5 510(K) SUMMARY

5.1 Device Name:

BD Vacutainer® K_2EDTA Blood Collection Tubes

5.2 Summary Preparation Date:

Date: July 27, 2023

5.3 Submitted by:

Becton, Dickinson and Company
1 Becton Drive
Franklin Lakes, NJ 07417-1885
Phone: (201) 847-6800

5.4 Contact:

Alexandra Kirby
Staff Regulatory Affairs Specialist
Email: Alexandra.Kirby@bd.com
Phone: (862) 774-2318

5.5 Alternate Contact:

Matthew Trachtenberg
Director Regulatory Affairs
Email: Matthew.Trachtenberg@bd.com
Phone: (201) 847-6337

5.6 Proprietary Names:

BD Vacutainer® K_2EDTA Blood Collection Tubes

5.7 Common or Usual Names:

EDTA Blood Collection Tube

5.8 Regulatory Information:

Classification Name: Tubes, Vacuum Sample, With Anticoagulant
Classification Regulation: 21 CFR § 862.1675
Regulatory Class: Class II
Product Code: GIM

5.9 Predicate Device(s):

BK050036 BD Vacutainer® Plus K_2EDTA Tubes

5.10 Device Establishment

Becton, Dickinson and Company

5.11 Registration Number:

2243072

5.12 Performance Standards:

- ASTM D4169-22 Standard Practice for Performance Testing of Shipping Containers and Systems
- ANSI AAMI ISO 11137-1:2006/(R)2015 Sterilization of health care products - Radiation - Part 1: Requirements for development, validation, and routine control of a sterilization process for medical devices [Including: Amendment 1 (2013) and Amendment 2 (2019)]
- ANSI AAMI ISO 11137-2:2013/(R)2019 Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose
- ANSI/AAMI/ISO 11137-3:2017 Sterilization of health care products - Radiation - Part 3: Guidance on dosimetric aspects of development, validation and routine control
- ANSI/AAMI/ISO 11737-1:2018 Sterilization of health care products - Microbiological methods - Part 1: Determination of a population of microrganisms on products
- ANSI/AAMI/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
- ANSI AAMI ST67:2019 Sterilization of health care products - Requirements and guidance for selecting a sterility assurance level (SAL) for products labeled "sterile"
- EN ISO 14971:2019 Medical Devices – Application of risk management to medical devices

5.13 Intended Use

BD Vacutainer® K_2EDTA Blood Collection Tubes are plastic, evacuated, sterile, single use, *in vitro* diagnostic medical devices. They are intended to be used by trained healthcare professionals for the collection, containment, preservation, and transport of human venous blood specimens used for *in vitro* diagnostic testing.

BD Vacutainer® K_2EDTA Blood Collection Tubes may be used for immunohematology testing, such as ABO blood grouping and Rh typing.

The performance characteristics of these tubes have not been established for immunohematology testing in general; therefore, users must validate the use of these tubes for their specific assay-instrument/reagent system combinations and specimen storage conditions.

5.14 Device Description

BD Vacutainer® K_2 EDTA Blood Collection Tubes are used for collection, containment, preservation, and transport of human venous blood specimens in a closed tube. The evacuated blood collection tube consists of a Vacutainer® Hemogard™ Closure Assembly, a plastic tube and EDTA additive. The EDTA anticoagulant is spray coated in the dipotassium (K_2) form. The EDTA additive prevents specimen coagulation.

The plastic tubes are closed with the Vacutainer® Hemogard™ Closure Assembly which consists of a rubber stopper and protective plastic shield. The Hemogard™ Closure Assembly, introduced in 1995, is intended to help reduce user exposure to blood. All stopper/closures are color coded to reflect additive type; the closures included in this submission are lavender to indicate the presence of the EDTA additive.

The plastic tube is manufactured from Polyethylene terephthalate (PET). These plastic tubes were introduced in 1990. Plastic tubes enhance user safety and disposal because of the reduced risk of tube breakage and the availability of incineration as a method of disposal.

