August 25, 2023

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

Re: K213670
Trade/Device Name: BD Vacutainer K2EDTA Blood Collection Tubes, BD Vacutainer K3EDTA Blood Collection Tubes
Regulation Number: 21 CFR 862.1675
Regulation Name: Blood specimen collection device
Regulatory Class: Class II
Product Code: GIM
Dated: November 19, 2021
Received: November 22, 2021

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 and Part 809); 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,

Min Wu -S

Min Wu, Ph.D.
Branch Chief
Division of Immunology and Hematology Devices
OHT7: Office of In Vitro Diagnostics
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)*
K213670

Device Name
BD Vacutainer® K2EDTA Blood Collection Tubes and BD Vacutainer® K3EDTA Blood Collection Tubes

Indications for Use *(Describe)*
BD Vacutainer® 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® K2EDTA and K3EDTA Blood Collection Tubes are used for testing in hematology including white blood cells (WBC), red blood cells (RBC), red blood cell distribution width (RDW), hemoglobin (HgB), hematocrit (HCT), mean corpuscular volume (MCV), mean corpuscular hemoglobin (MCH), mean corpuscular hemoglobin concentration (MCHC), platelets, and 5-part white blood cell (WBC) differential counts (neutrophils, lymphocytes, monocytes, eosinophils, basophils).

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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1 510(K) SUMMARY

1.1 Device Name

BD Vacutainer® K_2EDTA Blood Collection Tubes and BD Vacutainer® K_3EDTA Blood Collection Tubes

1.2 Summary Preparation Date:

Date: 5/21/2023

1.3 Submitted by:

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

Phone: (201) 847-6800

1.4 Contact:

Katherine Kenner Lemus, MS, RAC-US
Senior Regulatory Affairs Specialist
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1.5 Alternate Contact:

Matthew Trachtenberg
Director Regulatory Affairs
email: Matthew.trachtenberg@bd.com

Phone: (201) 847-6337
Work: (201) 847-6800

1.6 Proprietary Names:

BD Vacutainer® K_2EDTA Blood Collection Tubes and BD Vacutainer® K_3EDTA Blood Collection Tubes

1.7 Common or Usual Names:

EDTA Blood Collection Tube

1.8 Regulatory Information:

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

1.9 Predicate Device(s):

K981013 Vacutainer® Brand Plus Tube with EDTA Anticoagulant

1.10 Device Establishment

Becton, Dickinson and Company

1.11 Registration Number:

2243072

1.12 Performance Standards:

ASTM D4169-16 Standard Practice for Performance Testing of Shipping Containers and Systems

ANSI/AAMI/ISO 11137-1:2006, A1: 2013, A2 2018 Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices

ANSI/AAMI/ISO 11137-2: 2013 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 14971:2012 Medical Devices – Application of risk management to medical devices

1.13 Intended Use

BD Vacutainer® 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® K_2EDTA and K_3EDTA Blood Collection Tubes are used for testing in hematology including white blood cells (WBC), red blood cells (RBC), red blood cell distribution width (RDW), hemoglobin (HgB), hematocrit (HCT), mean corpuscular volume (MCV), mean corpuscular hemoglobin (MCH), mean corpuscular hemoglobin concentration (MCHC), platelets, and 5-part white blood cell (WBC) differential counts (neutrophils, lymphocytes, monocytes, eosinophils, basophils).

1.14 Device Description

BD Vacutainer® K_2EDTA Blood Collection Tubes and BD Vacutainer® K_3EDTA Blood Collection Tubes are for collecting, transporting and centrifuging blood in a closed tube. The blood collection tube consists of closure assembly, a plastic or glass tube and EDTA additive.

The standard closure assembly is a basic rubber stopper. The tube is also available with the Vacutainer® Hemogard™ Closure Assembly which consists of a rubber stopper and protective plastic shield to reduce user exposure to blood. All stopper/closures are color coded to reflect additive type; the closures included in this submission are either pink or lavender to indicate the presence of the EDTA additive.

1.15 Substantial Equivalence

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

For the BD Vacutainer® K_3EDTA Blood Collection Tubes, a reference device is included in this submission to support the inclusion of the K_3EDTA additive.

