March 24, 2023

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

Re: K220212
Trade/Device Name: BD Vacutainer® Push Button Blood Collection Set, BD Vacutainer® Push Button 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: February 24, 2023
Received: February 24, 2023

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 (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.
Acting 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)*
K220212

Device Name
BD Vacutainer® Push Button Blood Collection Set, BD Vacutainer® Push Button Blood Collection Set with Pre-Attached Holder

Indications for Use *(Describe)*
The BD Vacutainer® Push Button 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 with venipuncture to obtain blood specimens from patients, including those patients 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 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.

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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K220212 510(K) SUMMARY

BD Vacutainer® Push Button Blood Collection Set

Summary Preparation Date:

March 24, 2023

Submitted by:

Becton, Dickinson and Company
1 Becton Drive
Franklin Lakes, NJ 07417-1885

Phone: (201) 847-6800

Contact:

Kelly Hilliger
Staff Regulatory Affairs Specialist
email: Kelly.hilliger@bd.com

Phone: (551) 554-1675

Proprietary Names:

BD Vacutainer® Push Button Blood Collection Set,
BD Vacutainer® Push Button Blood Collection Set with Pre-Attached Holder

Common or Usual Names:

Blood Collection Tubes, Vials, Systems, Serum Separators

Regulatory Information

Classification Name: Blood Collection Set
Classification Regulation: 21 CFR §862.6175
Regulatory Class: Class II
Primary Product Code: JKA
Secondary Product Code: FPA
Classification Panel: Clinical Chemistry

Predicate Device:

BD Vacutainer® Push Button Blood Collection Set (K030573)

Device Description

The BD Vacutainer® Push Button Blood Collection Set is a sterile, multiple-sample, single-use device used for venipuncture to obtain blood specimens from patients and may be used for the short-term intravenous administration of fluids. The BD Vacutainer® Push Button Blood Collection Set is a winged blood collection set with flexible tubing, a female luer connector and an optional male luer adapter. The BD Vacutainer® Push Button Blood Collection Set also contains a needle protector. The wingset is designed with a safety mechanism to protect against needlesticks. When the button is depressed by the user, the needle fully retracts and is enclosed and locked within the barrel of the device. The retraction of the intravenous (IV) end of the needle aids in the prevention of accidental needlestick injury.

The BD Vacutainer® Push Button Blood Collection Set consists of:

- Stainless steel cannula (Intravenous end and non-patient end of cannula)
- Stainless steel spring
- Hub, front and rear barrel
- Wings (color coded according to needle gauge)
- Tubing
- Female luer connector and an optional male luer adapter
- Intravenous (IV) needle protector (covers the needle before use)
- Pre-attached holder (connected by male luer adapter in some models)

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. Some models come with a pre-attached holder connected to the male luer adapter for user convenience. A spring is loaded onto the front barrel of the hub. Once the sample is collected, and without removing the needle from the patient vein, the user depresses the raised push button on top of the hub which activates the spring mechanism to automatically retract the needle from the vein into the device. In this retracted (locked) position, the IV point of the needle is fully contained within the body of the device. This will prevent the needle from coming out of the front barrel once it has retracted as well as preventing accidental overriding of the safety feature.

The blood collection set with a male luer adapter contains threads for attachment to a Vacutainer® Brand Needle Holder, and a non-patient cannula for blood collection into evacuated blood collection tubes and/or blood culture bottles. For models without the pre-attached holder, the user is instructed to attach a holder before using the device. The pre-attached holder models come with the BD Vacutainer® Brand Holder pre-attached for user convenience. The non-patient end cannula of the luer adapter has a sleeve that recovers over the cannula to stop blood flow in between collection of multiple tubes.

When used without the male adapter, the device allows the clinician to obtain a blood specimen from the female hub with a syringe, if necessary. The device can be used for short-term, single infusions (up to 2 hours) with consideration given to patient size and appropriateness for the solution being infused.

