April 10, 2026

Becton, Dickinson and Company
Kelly Hilliger
Staff Regulatory Affairs Specialist
1 Becton Drive
Franklin Lakes, New Jersey 07417

Re: K252506
Trade/Device Name: BD Vacutainer® Safety-Lok™ Blood Collection Set; BD Vacutainer® Safety-Lok™ Blood Collection Set with Pre-Attached Holder
Regulation Number: 21 CFR 862.1675
Regulation Name: Blood Specimen Collection Device
Regulatory Class: Class II
Product Code: JKA, FPA
Dated: March 13, 2026
Received: March 13, 2026

Dear Kelly Hilliger:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

PAPATYA KANER -S

Papatya Kaner, Ph.D.
For David Wolloscheck, Ph.D.
Assistant Director
DHT3C: Division of Drug Delivery and
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K252506

Device Name
BD Vacutainer® Safety-Lok™ Blood Collection Set
BD Vacutainer® Safety-Lok™ Blood Collection Set with Pre-Attached Holder

Indications for Use *(Describe)*
The BD Vacutainer® Safety-Lok™ Blood Collection Set is a sterile, multi-sample, single-use fixed winged blood collection set intended for use in the general population by healthcare professionals experienced in phlebotomy for venipuncture to obtain blood specimens from patients, including those with difficult vein access who may have small, fragile, and/or non-palpable veins, into evacuated blood collection tubes and/or blood culture bottles. When used without the male Luer adapter, the device allows the clinician to obtain a blood specimen from the female Luer connector with a syringe, if necessary. The device can be used by healthcare professionals with infusion experience 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 is to remain under the direct supervision of a clinician.

The safety shield is designed to mitigate the possibility of an accidental needlestick injury if manually activated after 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.

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K252506 - 510(K) SUMMARY

Summary Preparation Date: April 10, 2026

I. Submitter

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II. Device

Proprietary Names:

BD Vacutainer® Safety-Lok™ Blood Collection Set
BD Vacutainer® Safety-Lok™ Blood Collection Set with Pre-Attached Holder

Common or Usual Name(s):

Tubes, Vials, Systems, Serum Separators, Blood Collection
Set, Administration, Intravascular

Regulatory Information

Regulation Description: Blood Specimen Collection Device, Intravascular Administration Set
Classification Regulation: 21 CFR § 862.1675
Regulatory Class: II
Primary Product Code: JKA
Secondary Product Code: FPA
Classification Panel: Clinical Chemistry

III. Predicate Device:

BD Vacutainer® Safety-Lok™ Blood Collection Set (K980414)
Classification Name: Blood Collection Set
Classification Regulation: 21 CFR §862.1675
Regulatory Class: Class II
Product Code: JKA
Classification Panel: Clinical Chemistry

IV. Device Description

The BD Vacutainer® Safety-Lok™ Blood Collection Set (SLBCS) is a sterile, multi-sample, single-use fixed winged blood collection set used for venipuncture to collect blood specimens from patients and for short-term IV administration (up to 2 hours under direct supervision of a clinician). The device consists of an IV cannula, IV protector, wings, tubing, female luer connector, an optional male luer adapter and a protective safety shield. The BD Vacutainer® Safety-Lok™ Blood Collection Set also comes in pre-attached holder (SLBCS PAH) configuration. The device configuration is similar to the BD Vacutainer® Safety-Lok™ Blood Collection Set, except that it has the BD Vacutainer® One Use Holder (K242320) integrated. The BD Vacutainer® One Use Holder is attached to the male luer adapter of the BD Vacutainer® Safety-Lok™ Blood Collection Set.