5.15 Substantial Equivalence

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

Table 2. Substantial Equivalence Comparison

Characteristic	Subject Device BD Vacutainer® K_2EDTA Blood Collection Tubes	Predicate Device BD Vacutainer® Plus K_2EDTA Tubes BK050036	Comments
Indication for use	BD Vacutainer® K_2EDTA Blood Collection Tubes are plastic, evacuated, sterile, single use, *in vitro* diagnostic medical devices. They are intended to be used by trained healthcare professionals for the collection, containment, preservation, and transport of human venous blood specimens used for *in vitro* diagnostic testing. BD Vacutainer® K_2EDTA Blood Collection Tubes may be used for immunohematology testing, such as ABO blood grouping and Rh typing. The performance characteristics of these tubes have not been established for immunohematology testing in general; therefore, users must validate the use of these tubes for their specific assay-instrument/reagent system combinations and specimen storage conditions.	BD Vacutainer® Plus Serum Tubes, BD Vacutainer® SST™ Plus Tubes, BD Vacutainer® SST™ Glass Tubes, and BD Vacutainer® SST™ II Advance Tubes may be used for routine blood donor screening and diagnostic testing of serum for infectious disease. The performance characteristics of these tubes have not been established for infectious disease testing in general; therefore, users must validate the use of these tubes for their specific assay-instrument/reagent system combinations and specimen storage conditions. BD Vacutainer® Plus Serum and BD Vacutainer® Plus K_2EDTA Tubes may be used for routine immunohematology testing and blood donor screening. The performance characteristics of these tubes have not been established for immunohematology testing in general; therefore, users must validate the use of these tubes for their specific assay-instrument/reagent system combinations and specimen storage conditions.	The proposed indication for use is the same as the predicate with regards to the claim for immunohematology testing and the performance characteristics disclaimer, with the exception of more explicitly stating the intended user (trained healthcare professional) and removing blood donor screening. The removal of the blood donor screening claim is due to internal business decisions and not due to safety or performance concerns with the subject tubes. The subject device indication for use provides additional clarity on certain information consistent with current best practices. Therefore, the subject and predicate devices have the same intended use.

Characteristic	**Subject Device BD Vacutainer® K_2EDTA Blood Collection Tubes**	**Predicate Device BD Vacutainer® Plus K_2EDTA Tubes BK050036**	**Comments**
Intended Population	General Use – all populations	General Use – all populations	Identical.
Evacuated Blood Collection Tube	Yes	Yes	Identical.
Clot/Anti-coagulation	Anti-coagulation	Anti-coagulation	Identical.
Additive Type	K_2EDTA	K_2EDTA	Identical.
Additive Quantity	1.8 mg/mL	1.8 mg/mL	Identical.
Tube Dimensions (mm)	13x75, 13x100, 16x100	13x75, 13x100, 16x100	Identical.
Draw Volume	2, 3, 4, 6, 10 mL	2, 3, 4, 6, 10 mL	Identical.
Tube Material	Plastic	Plastic	Identical.
Tube Closure	Hemogard™ Safety Closure	Conventional or Hemogard™ Safety Closure	Only Hemogard™ Safety Closure versions are included in this 510(k) submission. This difference does not raise different questions of safety or effectiveness.
Stopper Fabrication	Compression Molded Rubber	Compression Molded Rubber	Identical
Hemogard™ Shield fabrication	Injection Molded Plastic	Injection Molded Plastic	Identical
Additive Dispense	Spray Dry (K_2EDTA)	Spray Dry (K_2EDTA)	Identical
Tube Evacuation	Vacuum Chamber	Vacuum Chamber	Identical
Unit Labeling	Printed paper label	Printed paper label or imprinted on tube	Changing from paper label and imprinted label options to paper label only does not raise different questions of safety or effectiveness.
Sterilization Method	Gamma Irradiation	Gamma Irradiation	Identical

Characteristic	**Subject Device** **BD Vacutainer® K_2EDTA Blood Collection Tubes**	**Predicate Device** **BD Vacutainer® Plus K_2EDTA Tubes** **BK050036**	**Comments**
Sterility Assurance Level (SAL)	$\leq 10^{-3}$	$\leq 10^{-3}$	Identical
Shelf-Life	12-16 months	15-24 months	Differences in shelf-life are based on the data available at the time of submission for each tube configuration and do not raise different questions of safety or effectiveness.
Packaging	Unit – tube and closure Shelf – shrink wrapped polystyrene tray Case – corrugated cardboard	Unit – tube and closure Shelf – shrink wrapped polystyrene tray Case – corrugated cardboard	Identical

The following discussion on substantial equivalence is pursuant to FDA Guidance dated July 28, 2014, the 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications.

