allows the clinician to obtain blood sampling to the female hub with a syringe, if necessary, or can be used for short-term, single infusions with consideration given to patient size and appropriateness for the solution being infused. The device is not to be left in place and remain under the direct supervision of a clinician. The recommended use of the device is to activate the needle safety feature prior to removal from the venipuncture site. The retraction of the intravenous (IV) end of the needle aids in the prevention of accidental needlestick injury.	Different See Comment 1
Configuration	Three configuration: Without holder, With holder, Without male adapter	Two configuration: with an integrated male luer adapter which connects to a holder, without the male luer adapter	Different See Comment 2
Consisted of	(1) Needle cap, (2) Needle, (3) Spring, (4) Butterfly wings, (5) Hub, (6) Safety sheath, (7) Flexible tube, (8) Female luer, (9) Male luer hub, (10) Puncture needle, (11) Rubber sleeve, (12) Puncture needle protect cover or holder, (13) Safety	Needle protector, Stainless steel cannula (Intravenous end and Non-patient end of cannula), Stainless steel spring, Hub, front and rear barrel, Wings, Tubing, Female luer connector and an	Same

	push button protect cover.	optional male luer adapter, Luer Cap	
patient contact material	Stainless steel SUS304, Methyl methacrylate acrylonitrile butadiene styrene plastics(MABS), Acrylonitrile Butadiene Styrene Copolymer(ABS), Polyvinyl chloride(PVC), Isoprene Rubber, Polydimethysiloxane, Color additive	Polypropylene, Stainless Steel 304, PVC, Silicone, ABS, Isoprene Rubber	See Comment 3
Expiration Date	3 years	2 years	See Comment 4
Sterile	Sterile	Sterile	Same
Sterile method	EtO Sterilized	Gamma	See Comment 5
SAL	10^{-6}	10^{-6}	Same
Single use	Yes	Yes	Same
Environment of use	Healthcare facilities by trained medical professional	Healthcare facilities by trained medical professional	Same
Needle size	Needle gauge 25G,23G,22G,21G, 20G, Needle length 1/2", 5/8", 3/4"	Needle gauge 25G,23G,21G Needle length 3/4"	See Comment 6
Tube length	10cm(4"), 180cm(7"), 30cm(12")	7" and 12"	See Comment 6
principles of operation	When vacuum blood collection tube is use, blood flow into blood collection tube via the device under the action of differential pressure.	When vacuum blood collection tube is use, blood flow into blood collection tube via the device under the action of differential pressure.	Same
Activation mode	Manual, active safety feature, retraction by spring	Manual, active safety feature, retraction by spring	Same

Comment 1

The proposed indications for use, are similar to the predicate indications for use. The difference is commented as follows:

-the short term is clearly defined for up to 2 hours in indications for use of proposed device. It does not raise new questions of safety/effectiveness, however users are more aware of the safe use time.

-in predicate indications for use, the recommended use is to activate the needle safety feature prior to removal from the venipuncture site. The needle safety feature can be activated before or after the needle leaves the body, which will not cause new safety/effectiveness. It aids in the prevention of accidental needle stick through the use of an active safety feature.

So the differences are not a significant change.

Comment 2

The predicate device is two configuration: with an integrated male luer adapter which connects to a holder(without holder) and without the male luer adapter. The male luer adapter is intended to installed the holder and held during operation. The proposed device is expanded into two configurations, pre installed holder and without holder. This gives users more choices. The pre installed holder do not change any function of proposed device. So the differences are not a significant change.

Comment 3

The patient contact materials for the proposed device are different from predicate device. According to guidance, Use of International Standard ISO 10993-1 "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process", the proposed device is external communicating device of Blood path, indirect and limited contact. The Cytotoxicity test, Sensitization test, Irritation test, Acute systemic toxicity test, Pyrogen test, Hemolysis test have been performed for proposed device. Therefore, this material difference does not affect substantially equivalence on safety and effectiveness.

Comment 4

The expiration date for the proposed device is different from predicate device. The proposed devices have been performed 3 years accelerated aging and demonstrated that the aged samples also complied with the requirements of relevant performance standards. The ability of immediate package of the proposed device to maintain the device in a sterile state for a period of 3 years has been validated in accordance with ISO 11607 and ISTA 3A. Therefore, this expiration date difference does not affect substantially equivalence on safety and effectiveness.

Comment 5

The sterile method of proposed device is Eto, the sterile method of predicate device is Gamma. Both of them achieve a Sterility Assurance Level (SAL) of 10^{-6}. Examination of the Ethylene Oxide (EO) and Ethylene Chlorohydrin (ECH) residuals have met with ISO 10993-7,AMD1:2019, this sterilization difference does not affect substantially equivalence on safety and effectiveness.

Comment 6

The needle size and tube length is different between proposed device and predicate device. The proposed device have expanded of needle and tube range. These extended devices have been verified according to ISO 9626, ISO 7864, ISO 8536-4. The difference does not affect substantially equivalence on safety and effectiveness.

8. Non-Clinical Test Conclusion

Non-clinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies applicable parts of the following standards:

- ISO 10993-7:2008 AMD.1:2019 Biological evaluation of medical devices- Part 7: Ethylene Oxide Sterilization Residuals
- ISO 10993-5:2009 Biological evaluation of medical devices- Part 5: Test for in vitro cytotoxicity
- ISO 10993-10:2010 Biological evaluation of medical devices- Part 10: Test for irritation and delayed-type hypersensitivity
- ISO 10993-11:2017 Biological evaluation of medical devices -- Part 11: Tests for systemic toxicity
- USP <151> Pyrogen Test
- 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.
- ASTM F88/F88M-21 standard method for seal strength of flexible barrier materials
- ASTM F1886/F1886M-16, Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection
- USP <85> Bacterial Endotoxins Test
- ISO 80369-7:2021 Small-bore connectors for liquids and gases in healthcare applications -Part 7:Connectors for intravascular or hypodermic applications
- ISO 8536-4:2019 Infusion equipment for medical use - Part 4: Infusion sets for single use, gravity feed
- ISO 9626:2016 Stainless steel needle tubing for the manufacture of medical devices - Requirements and test methods
- ISO 7864:2016 Sterile hypodermic needles for single use - Requirements and test methods

In addition, the following verification or testing is performed to meet the stated performance requirements:

- Extraction force testing in simulation using
- Simulated Clinical Study for safety feature
- Sharps injury protection testing in accordance with ISO 23908

9. Clinical Test Conclusion

No clinical study was included in this submission.

10. Substantially Equivalent (SE) Conclusion

Based on the comparison and analysis above, the proposed devices are determined to be Substantially Equivalent (SE) to the predicate device in intended use, principles of operation, technology, design, materials and performance.