Indications for Use

Subject Device BD Vacutainer® Push Button Blood Collection Set K220212	**Predicate Device** BD Vacutainer® Push Button Blood Collection Set K030573
The BD Vacutainer® Push Button 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 with** venipuncture to obtain blood specimens from patients, **including those patients 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 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.	The BD Vacutainer® Push Button Blood Collection Set is a sterile, **multiple**-sample, single-use winged blood collection set intended for venipuncture to obtain blood specimens from patients. The BD Vacutainer® Push Button Blood Collection Set is also indicated for the intravenous administration of fluids as indicated in 21 CFR 880.5440. It may be used for any patient population with consideration given to patient size and appropriateness for the solution being infused and duration of therapy. 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.

The proposed indications for use are similar to the predicate indications for use, except for the addition of healthy patients and patients with vascular anatomy and/or co-morbidities which may cause difficulty in locating a vein. Healthy patients and patients with these conditions often exhibit small, fragile, and/or non-palpable veins, commonly referred to as DVA. The addition of DVA in the revised indications for use statement does not significantly change the intended use as butterfly needles have historically been used on patients with small veins and similar statements were included for previous device iterations and were inadvertently removed in subsequent submissions. This is supported by the Clinical Laboratory Standards Institute (CLSI) guideline GP41[1], which

[1] Clinical Laboratory Standards Institute (CLSI) Guidelines. Collection of Diagnostic Venous Blood Specimens. 7th ed. CLSI standard GP41. Wayne, PA: Clinical and Laboratory Standards Institute; 2017.

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. BD believes that the addition of specific reference to patients with DVA does not raise new questions of safety/effectiveness.

Furthermore, the use of a syringe was part of the instructions for use cleared under K030573, but was unintentionally omitted from the indications for use. 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. BD believes this does not raise new questions of safety/effectiveness.

Substantial Equivalence[3]

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

Table 1: Substantial Equivalence Comparison

Characteristic	Subject Device BD Vacutainer® Push Button Blood Collection Set	Predicate Device BD Vacutainer® Push Button Blood Collection Set K030573	Comparison
Intended Population	General use including patients with difficult vein access (DVA), who may have small, fragile, and/or non-palpable veins	General use	Different Comment # 1 Added specific reference to patients with DVA which is a subset of 'General Use' – no effect on device safety or effectiveness
Needle Diameter OD	21G, 23G and 25G	21G, 23G and 25G	Same
Needle Diameter ID	Thin wall	Thin wall	Same
Needle Point Geometry	3 Bevel	3 Bevel	Same
Needle Length	¾ inch	¾ inch	Same
Wing	Polyolefin	Polyolefin	Same material
Hub	Polycarbonate	Polycarbonate	Same material
Button Ink	UV Curable Ink	UV Curable Ink	Same material

[2] WHO guidelines on drawing blood: best practices in phlebotomy. World Health Organization; Geneva, Switzerland, 2010.

[3] The term "substantial equivalence" as used in this 510(k) notification is limited to the definition of substantial equivalence as found in the Federal Food, Drug and Cosmetic Act, as amended and as applied under 21 CFR 807, Subpart E under which a device can be marketed without pre-market approval or reclassification. A determination of substantial equivalency under this notification is not intended to have any bearing whatsoever on the resolution of patent infringement suits or any other patent matters. No statements related to, or in support of substantial equivalence herein shall be construed as an admission against interest under the US Patent Laws or their application by the courts.