The device is supplied in three (3) configurations:

1. BD Vacutainer® Safety-Lok™ Blood Collection Set with male luer adapter
2. BD Vacutainer® Safety-Lok™ Blood Collection Set with dust cap (without male luer adapter)
3. BD Vacutainer® Safety-Lok™ Blood Collection Set with Pre-Attached Holder

The BD Vacutainer® Safety-Lok™ Blood Collection Set consists of:

- Stainless steel cannula (Intravenous end and non-patient end of cannula)
- Intravenous (IV) needle protector (covers the needle before use)
- Wings (color coded according to needle gauge)
- Safety Shield
- Tubing
- Female luer connector and an optional male luer adapter or dust cap
- Pre-attached holder (PAH) (connected by male luer adapter in some models)

The wings are color coded according to the needle gauge. The intravenous needle of the blood collection set is bonded to one end of the hub. The other end of the hub is bonded to the blood collection set tubing, the end of which is then bonded to a female luer connector with an optional attached male luer adapter. The male luer adapter consists of threads to attach a BD Vacutainer® brand needle holder, and a non-patient (NP) cannula to puncture BD Vacutainer® brand blood collection tube stoppers or BD BACTEC™ brand blood culture bottles. The NP cannula accesses blood collection tubes via a sharpened tip that penetrates the tube's stopper and has a pierceable

rubber sleeve seal that covers the non-patient needle in between sample collections to prevent blood leakage. The variant without a male luer adapter contains a dust cap which is attached to the female luer connector. The dust cap maintains sterility of the device when connected with the female luer connector.

Some models come with a pre-attached holder connected to the male luer adapter for user convenience. The combination of the BD Vacutainer® Safety-Lok™ Blood Collection Set and the BD Vacutainer® One Use Holder eliminates the need for the user to attach a holder before use, thus offering increased convenience. Use of the device with a holder minimizes exposure of the user to the non patient end of the needle after blood collection.

Multiple samples of blood can be collected via the BD Vacutainer® Blood Collection Tubes when inserted into the holder and punctured by the non-patient (NP) cannula. The blood is drawn into the evacuated tube automatically due to the vacuum. The non-patient cannula sleeve enables a multi-sample blood collection.

The device incorporates a safety shield to mitigate the possibility of an accidental needlestick injury if manually activated after use. After the blood is collected or the solution is infused, the needle is withdrawn from the vein by grasping the wings and pulling out gently. This is followed by pushing the yellow safety shield forward until a click is heard indicating that the needle is completely retracted, and the safety shield is locked in place/activated. This is designed to prevent accidental override of the safety feature.

See Attachment 1 for a list of configurations.

V. Indications for Use

The BD Vacutainer® Safety-Lok™ Blood Collection Set is a sterile, multi-sample, single-use fixed winged blood collection set intended for use in the general population by healthcare professionals experienced in phlebotomy for venipuncture to obtain blood specimens from patients, including those with difficult vein access who may have small, fragile, and/or non-palpable veins, into evacuated blood collection tubes and/or blood culture bottles. When used without the male Luer adapter, the device allows the clinician to obtain a blood specimen from the female Luer connector with a syringe, if necessary. The device can be used by healthcare professionals with infusion experience 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 is to remain under the direct supervision of a clinician.

The safety shield is designed to mitigate the possibility of an accidental needlestick injury if manually activated after use.

VI. Comparison of Technological Characteristics

The subject and predicate device are substantially equivalent as described in **Table 1**.

Table 1: Substantial Equivalence Comparison

Characteristic	Subject Device BD Vacutainer® Safety-Lok™ Blood Collection Set BD Vacutainer® Safety-Lok™ Blood Collection Set with Pre-Attached Holder (K252506)	Predicate Device Vacutainer® Brand Blood Collection Set and Safety-Lok™ Blood Collection Set (K980414)	Comparison
Product Code	JKA, FPA	JKA	Different. See analysis below.
Device Class	Class II	Class II	Same
Regulation	21 CFR § 862.1675 - Blood specimen collection device	21 CFR § 862.1675 - Blood specimen collection device	Same

