DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

February 12, 2016

Becton, Dickinson and Company
Mr. Pasquale Amato
Staff Regulatory Affairs Specialist
1 Becton Drive
Franklin Lakes, New Jersey 07417

Re: K153309
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: II
Product Code: JKA, FPA
Dated: December 16, 2015
Received: January 11, 2016

Dear Mr. Amato:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Erin I. Keith, M.S.
Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K153309

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, 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.

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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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(K) SUMMARY
K153309

1. **Submitted By:**

Pasquale Amato
Staff Regulatory Affairs Specialist

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

Phone: 201-847- 4513
Email: Pasquale_Amato@BD.com

Date Prepared: February 05, 2016

2. **Device:**

Trade Name:	BD Vacutainer® UltraTouch™ Push Button Blood Collection Set
Common Names:	Blood Collection Set
Classification Name:	Blood Specimen Collection Device
Classification:	Class II, 21 CFR 862.1675
Product Code:	JKA and FPA

3. **Predicate Device:**

BD Vacutainer® Push Button Blood Collection Set – K030573
Manufactured by: Becton, Dickinson and Company

4. **Device Description:**

The BD Vacutainer® Push Button Blood Collection Set has two models. One is a steel winged blood collection set with flexible tubing, female luer connector, with an integrated male luer adapter which connects to a Vacutainer® Brand Needle Holder and is intended to be used with blood collection tubes. The other model is sold identical except without the male luer adapter. This model allows the clinician to obtain blood sampling with a syringe, if necessary, or can be used for short-term, single infusions. The device is not to be left in place and remain under the supervision of a clinician.

The BD Vacutainer® Push Button Blood Collection Set also contains a sharps injury prevention feature. The wing set is designed with an active retraction method. When the button is actively depressed, 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 is designed to protect users from an accidental needle sticks.

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)
- Luer Cap (provided if there is no luer adapter attached)

The intravenous needle of the blood collection set is bonded to one end of the hub. The tubing of the blood collection set is bonded to the other end of the hub and the female luer connector. A spring is assembled over the needle protector and onto the front of the hub. Once the sample is collected the user will depress the button that projects through the barrel. As soon as the button is depressed, the needle assembly moves using spring energy. 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 optional male luer adapter contains threads for attachment to a Vacutainer® Brand Needle Holder, and a non-patient cannula for puncture of evacuated blood collection tube stoppers. The non-patient end (NP) of the cannula of the luer adapter has a sleeve that recovers over the cannula to stop blood flow during collection of multiple tubes.

The purpose of this Special 510(k) is to expand the needle range to include the BD Vacutainer® UltraTouch™ Push Button Blood Collection Set design with ultra thin wall cannula and a five bevel point. The intended use for the modified device remains the same as the predicate device.

5. **Indications for 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.

6. **Technological Characteristics:**

The subject BD Vacutainer® UltraTouch™ Push Button Blood Collection Set is equivalent to that of the predicate BD Vacutainer® Push Button Blood Collection Set in intended use, materials and performance characteristics. The Indications for Use are not identical; however, the intended use remains the same for blood collection/sampling.

Characteristic	**Subject Device** BD Vacutainer® UltraTouch™ Push Button Blood Collection Set, 21G, 23G and 25G	**Predicate Device** BD Vacutainer® Push Button Blood Collection Set 21G, 23G and 25G (k030573)
Indications for 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.	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® UtraTouch™ Push Button Blood Collection Set is also indicated for the intravenous administration of fluids. 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 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.
Needle Diameter OD	21G, 23G and 25G	same
Needle Diameter ID	Ultra Thin Wall	Thin Wall

Needle Point	5 bevel	3 bevel
Needle Length	3/4in	same
Wing	Polyolefin	same
Hub	Polypropylene	same
Button Ink	UV curable Ink	same
Front Barrel	Polypropylene	same
Rear Barrel	Acrylic	same
Rear Barrel Lubricant	Silicone	same
Rear Barrel Lubricant Diluent	Isopropyl Alcohol	same
Spring	Stainless Steel 302	same
IV Protector (Cannula Protector)	Polyethylene	same
IV Cannula/NP Cannula	Stainless Steel 304	same
Tubing	PVC	same
Cannula Lubricant	Silicone	same
Cannula Adhesive	UV cured adhesive	same
Hub-Tubing Adhesive	UV cured adhesive	same
Female Luer Connector	ABS	same
Luer Adapter Hub	Polypropylene	same
NP Sleeve	Synthetic Isoprene Rubber	same
Luer Adhesive	Heat Curing Epoxy	same
Luer Cannula Lubricant	Medical Grade Silicones	same
Luer Cap	Polypropylene	same
Top Web	Paper	same
Blister	PETG Copolyester	same
Materials – comply with ISO 10993-1	Yes	same
Non-pyrogenic	Yes	same
Non-toxic	Yes	same
Sterile	Yes	same
SAL 10^{-6}	Yes	same
Sterilization	Gamma	same
Shelf Life	2 years	same

7. **Performance:**

BD has performed the following design verification testing based on the risk analysis conducted and the results of these tests demonstrate that the BD Vacutainer® UltraTouch™ Push Button Blood Collection Set performed in an equivalent manner to the predicate device.

Performance Characteristic	Acceptance Criteria
Tubing diameters 21G, 23G and 25G	Tubing dimensions meet OD and ID requirement. Tested in accordance to ISO 9626, section 8, Dimensions, and to VS10362 BD requirements for Ultra thin wall cannula
Retraction and Lockout	Equivalence to predicate device
Flow Rate	Equivalence to predicate device
IV Cannula Removal Force	Equivalence to predicate device
Leak Testing	Equivalence to predicate device
Hemolysis	Equivalence to predicate device
Resistance to breakage	Tested in accordance to ISO 9626, section 10, resistance to breakage, annex D, and to VS10362 BD requirements for Ultra thin wall cannula
90° Penetration Testing/Bevel Sharpness	Per BD Test Method TP700279
20° Penetration Testing	Equivalence to predicate device

8. **Substantial Equivalence:**

The BD Vacutainer® UltraTouch™ Push Button Blood Collection Set is substantially equivalent to the predicate device in intended use, principles of operation, technology, design, materials and performance.

9. **Conclusion:**

The BD Vacutainer® UltraTouch™ Push Button Blood Collection Set has been verified to meet the established performance criteria above. The results of the design verification testing demonstrate that the BD Vacutainer® UltraTouch™ Push Button Blood Collection Set performs as intended and performs as well as the legally marketed predicate device.