Characteristic	Subject Device BD Vacutainer® Push Button Blood Collection Set	Predicate Device BD Vacutainer® Push Button Blood Collection Set K030573	Comparison
Front Barrel	Polypropylene	Polypropylene	Same material
Rear Barrel	Acrylic	Acrylic	Same material
Rear Barrel Lubricant	Silicone	Silicone	Same material
Spring	Stainless Steel 302	Stainless Steel 302	Same material
IV Protector (Cannula Protector)	Polyethylene	Polyethylene	Same material
IV Cannula/NP Cannula	Stainless Steel 304	Stainless Steel 304	Same material
Tubing	Polyvinyl Chloride	Polyvinyl Chloride	Same material
Cannula Lubricant	Silicone	Silicone	Same material
Cannula Adhesive	UV cured adhesive	UV cured adhesive	Same material
Viscous Fluid	Not included in manufacture of device	Included in manufacture of device	Material is not part of subject device. The difference does not raise new questions on the safety and effectiveness of the subject device.
Hub-Tubing Adhesive	UV cured adhesive	UV cured adhesive	Same material
Female Luer Adapter (Connectors)	Acrylonitrile Butadiene Styrene	Acrylonitrile Butadiene Styrene	Same material
Luer Adapter Hub	Polypropylene	Polypropylene	Same material
NP Sleeve	Synthetic Isoprene Rubber	Synthetic Isoprene Rubber	Same material
Luer Adhesive	Heat Curing Epoxy	Heat Curing Epoxy	Same material
Luer Cannula Lubricant	Medical Grade Silicone	Medical Grade Silicone	Same material
Luer Cap	Polypropylene	Polypropylene	Same material
Top Web	Paper	Paper	Same material
Blister	Polyethylene terephthalate – glycol modified	Polyethylene terephthalate – glycol modified	Same material

Characteristic	Subject Device BD Vacutainer® Push Button Blood Collection Set	Predicate Device BD Vacutainer® Push Button Blood Collection Set K030573	Comparison
Pre-attached holder	Polypropylene	N/A	Different Comment #2 Model numbers were added to include devices assembled with the legally marketed holder pre-attached for user convenience. This non-significant change does not affect safety or effectiveness.
Materials	Compliant with ISO 10993 series	Compliant with ISO 10993 series	Same
Non-pyrogenic	Yes	Yes	Same
Non-toxic	Yes	Yes	Same
Sterile	Yes	Yes	Same
Sterility Assurance Level (SAL) 10^{-6}	Yes	Yes	Same
Sterilization Method	Gamma	Gamma	Same
Shelf Life	2 years	2 years	Same
Models	367323 367324 **367352** 367326 **367354** 367335 **367355** 367336 **368656** 367338 **368657** 367341 **368658** 367342 **368659** 367344	367323 367324 367326 367335 367336 367338 367341 367342 367344	Model numbers were added to include devices assembled with the legally marketed holder pre-attached for user convenience. This change does not raised new questions of safety or effectiveness.

Substantial Equivalence Discussion:

Comment #1

The subject device indicates that the intended population is for general use, including a subset of patients who may have difficult veins, whereas the predicate device population is general use. Both devices are used on all patient populations regardless of their vein status. Adding a reference to patients with difficult veins has no effect on clinical safety or effectiveness. This is supported by

the Clinical Laboratory Standards Institute (CLSI) guideline GP41[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.

Comment #2

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. Adding models with the pre-attached holder to the subject device is a user convenience and does not affect clinical safety or effectiveness.

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 demonstrate acceptable performance for the subject device and complies to applicable parts of the following standards:

I. Performance Testing

- 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
- EN ISO 9626:2016 Stainless steel needle tubing for the manufacture of medical devices - Requirements and test methods
- ISO 594-1-1986 Conical fittings with 6 % (Luer) taper for syringes, needles and certain other medical equipment – Part 1: General requirements
- ISO 594-2-1998 Conical fittings with 6 % (Luer) taper for syringes, needles and certain other medical equipment —Part 2: Lock fittings
- EN ISO 14971:2019 Medical Devices – Application of risk management to medical devices

II. Sterilization, Package Integrity, Shipping and Shelf Life

The devices are sterilized via gamma irradiation. The sterilization and package integrity, shipping and shelf life validations to support the shelf life claim was conducted according to the following standards:

- EN ISO 11137-1:2015/A2:2019 Sterilization of health care products - Radiation Part 1: Requirements for development, validation, and routine control of a sterilization process for medical devices