Characteristic	**Subject Device** **BD Vacutainer® Safety-Lok™ Blood Collection Set** **BD Vacutainer® Safety-Lok™ Blood Collection Set with Pre-Attached Holder** **(K252506)**	**Predicate Device** **Vacutainer® Brand Blood Collection Set and Safety-Lok™ Blood Collection Set** **(K980414)**	Comparison
Intended Use / Indications for Use	The BD Vacutainer® Safety-Lok™ Blood Collection Set is a sterile, multi-sample, single-use fixed winged blood collection set intended for use in the general population by healthcare professionals experienced in phlebotomy for venipuncture to obtain blood specimens from patients, including those with difficult vein access who may have small, fragile, and/or non-palpable veins, into evacuated blood collection tubes and/or blood culture bottles. When used without the male Luer adapter, the device allows the clinician to obtain a blood specimen from the female Luer connector with a syringe, if necessary. The device can be used by healthcare professionals with infusion experience 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 is to remain under the direct supervision of a clinician. The safety shield is designed to mitigate the possibility of an accidental needlestick injury if manually activated after use.	The VACUTAINER® Brand Blood Collection Set and Safety-Lok™ Blood Collection Set are winged blood collection needles with flexible tubing and a female luer adapter intended for venipuncture to obtain blood samples from patients or monitoring blood pressure. The Safety-Lok™ Blood Collection Set is provided with a safety shield for covering the used needle prior to disposal. The male luer adapter contains a non-patient needle end for puncturing the stopper of an excavated blood collection tube. Those without a male luer adapter are provided with a protective cap on the end of the female luer adapter. The VACUTAINER® Brand Blood Collection Sets and Safety-Lok™ Blood Collection set is also indicated for the intravenous administration of fluids and may be used for any patient population with consideration given to patient size, appropriateness for the solution being infused and duration of therapy.	Different. See analysis below.

Characteristic	**Subject Device** **BD Vacutainer® Safety-Lok™ Blood Collection Set** **BD Vacutainer® Safety-Lok™ Blood Collection Set with Pre-Attached Holder** **(K252506)**	**Predicate Device** **Vacutainer® Brand Blood Collection Set and Safety-Lok™ Blood Collection Set** **(K980414)**	Comparison
Single Use Only	Yes	Yes	Same
Needle Point	3-bevel	3-bevel	Same
Needle Length	¾ in	¾ in	Same
Needle Gauge	21G, 23G, 25G	21G, 23G, 25G	Same
Needle Inner Diameter (ID)	Extra Thin Wall (non-Pre-Attached Models) Thin Wall (Pre-Attached Models)	Thin Wall	Different. See analysis below.
Integrated Safety Feature	Yes	Yes	Same
Integrated Needle Holder (Pre-attached holder)	Pre-attached models available; Non-Pre-Attached models are supplied without a holder	No (Non-Pre-Attached models are supplied without a holder)	Different. See analysis below.
Tubing Length	7in or 12in	7in or 12in	Same
Component Materials			
Wing	Polyvinyl Chloride (PVC)	Polyvinyl Chloride (PVC)	Same
IV Cannula	Stainless steel 304	Stainless steel 304	Same
IV Protector (Shield)	Polyethylene	Polyethylene	Same
IV Cannula Lubricant	Silicone Oil	Silicone Oil	Same
Male Luer Hub (Finger-Grip Luer Adapter)	Polypropylene	Polypropylene	Same
NP Cannula	Stainless steel 304	Stainless steel 304	Same
NP Cannula Lubricant	Silicone Oil	Silicone Oil	Same
NP Sleeve	Synthetic Isoprene Rubber	Synthetic Isoprene Rubber	Same

Characteristic	Subject Device BD Vacutainer® Safety-Lok™ Blood Collection Set BD Vacutainer® Safety-Lok™ Blood Collection Set with Pre-Attached Holder (K252506)	Predicate Device Vacutainer® Brand Blood Collection Set and Safety-Lok™ Blood Collection Set (K980414)	Comparison
Female Luer Connector	Acrylonitrile Butadiene Styrene (ABS)	Acrylonitrile Butadiene Styrene (ABS)	Same
Safety Shield	Polypropylene	Polypropylene	Same
Tubing	PVC	PVC	Same
Dust Cap (only on devices without Male Luer Adapter)	Polypropylene	Polypropylene	Same
Integrated Needle Holder (Pre-attached holder)	Polypropylene	N/A	Different. See analysis below.
Biocompatibility	Compliant with ISO 10993	Compliant with ISO 10993	Same
Sterile	Yes	Yes	Same
Sterilization Method	Ethylene Oxide	Ethylene Oxide	Same
Sterility Assurance Level (SAL)	10^{-6}	10^{-6}	Same
Non-Pyrogenic	Yes	Yes	Same
Shelf Life	3 years (non Pre-Attached Models) 2 years (Pre-Attached Models)	3 years	Different. See analysis below.

