August 31, 2022

Becton, Dickinson and Company
Katherine Lemus
Senior Regulatory Affairs Specialist
1 Becton Drive
Franklin Lakes, New Jersey 07417

Re: K212724
Trade/Device Name: BD Vacutainer UltraTouch 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

Dear Katherine Lemus:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination for your device cleared on February 4, 2022. Specifically, FDA is updating this SE letter due to the clearance date not appearing on the original letter.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Payal Patel, OHT3: Office of GastroRenal, ObGyn, General Hospital and Urology Devices, 240-402-6029, payal.patel@fda.hhs.gov.

Sincerely,

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

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Katherine Lemus
Senior Regulatory Affairs Specialist
1 Becton Drive
Franklin Lakes, New Jersey 07417

Re: K212724
Trade/Device Name: BD Vacutainer UltraTouch 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: December 29, 2021
Received: January 5, 2022

Dear Katherine Lemus:

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,

Gang Peng 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)*
K212724

Device Name
BD Vacutainer® UltraTouch™ Push Button Blood Collection Set

Indications for Use *(Describe)*

The BD Vacutainer® UltraTouch™ Push Button Blood Collection Set is a sterile, multi-sample, single-use fixed winged blood collection set intended to be used by trained healthcare professionals for 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 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 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Food and Drug Administration
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PRAStaff@fda.hhs.gov

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K212724 510(K) SUMMARY

Summary Preparation Date:

2/4/2022

Submitted by:

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

Phone: (201) 847-6800

Contact:

Katherine Kenner Lemus, MS, RAC-US
Senior Regulatory Affairs Specialist
email: Katherine.lemus@bd.com

Phone: (801) 541-9274
Work: (201) 847 6800:

Proprietary Names:

BD Vacutainer® UltraTouch™ Push Button Blood Collection Set*:*

Common or Usual Names:

Blood Collection Set, IV Administration Set

Regulatory Information

Classification Name: Blood Collection Set, IV Administration Set
Classification Regulation: 21 CFR §862.6175 and 880.5440
Regulatory Class: Class II
Product Code: JKA, FPA

Predicate Device(s)

BD Vacutainer® UltraTouch™ Push Button Blood Collection Set (K153309)

Device Description

The BD Vacutainer® UltraTouch™ Push Button Blood Collection Set is a winged blood collection set with flexible tubing, a female luer connector and a male luer adapter. The BD Vacutainer® UltraTouch™ Push Button Blood Collection Set also contains a needle protector.

The BD Vacutainer® UltraTouch™ Push Button Blood Collection Set models available consist of a combination of different needle gauges (21G, 23G, 25G), tubing length (12-inch, 7 inch), and are available with or without a pre-attached holder.

Indications For Use

Subject Device The BD Vacutainer® UltraTouch™ Push Button Blood Collection Set K212724	**Predicate Device** BD Vacutainer® UltraTouch™ Push Button Blood Collection Set K153309
The BD Vacutainer® UltraTouch™ Push Button Blood Collection Set is a sterile, **multi**-sample, single use fixed winged blood collection set intended **to be used by trained healthcare professionals** for 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 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 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® 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.

The proposed indications for use, are similar to the predicate indications for use, except for the inclusion of both 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, non-palpable veins, commonly referred to as difficult vein access (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. BD believes that the addition of specific reference to patients with DVA does not raise new questions of safety/effectiveness.

Substantial Equivalence[1]/Technical Comparison

The subject and predicate device are substantially equivalent as described in Table 2.

Table 1: Substantial Equivalence Comparison

Characteristic	Subject Device BD Vacutainer® UltraTouch™ Push Button Blood Collection Set	Predicate Device BD Vacutainer® UltraTouch™ Push Button Blood Collection Set K153309	Comparison
Intended Population	General use including patients with difficult vein access (DVA)	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	Ultra-Thin wall	Ultra-Thin wall	Same
Needle Point	5 Bevel	5 Bevel	Same
Needle Length	¾ inch	¾ inch	Same
Wing	Polyolefin	Polyolefin	Same
Hub	Polypropylene	Polypropylene	Same
Button Ink	UV Curable Ink	UV Curable Ink	Same
Front Barrel	Polypropylene	Polypropylene	Same
Rear Barrel	Acrylic	Acrylic	Same
Rear Barrel Lubricant	Silicone	Silicone	Same
Rear Barrel Lubricant Diluent	Isopropyl Alcohol	Isopropyl Alcohol	Same
Spring	Stainless Steel 302	Stainless Steel 302	Same
IV Protector (Cannula Protector)	Polyethylene	Polyethylene	Same
IV Cannula/NP Cannula	Stainless Steel 304	Stainless Steel 304	Same
Tubing	Polyvinyl Chloride	Polyvinyl Chloride	Same