- EN ISO 11137-2:2015 Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose

- EN ISO 11737-1:2018 Sterilization of health care products - Microbiological methods - Part 1: Determination of a population of microorganisms on products

- EN ISO 11737-2:2019 Sterilization of medical devices - Microbiological methods – Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process

- ISO 11607-1:2019 Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems

- ISO 11607-2:2019 Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes

- 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 Standard Test Method for Seal Strength of Flexible Barrier Materials

III. Biocompatibility

The BD Vacutainer® Push Button Blood Collection Set is classified as an externally communicating device that comes into direct contact with circulating blood for a limited (≤ 24 hours) duration. Biocompatibility was evaluated on the final, finished device with the following endpoints:

- Cytotoxicity (ISO 10993-5:2009)
- Sensitization (ISO 10993-10:2010)
- Irritation (ISO 10993-10:2010)
- Acute Systemic Toxicity (ISO 10993-11:2017)
- Pyrogenicity (ISO 10993-11:2017, USP<151>)
- Hemocompatibility: Coagulation, Platelet Activation, Complement Activation and Hemolysis (ISO 10993-4:2017, ISO 10993-7:2017)
- Particulates (USP<788>)

Non-clinical Performance Summary

The non-clinical performance tests below were conducted to verify that the proposed devices met all design specifications and performance standards and are each Substantially Equivalent (SE) to the predicate device.

- IV Protector Pull Test
- IV Cannula Removal Test
- Flow Rate
- Torque to Rotate Wing
- Wing Removal Test
- Front Barrel/Rear Barrel Separation Test
- Tubing to Female Luer Adapter Pull Test
- Tubing to Hub Pull Test
- Product (safety feature) Pre-Activation
- Retraction and Lock-out
- Force to Override Lock Mechanism
- Luer Cap Removal Torque
- Luer Separation Test
- NP Cannula Pull Test
- Male Luer Adapter Spin Out from Holder Test
- Torque to Unseat
- NP Sleeve Function
- Tube Push Off
- IV Cannula Penetration Test
- Submerged Leak Test (Device)
- Air Leakage Test
- Package Integrity Test
- Luer Compatibility as per ISO 594-1 and ISO 594-2
- Sharps Injury Protection Testing as per ISO 23908
- Stainless Steel Needle Tubing testing as per ISO 9626

Performance Testing – Animal Summary

Not applicable

Performance Testing – Clinical Summary

The real-world clinical data of the study submitted as part of this 510(k) indicate that the BD Vacutainer® Push Button Blood Collection Set was 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)[4]. Additionally, winged blood collection sets, such as the subject device, were shown to improve venipuncture collection for patients with DVA. The BD

[4] 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.

Vacutainer® Push Button Blood Collection Set 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)[5]. In this study, venipuncture blood draws were collected from a total of 89 oncology outpatients ≥18 years of age using the BD Vacutainer® Push Button Blood Collection Set or 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)[6]. 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)[5].

Conclusion

In summary, the BD Vacutainer® Push Button Blood Collection Set has the same intended use as its predicate device. In addition, the BD Vacutainer® Push Button Blood Collection Set has the same technological characteristics and principles of operation as its predicate. The clinical literature sufficiently supports the determination that patients with DVA (small, fragile and non-palpable veins) is a subset of the current patient population for the BD Vacutainer® Push Button Blood Collection Set. The risk profile of patients with small, fragile, and/or non-palpable veins is not substantially different from that of the general patient population and is supported by the clinical literature evidence presented under this submission. Furthermore, the changes made to the device since K030573, do not raise different questions of safety or effectiveness because they do not alter the device's diagnostic/therapeutic purpose, blood collection functionality, mechanism of action, or method of use. Performance testing confirms that the subject device performs as intended and is as safe and effective as the predicate device. Based on information provided in this submission the proposed device is substantially equivalent to the predicate device.

[5] 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.*

[6] Lynn K. (2011). Challenges of the oncology draw. MLO: medical laboratory observer, 43(1), 22.