Substantial Equivalence Discussion

Product Code

The addition of FPA (Set, Administration Intravascular) as a subsequent product code for the subject device, as the device is intended for short-term, single infusions, does not raise new or different questions of safety and effectiveness as the predicate device is also intended for short-term, single infusions.

Intended Use/Indications for Use

The subject device indications for use are similar to the predicate device indications for use. Both the subject and predicate device are intended for blood collection or short-term single infusions used by healthcare professionals. There were minor changes made to the indications for use to best align with appropriate use of the product. Statement for use with

a syringe was added. The use of a syringe was part of the instructions for use cleared under K980414 but was unintentionally omitted from the indications. The inclusion of the use of a syringe has been added back to the indications for use. Based on this, BD has concluded the use of a syringe with this device is not a new intended use. Furthermore, added reference to a specific user population (trained healthcare providers, previously implied) and indication for patients with difficult vein access (clarification of the indications in the predicate device for use in patients with small veins). The addition of "patients with difficult vein access who may have small, fragile, and/or non-palpable veins" in the indications is consistent with previous clearance K220212 (BD Vacutainer® Push Button Blood Collection Set) because it was cleared with identical "difficult vein access" language and the same product codes (JKA, FPA). Both the subject device and K220212 are butterfly-type winged blood collection sets with the same fundamental design (winged needle with flexible tubing and luer connector), identical needle specifications (21G, 23G, 25G gauges with ¾ inch length), and same intended use (venous blood collection and short-term infusion). Since the subject device shares the same design characteristics and needle specifications as K220212, the "difficult vein access" language is appropriate and supported by the Clinical Laboratory Standards Institute (CLSI) guideline PRE02[1], which states that winged blood collection sets are recommended for accessing smaller, fragile, or difficult-to-locate veins. Additionally, per the World Health Organization (WHO) Guidelines[2], winged blood collection sets can provide easier access and movement and better precision when drawing blood from patients with small or difficult veins. Hence, the changes in indications for use do not raise new or different questions of safety and effectiveness. clinical guidelines (CLSI PRE02, WHO Guidelines) indicating that winged blood collection sets are recommended for accessing smaller, fragile, or difficult-to-locate veins. These changes do not result in a new intended use for the subject device.

Needle Inner Diameter (ID)

The needle inner diameter (ID) is different between subject device and predicate device. NOTE: this difference only applies to the subject configurations supplied without the Pre-Attached Holder; the needle ID is the same between subject devices supplied with the Pre-Attached Holder and the predicate device. The needle wall thickness for the subject device supplied without the Pre-Attached Holder has been decreased to increase the ID of the needle. Performance testing demonstrated that the change in inner diameter of the needle does not raise new or different questions of safety and effectiveness when compared to the predicate device. Additionally, the dimensions and performance of the subject device and predicate device are both compliant to ISO 9626.

Integrated Needle Holder (Pre-attached holder)

The subject device is available in models with and without a pre-attached holder. The predicate device is only available in models without the pre-attached holder and requires the user to add a holder in order to use the device for blood collection. Model/SKU numbers

[1] Clinical Laboratory Standards Institute (CLSI) Guidelines. Collection of Diagnostic Venous Blood Specimens. 8th ed. CLSI standard PRE02. Clinical and Laboratory Standards Institute; 2025.
[2] WHO guidelines on drawing blood: Best practices in phlebotomy. World Health Organization; Geneva, Switzerland, 2010.

were added for the subject device to include device configurations assembled with the legally marketed holder (K242320) that is pre-attached for user convenience. Adding models with the pre-attached holder to the subject device is a user convenience and does not affect clinical safety or effectiveness.

Shelf Life

The shelf life for subject device configurations supplied with the Pre-Attached Holder is different than the predicate device. Shelf life is established based on available shelf-life testing results. Performance testing was conducted on the subject device and the design outputs met the design inputs over the proposed shelf life. Therefore, the difference in shelf-life does not raise new or different questions of safety and effectiveness.

