510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY

I Background Information:

A 510(k) Number

K231373

B Applicant

Becton, Dickinson and Company

C Proprietary and Established Names

BD Vacutainer® K2 EDTA Blood Collection Tubes

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
JKA	Class II	21 CFR 862.1675 - Blood Specimen Collection Device	CH - Clinical Chemistry
GIM	Class II	21 CFR 862.1675 - Blood specimen collection device	CH - Clinical Chemistry

II Submission/Device Overview:

A Purpose for Submission:

New Device

B Measurand:

Not applicable – Blood collection tube.

C Type of Test:

Not applicable

III Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) for Use:

BD Vacutainer® K2 EDTA Blood Collection Tubes are 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® K2 EDTA Blood Collection Tubes are used for Hemoglobin A1c (HbA1c) testing.

C Special Conditions for Use Statement(s):

- Rx - For Prescription Use Only
- In vitro diagnostic use only
- Do not use if foreign matter is present or if tube is damaged.
- Examine tubes prior to use. K2EDTA is visible in the tube and should appear as clear and colorless dots. K2EDTA spray coated additives may have a white to slightly yellow appearance; this does not affect the performance of the EDTA additive. Do not use the tube if the additive is missing, discolored, or if foreign matter or precipitate is present.
- BD Vacutainer® K2 EDTA Blood Collection Tubes have been validated for use with HbA1c and hemotology analytes. They have not been evaluated for Chemistry or Molecular testing in whole blood or plasma.
- Do not use BD Vacutainer® K2 EDTA Blood Collection Tubes with lavender caps for trace element testing. Use only BD Vacutainer® Trace Element Tubes with royal blue caps for trace element testing.
- Samples collected in BD Vacutainer® K2 EDTA Blood Collection Tubes are known to have interferences with Magellan Diagnostics LeadCare® assays employing the Anodic Stripping Voltammetry (ASV) methodology, and should not be used with assays employing ASV methodology.
- Venous blood gas samples collected with plastic tubes made from polyethylene terephthalate (PET), including BD Vacutainer® K2 EDTA tubes, should not be used when testing carboxyhemoglobin (COHb). A clinically significant positive bias with COHb results may occur.
- BD Vacutainer® K2 EDTA Blood Collection Tubes should not be used to measure divalent cations (e.g. calcium and magnesium) because the EDTA additive may bind to divalent cations and may cause interference in their measurement, depending on the test methodology.
- Do not use BD Vacutainer® K2 EDTA Blood Collection Tubes containing K2EDTA for potassium measurement.
- Follow your facility's procedures if clots or other visible obstructions are present in the sample as this could lead to the inability to test the sample.
- Any change in blood collection tube type, size, handling, processing or storage condition for a particular laboratory assay should be evaluated by the laboratory for each instrument/reagent system per the laboratory's standard procedure.
- BD Vacutainer® K2 EDTA Tubes may contain trace levels of Acetone, tert Butanol, Ethylbenzene, Hexane, 2 Methylpentane, 3 Methylpentane, and Xylene. It has not been

determined if the presence of trace levels of these compounds will affect test results in chromatography-based assays.

D Special Instrument Requirements:

Not applicable. Several FDA cleared test systems with different technologies were used in the validation studies.

IV Device/System Characteristics:

A Device Description:

BD Vacutainer® K2 EDTA Blood Collection Tubes are plastic, evacuated, sterile, single use, in vitro diagnostic medical devices. The tube consists of a Vacutainer® Hemogard™ Closure Assembly, a plastic tube, and EDTA (dipotassium) additive. The EDTA anticoagulant is spray coated in the dipotassium (K2) form. The EDTA additive prevents specimen coagulation. The tube closure is lavender color-coded to indicate the presence of the EDTA additive. Tube stoppers are lubricated with silicone to facilitate stopper insertion. The tubes are available in 13x75mm, 13x100mm and 16x100mm configurations with draw volumes ranging from 2.0 to 10.0 mL. The same BD Vacutainer® K2 EDTA Blood Collection Tubes for hematology testing were cleared in K213670.

B Principle of Operation:

The BD Vacutainer® K2 EDTA Blood Collection Tubes use controlled vacuum to draw a specific volume of blood into the sterile interior of the tube. The interior of the tube wall is spray coated with K2EDTA which binds calcium ions thus blocking the coagulation cascade. The presence of a surfactant is intended to reduce adhesion of red blood cells and fibrin to the tube walls. The tubes are compatible with BD Vacutainer® Blood Collection Needles, Blood Collection Sets, Transfer Devices, Holders and Adapters. Once the vein of the patient has been penetrated using a standard needle, the collection tube is centered in the holder and pushed onto the needle, puncturing the stopper of the tube. Once the pressure is equalized, the blood flow ceases and the tube is removed from the needle holder or needle. Immediately after the blood has been drawn, the tube is gently inverted 8-10 times to mix the blood with the anticoagulant.