5.15.1.1 Intended Use/Indications for Use

The predicate 510(k) for BD Vacutainer® Plus K_2EDTA Tubes (BK050036) refers to an immunohematology intended use in addition to use for blood donor screening. The proposed indication for use is the same as the predicate with regards to the claim for immunohematology testing and the performance characteristics disclaimer, with the exception of more explicitly stating the intended user (trained healthcare professional) and removing blood donor screening. The removal of the blood donor screening claim was due to internal business decisions and not due to safety or performance concerns with the subject tubes. The subject device indication for use provides additional clarity on certain information consistent with current best practices; e.g., the statement, "such as ABO blood grouping and Rh typing." This additional terminology is consistent with what was cleared under BK980011 for BD Vacutainer® Plus K_2EDTA Tubes, and more recently under BK210649 for BD Vacutainer® ACD Blood Collection Tubes.

As with the predicate device, the subject device will be used for all patient populations in settings where a venous sample is collected by a trained healthcare professional.

Therefore, using BK050036 as the predicate satisfies the requirement to have an appropriate predicate where both the subject and predicate devices have the same intended use.

5.15.1.2 Technological Characteristics

Both the subject and predicate tubes cleared under BK050036 have similar technological characteristics. They both use K_2EDTA anticoagulant that has been spray dried onto a sterile evacuated plastic tube and closed with a Hemogard™ closure.

Differences between the subject and predicate and justification that such differences do not raise different questions of safety and effectiveness are described below:

Tube Closure: Only Hemogard™ Safety Closure versions are included in this 510(k) submission. Limiting the tube closure to only one version does not raise different questions of safety and effectiveness.

Unit Labelling: Changing from paper label and imprinted label options to a paper label only does not raise different questions of safety or effectiveness.

Shelf-Life: Regarding the varied shelf-life, the shelf-life is established based on available shelf-life data so difference in shelf-life do not raise different questions of safety and effectiveness. Testing was completed on the subject device and demonstrated that the product requirements were met.

5.16 Performance Testing – Bench Summary

Non-clinical performance testing was conducted following defined protocols and with established acceptance criteria to evaluate the following attributes of the BD Vacutainer®

K_2EDTA Blood Collection Tubes at time-zero and over the proposed shelf-life: Draw Volume, X-Value, Second Stopper Pullout, Stopper/Shield Separation, Stopper Leakage, Tube Leakage, Resistance to Breakage during Drop Testing, and Resistance to Breakage During Centrifugation. Additionally, Ship Testing was conducted to assess the functional performance of the packaging materials.

All bench testing was completed on final, finished devices and conducted on a minimum of three unique lots of product to assess potential sources of lot-to-lot variability. Each test was also completed on a subset of product sterilized in excess of the maximum specified irradiation dosage. Testing over shelf-life was conducted over 13-20 months of accelerated aging, during which the devices were subjected to storage at 40°C and 50% Relative Humidity (RH) to accelerate the aging process according to the Arrhenius equation, and over 13-20 months of real time aging, during which the devices were subjected to storage at 25°C and 50% RH. Test intervals were selected as at least 16 months K_2 EDTA products with a 15-month shelf-life; at least 17 months for K_2EDTA products with a 16-month shelf-life; at least 13 months for K_2EDTA products with a 12-month shelf-life. Real time aging studies were completed to confirm all accelerated aging data, and both sets of aging results met the predetermined acceptance criteria.

5.17 Performance Testing – Animal Summary

No animal studies were performed in support of this submission.

5.18 Performance Testing – Clinical Summary

Clinical testing was conducted on blood collected in both the subject devices (BD Vacutainer® K_2EDTA Blood Collection Tubes) and legally marketed comparator devices to demonstrate Clinical Equivalence. Additional clinical testing was completed to evaluate Within-Tube Stability, Shelf-Life Performance, and Repeatability/Reproducibility. Clinical testing was conducted for a representative panel of immunohematology test parameters, with the distribution of ABO grouping/Rh typing subjects selected to be approximately representative of the general US population.

Results based on pre-determined acceptance criteria demonstrated the BD Vacutainer® K_2EDTA Blood Collection Tubes are suitable for use in immunohematology testing.

5.19 Conclusion

The technical performance characteristics of the subject device are unchanged. The BD Vacutainer® K_2EDTA Blood Collection Tubes and the predicate devices have the same intended use and any differences in technological characteristic do not raise different questions of safety and effectiveness. Non-Clinical and Clinical Performance Testing support the determination that the subject BD Vacutainer® K_2EDTA Blood Collection Tubes continue to perform as intended. Based on information provided in this submission, the subject device is substantially equivalent to the predicate devices.