VII. Performance Testing

Non-Clinical Bench Summary

Non-Clinical Bench, Biocompatibility, and Sterilization testing were conducted on the subject device to validate that the device performs as intended over the course of the product shelf life and was substantially equivalent (SE) to the predicate device. Results of testing demonstrated acceptable performance for the subject device.

Performance

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

- ISO 80369-7:2021 Small-bore connectors for liquids and gases in healthcare applications-Connectors for intravascular or hypodermic applications
- ISO 9626:2016 Stainless steel needle tubing for the manufacture of medical devices - Requirements and test methods
- EN ISO 23908:2013 Sharps injury protection - Requirements and test methods - Sharps protection features for single-use hypodermic needles introducers for catheters and needles used for blood sampling

Biocompatibility

In accordance with ISO 10993-1, the needle is classified as: Externally Communicating Device, Blood Path Indirect, Limited Contact (<24 hours). The following was conducted:

- Cytotoxicity (ISO 10993-5)
- Sensitization (ISO 10993-10)
- Irritation (ISO 10993-10)
- Intracutaneous Reactivity (ISO 10993-10)

- Acute systemic toxicity (ISO 10993-11)
- Pyrogenicity (ISO 10993-11 and USP<151>)
- Hemocompatibility: Coagulation, Platelet Activation, Complement Activation and Hemolysis (ISO 10993-4, ASTM F756-17, ASTM F2382, ASTM F2888)
- Particulates (USP<788>)

Sterilization, Packaging and Shelf Life

The devices are sterilized via ethylene oxide (EO). The sterilization, package integrity, shipping and shelf-life validations to support the shelf life claim was conducted according to the following standards:

- EN 556-1:2001/AC:2006 Sterilization of medical devices - Requirements for medical devices to be designated 'STERILE' - Part 1: Requirements for terminally sterilized medical devices
- EN ISO 11607-1:2019 Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
- EN ISO 11607-2:2019 Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes
- EN ISO 11737-1:2018 /A1:2021 Sterilization of health care products – Microbiological methods - Part 1: Determination of a population of microorganisms on products
- EN ISO 11737-2:2020 Sterilization of health care products. Microbiological methods-Tests of sterility performed in the definition, validation and maintenance of a sterilization process
- ISO 11737-3:2023 Sterilization of health care products - Microbiological methods - Part 3: Bacterial endotoxin testing
- EN ISO 11138-1:2017 Sterilization of health care products – Biological indicators – Part 1: General Requirements
- EN ISO 11138-2:2017 Sterilization of health care products - Biological indicators - Part 2: Biological indicators for ethylene oxide sterilization processes
- EN ISO 11135:2014/A1:2019 Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices - Amendment 1: Revision of Annex E, Single batch release
- ASTM F1980-16 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
- ASTM D4169-16 Standard Practice for Performance Testing of Shipping Containers and Systems
- ASTM F2096-11 Standard Test Method for Detecting Gross Leaks in Packaging by Internal Pressurization (Bubble Test)
- ASTM F88/F88M-21 Standard Test Method for Seal Strength of Flexible Barrier Materials

Clinical Summary

Clinical studies to support the addition of "patients with difficult vein access who may have small, fragile, and/or non-palpable veins" in the indications were submitted as part of a previous clearance for a similar device, K220212 (BD Vacutainer® Push Button Blood Collection Set). Both the subject device and K220212 are butterfly-type winged blood collection sets with the same fundamental design (winged needle with flexible tubing and luer connector), identical needle specifications (21G, 23G, 25G gauges with ¾ inch length), and same intended use (venous blood collection and short-term infusion).