V Substantial Equivalence Information:

A Predicate Device Name(s):
Vacutainer® Brand Plus Tube with EDTA Anticoagulant

B Predicate 510(k) Number(s):
K981013

C Comparison with Predicate(s):

Device & Predicate Device(s):	K231373	K981013
Device Trade Name	BD Vacutainer® K2 EDTA Blood Collection Tubes	Vacutainer® Brand Plus Tube with EDTA Anticoagulant
General Device Characteristic Similarities		
Intended Use/Indications For Use	Evacuated blood collection tubes used for the collection, transportation, and processing of blood in a closed tube.	Same
Evacuated Blood Collection Tube	Yes	Same
Clot/Anticoagulation	Anti-coagulation	Same
General Device Characteristic Differences		
Analytes Tested	Blood collection for Hemoglobin A1c (HbA1c) testing	Blood collection for Hematology testing
Draw Volume	2, 3, 4, 6, 10 mL	6 mL

VI Standards/Guidance Documents Referenced:

- 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 microorganisms 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

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:

This study was conducted to evaluate the repeatability (within tube) and reproducibility (lot to lot and tube to tube) of BD Vacutainer® K2 EDTA Blood Collection Tubes for Hemoglobin A1c (HbA1c) testing.

The study included fifty-two participants from clinical settings. Blood was collected from each subject into six BD Vacutainer® K2 EDTA Blood Collection Tubes. Specimens were tested for HbA1c in duplicate per tube with 2 tubes per lot across 3 lots of tubes and 2 tubes per lot within two hours of collection on two FDA cleared HbA1c test systems with different technologies. Results are summarized in the table below.

Test System	HbA1c Mean (mg/dL)	Variance Component	%CV	SD	CV 95% CI	SD 95% CI
1	5.2	Within-Tube	0.8	0.042	0.7, 0.9	0.039, 0.047
		Between-Tubes	0.2	0.011	0.0, 0.4	0.0, 0.02
		Between Lots	0.1	0.007	0.1, 2.3	0.004, 0.118
		Total	0.9	0.044	0.7, 1.1	0.036, 0.058
2	5.4	Within-Tube	1.9	0.106	1.8, 2.1	0.099, 0.114
		Between-Tubes	0.0	0.0	0.0	0.0
		Between Lots	0.0	0.0	0.0	0.0
		Total	1.9	0.106	1.6, 2.5	0.086, 0.138

2. Linearity:

Not applicable

3. Analytical Specificity/Interference:

Benchtop studies were conducted to evaluate interference from stopper materials over the sample storage time. Study protocols, acceptance criteria, and results for this study were reviewed and found to be acceptable.

4. Assay Reportable Range:

Not applicable

5. Traceability, Stability, Expected Values (Controls, Calibrators, or Methods):

A. Within-Tube Stability (Analyte stability):

Stability studies were conducted to assess analyte within-tube stability in the BD Vacutainer® K2 EDTA Blood Collection Tubes. Stability studies were assessed for up to 24-hour storage at room temperature and 72-hour storage at refrigerated temperatures (2-8°C) for HbA1c testing. Analyte stability was tested on a FDA cleared instrument platform. The study protocols and acceptance criteria have been reviewed and found to be acceptable. These studies showed that the samples are stable up to 24 hours when stored at room temperature and 72 hours at 2-8°C.

B. Shelf-Life

Real Time stability testing of the BD Vacutainer® K2 EDTA Blood Collection Tubes showed that the candidate device is stable for 12-16 months when stored at 4 to 25°C. The stability study protocol and acceptance criteria has been reviewed and found to be acceptable. The claimed shelf-life of each tube is shown below:

K2EDTA Blood Tube Size	Draw Volume	Claimed Shelf-life
13x75	2 mL	15 months
13x75	3 mL	16 months
13x75	4 mL	16 months
13x75	4 mL	16 months
13x100	6 mL	15 months
16x100	10 mL	12 months

C. Additional bench testing on the candidate device

Benchtop studies were conducted to assess draw volume, X-value, 2nd stopper pullout, stopper/shield separation, stopper leakage, tube leakage, breakage resistance during drop testing, breakage resistance during centrifugation testing, barrier formation and packaging performance during shipping and handling. The study protocols were reviewed, and performance was considered acceptable.

6. Detection Limit:

Not applicable

7. Assay Cut-Off:

   Not applicable

B Comparison Studies:

1. Method Comparison with Predicate Device:

   Not applicable.

2. Matrix Comparison:

   Not applicable. These tubes are for venous whole blood only.

C Clinical Studies:

1. Clinical Sensitivity:

   Not applicable

2. Clinical Specificity:

   Not applicable

3. Other Clinical Supportive Data (When 1. and 2. Are Not Applicable):

   A study was conducted to evaluate equivalence between BD Vacutainer® K2 EDTA Blood Collection Tubes and the cleared comparator tube for Hemoglobin A1c testing.

   A total of 209 participants were enrolled in the study. Blood was collected from each participant into the required study tubes using standard phlebotomy techniques. HbA1c was evaluated on three FDA cleared test systems and demonstrated comparable results between the candidate tubes and the comparator tubes. HbA1c testing data was analyzed using Deming regression. Biases at the MDLs between tube types were estimated with 95% confidence intervals and determined to be acceptable. Regression analyses for a representative tube using each instrument platform are provided in the table below:

Analyte	Test System	N	Intercept (95% CI)	Slope (95% CI)	Correlation Coefficient
HbA1c	1	110	0.03 (-0.07, 0.13)	1.0 (0.99, 1.01)	0.999
	2	99	0.01 (-0.21, 0.24)	1.0 (0.96, 1.04)	0.992
	3	99	0.01 (-0.18, 0.20)	1.0 (0.97, 1.03)	0.995

D Clinical Cut-Off:

Not applicable

E Expected Values/Reference Range:

Not applicable

VIII Proposed Labeling:

The labeling supports the finding of substantial equivalence for this device.

IX Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.