Characteristic	Subject Device BD Vacutainer® UltraTouch™ Push Button Blood Collection Set	Predicate Device BD Vacutainer® UltraTouch™ Push Button Blood Collection Set K153309	Comparison
Cannula Lubricant	Silicone	Silicone	Same
Cannula Adhesive	UV cured adhesive	UV cured adhesive	Same
Hub-Tubing Adhesive	UV cured adhesive	UV cured adhesive	Same
Female Luer Connectors	Acrylonitrile Butadiene Styrene	Acrylonitrile Butadiene Styrene	Same
Luer Adapter Hub	Polypropylene	Polypropylene	Same
NP Sleeve	Synthetic Isoprene Rubber	Synthetic Isoprene Rubber	Same
Luer Adhesive	Heat Curing Epoxy	Heat Curing Epoxy	Same
Luer Cannula Lubricant	Medical Grade Silicone	Medical Grade Silicone	Same
Luer Cap	Polypropylene	Polypropylene	Same
Top Web	Paper	Paper	Same
Blister	Polyethylene terephthalate – glycol modified	Polyethylene terephthalate – glycol modified	Same
Pre-attached holder	Polypropylene	N/A	Different Comment #2 6 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

Characteristic	Subject Device BD Vacutainer® UltraTouch™ Push Button Blood Collection Set	Predicate Device BD Vacutainer® UltraTouch™ Push Button Blood Collection Set K153309	Comparison
Sterilization Method	Gamma	Gamma	Same
Shelf Life	2 years	2 years	Same
Models	367363 **368684** 367364 **368685** 367365 **368686** 367391 **368687** 367392 **368688** 367393 **368689**	367363 367364 367365 367391 367392 367393	6 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

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.

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.

Applicable Standards:

I. Performance Standards

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 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

EN ISO 14971:2012 Medical Devices – Application of risk management to medical devices

II. Sterilization, Package Integrity, Shipping and Shelf Life

EN ISO 11137-1:2015/A2:2019 Sterilization 15of 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 11137-3:2017 Sterilization of health care products - Radiation - Part 3: Guidance on dosimetric aspects of development, validation and routine control

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 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

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

III. Biocompatibility Standards

ISO 10993-1:2018 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process

EN ISO 10993-2:2006 Biological evaluation of medical devices - Part 2: Animal welfare requirements

ISO 10993-4:2017 Biological evaluation of medical devices – Part 4: Selection of tests for interactions with blood

ISO 10993-5:2009 Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity

ISO 10993-10:2010 Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization

ISO 10993-11:2017 Biological evaluation of medical devices – Part 11: Tests for systemic toxicity

ISO 10993-12:2012 Biological evaluation of medical devices – Part 12: Sample preparation and reference materials

ISO 10993-17:2002 Biological evaluation of medical devices – Part 17: Establishment of allowable limits for leachable substances

ISO 10993-18:2020 Biological evaluation of medical devices – Part 18: Chemical characterization of materials

Technical Performance Summary

The sponsor has determined that since the subject and predicate blood collection sets are the same, and the BD Vacutainer® Brand Holder is unchanged from clearance under K181730, new performance testing is not required. Specifically, because there has been no significant change to design, product materials, packaging materials, processing/assembly, packaging, or manufacturing that would affect device performance no new performance testing is provided in support of this submission.

Conclusion

The technical performance characteristics of the subject device are unchanged. The clinical literature, BD's sponsored studies, and Investigator sponsored studies sufficiently support the determination that patients with Difficult Vein Access (DVA) is a subset of the current patient population for the BD Vacutainer® UltraTouch™ Push Button Blood Collection Set. The risk profile of patients with DVA is not substantially different from that of the general patient population and is supported by the extensive clinical literature evidence presented under this submission. Based on information provided in this submission the proposed device is substantially equivalent to the predicate device.