Real-world clinical data submitted as part of K220212 indicate that winged blood collection sets were preferred by phlebotomists when compared to conventional blood collection needles as demonstrated by increased patient and phlebotomist satisfaction with the subject device as compared to a conventional (straight) blood collection needle (Ibarra AF and Villanueva, 2019)[3]. Additionally, winged blood collection sets, such as the subject device, were shown to improve venipuncture collection for patients with DVA. The subject device allows healthcare professionals to draw blood from patients with small, fragile, and/or non-palpable veins (DVA) without compromising sample quality as supported by clinical literature (Merrill, 2021)[4]. In this study, venipuncture blood draws were collected from a total of 89 oncology outpatients ≥18 years of age using devices similar to the subject device. Chemotherapy impacts the vasculature causing veins to become much smaller, fragile, and difficult to anchor for venous access (Lynn, 2011)[5]. Specimen quality (LDH, K and plasma free hemoglobin levels) were measured from specimens collected with each winged blood collection set. The results of the study indicate that the devices provided the ability to draw blood from oncology patients, who may have small, fragile and non-palpable veins (DVA), as each device achieved successful blood collections from each patient, and the sample quality was not compromised as LDH, K and plasma free hemoglobin levels were within the normal and acceptable analyte reference ranges (Merrill, 2021)[4]

VIII. Conclusions

The subject device, BD Vacutainer® Safety-Lok™ Blood Collection Set, has the same intended use, technological characteristics, and principles of operation as the predicate device. Non-clinical performance testing sufficiently supports the determination of substantial equivalence of the subject device. Changes made to the subject device do not raise any new questions of safety or effectiveness. Based on the information provided in this submission, the subject device is determined to be Substantially Equivalent (SE) to the predicate device.

[3] Ibarra AF and Villanueva, S. Evaluation of phlebotomy-related anxiety, pain and safety in a Mexican general hospital using winged blood collection sets. BJSTR 2019; 13(5):10219-10221. DOI: 10.26717/BJSTR.2019.13.002455. ISSN: 2574-1241.
[4] Merrill, V,D., Ward, M.D., Diaz-McNair, J., Picket, E.A., Duh, S.H., Christenson, R.H.. Assessing Phlebotomy device preference and specimen quality in an oncology outpatient clinic. J Appl Lab Med 2021; jfab109, https://doi.org/10.1093/jalm/jfab109.
[5] Lynn K. (2011). Challenges of the oncology draw. MLO: medical laboratory observer, 43(1), 22.

Attachment 1- List of Configurations

SKU	Product Description	Wing Color	Needle Size & Tube Length	Needle Gauge	Configuration
367281	BD Vacutainer® Safety-Lok™ Blood Collection Set	Green	¾" 12" tubing	21G	Male Luer Adapter
367283	BD Vacutainer® Safety-Lok™ Blood Collection Set	Light Blue	¾" 12" tubing	23G	Male Luer Adapter
367285	BD Vacutainer® Safety-Lok™ Blood Collection Set	Dark Blue	¾" 12" tubing	25G	Male Luer Adapter
367287	BD Vacutainer® Safety-Lok™ Blood Collection Set	Green	¾" 7" tubing	21G	Male Luer Adapter
367292	BD Vacutainer® Safety-Lok™ Blood Collection Set	Light Blue	¾" 7" tubing	23G	Male Luer Adapter
367294	BD Vacutainer® Safety-Lok™ Blood Collection Set	Dark Blue	¾" 7" tubing	25G	Male Luer Adapter
367296	BD Vacutainer® Safety-Lok™ Blood Collection Set	Green	¾" 12" tubing	21G	Dust Cap
367297	BD Vacutainer® Safety-Lok™ Blood Collection Set	Light Blue	¾" 12" tubing	23G	Dust Cap
367298	BD Vacutainer® Safety-Lok™ Blood Collection Set	Dark Blue	¾" 12" tubing	25G	Dust Cap
368652	BD Vacutainer® Safety-Lok™ Blood Collection Set with Pre-Attached Holder	Green	¾" 12" tubing	21G	Pre-Attached Holder
368653	BD Vacutainer® Safety-Lok™ Blood Collection Set with Pre-Attached Holder	Light Blue	¾" 12" tubing	23G	Pre-Attached Holder
368654	BD Vacutainer® Safety-Lok™ Blood Collection Set with Pre-Attached Holder	Green	¾" 7" tubing	21G	Pre-Attached Holder
368655	BD Vacutainer® Safety-Lok™ Blood Collection Set with Pre-Attached Holder	Light Blue	¾" 7" tubing	23G	Pre-Attached Holder