Table 1: Substantial Equivalence Comparison

Characteristic	Subject Device BD Vacutainer® K_2EDTA Blood Collection Tubes and BD Vacutainer® K_3EDTA Blood Collection Tubes	Predicate Device Vacutainer® Brand Plus Tube with EDTA Anticoagulant K981013	Reference Device BD Vacutainer® K_3EDTA Blood Collection Tube Pre-Amendment Device	Comments
Indication for use	BD Vacutainer® 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® K2EDTA and K3EDTA Blood Collection Tubes are used for testing in hematology including white blood cells (WBC), red blood cells (RBC), red blood cell distribution width (RDW), hemoglobin (HgB), hematocrit (HCT), mean corpuscular volume (MCV), mean corpuscular hemoglobin (MCH), mean corpuscular hemoglobin concentration (MCHC), platelets, and 5-part white blood cell (WBC) differential counts (neutrophils, lymphocytes, monocytes, eosinophils, basophils).	The Vacutainer® Brand PLUS (plastic) Tube with EDTA anticoagulant and Vacutainer® Brand Serum Tube are evacuated blood collection tubes which provide a means of collecting, transporting separating and processing blood in a plastic tube. When the tube is used together with Vacutainer® Brand Needles and Holders, is a closed system for the collection of venous blood with the same indications as described herein. Blood collected in PLUS EDTA and PLUS Serum tubes can be used for immunohematology testing including ABO grouping, Rh grouping, and antibody screening which requires red cells and plasma or serum	BD Vacutainer® K_3EDTA Blood Collection Tubes are intended for the collection of a plasma specimen in a closed evacuated system. The tube may be used for *in vitro* diagnostic testing for chemistry and hematology determinations in plasma or whole blood.	The proposed indication for use is mostly equivalent to the indication cleared under K981013 with the exception of more explicitly stating use for testing in hematology. The K981013 510(k) Summary similarly states that the predicate EDTA tubes "is used primarily for clinical laboratory hematology studies." The subject and predicate devices have the same intended use
Intended Use	Blood Collection for hematology	Blood Collection for hematology and Immunohematology	Blood Collection for chemistry and hematology	The subject intended use is the same as the predicate intended use for hematology
Intended Population	General Use – all populations	General Use – all populations	General Use – all populations	No change

Characteristic	Subject Device BD Vacutainer® K_2EDTA Blood Collection Tubes and BD Vacutainer® K_3EDTA Blood Collection Tubes	Predicate Device Vacutainer® Brand Plus Tube with EDTA Anticoagulant K981013	Reference Device BD Vacutainer® K_3EDTA Blood Collection Tube Pre-Amendment Device	Comments
Evacuated Blood Collection Tube	Yes	Yes	Yes	No change
Clot/Anti-coagulation	Anti-coagulation	Anti-coagulation	Anti-coagulation	No change
Additive Type	K_2EDTA, K_3EDTA	K_2EDTA	K_3EDTA	The subject device includes tubes with both K_2EDTA and K_3EDTA additives. The K_2EDTA is the same additive as the predicate device cleared under K981013. The K_3EDTA additive is legally marketed per the referenced pre-amendment device. The additional additive does not raise new questions of safety or effectiveness.
Additive Quantity	1.8 mg/mL (K_2EDTA), 1.75 mg/mL (K_3EDTA)	1.8 mg/mL	1.2-4 mg/mL	There is no change in the blood-to-additive ratio for the K_2EDTA tube. The blood-to-additive ratio for the K_3EDTA tube is within the range cited for pre-amendment devices. This change does not result in new questions of safety or effectiveness.
Tube Dimensions (mm)	13x75, 13x100, 16x100	13x75	13x100	The difference in size does not raise new questions of safety or effectiveness.

Characteristic	Subject Device BD Vacutainer® K_2EDTA Blood Collection Tubes and BD Vacutainer® K_3EDTA Blood Collection Tubes	Predicate Device Vacutainer® Brand Plus Tube with EDTA Anticoagulant K981013	Reference Device BD Vacutainer® K_3EDTA Blood Collection Tube Pre-Amendment Device	Comments
Draw Volume	2, 3, 4, 6, 7, 10 mL	6 mL	2, 3, 3.5, 4, 5, 7, 10, 20 mL	The difference in draw volume does not raise new questions of safety or effectiveness.
Tube Material	Plastic (K_2EDTA), Glass (K_3EDTA)	Plastic	Glass	No change
Tube Closure	Conventional or Hemogard™ Safety Closure	Conventional or Hemogard™ Safety Closure	Conventional	No change
Stopper Fabrication	Compression Molded Rubber	Compression molded rubber	Compression molded Rubber	No change
Hemogard™ Shield fabrication	Injection Molded Plastic	Injection Molded Plastic	N/A	No change
Additive Dispense	Spray Dry (K_2EDTA), Liquid Fill (K_3EDTA)	Spray Dry (K_2EDTA)	Liquid Fill (K_3EDTA)	No change
Tube Evacuation	Vacuum Chamber	Vacuum Chamber	Vacuum Chamber	No change
Unit Labeling	Printed paper label	Printed paper label or imprinted on tube	Printed paper label	Changing from paper label and imprinted label options to paper label only does not raise new questions of safety or effectiveness.
Sterilization Method	Gamma Irradiation	Gamma Irradiation	Gamma Irradiation	No change
Sterility Assurance Level (SAL)	$\leq 10^{-3}$	$\leq 10^{-3}$	$\leq 10^{-3}$	No change
Shelf Life	11 Months (K_2EDTA), 10 Months (K_3EDTA)	15-24 months	12 months	Shelf-life dates are based on test data currently available for subject devices. Differences in shelf-life do not raise new questions of safety or effectiveness.

Characteristic	Subject Device BD Vacutainer® K_2EDTA Blood Collection Tubes and BD Vacutainer® K_3EDTA Blood Collection Tubes	Predicate Device Vacutainer® Brand Plus Tube with EDTA Anticoagulant K981013	Reference Device BD Vacutainer® K_3EDTA Blood Collection Tube Pre-Amendment Device	Comments
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	Unit – tube and closure Shelf – shrink wrapped polystyrene tray Case – corrugated cardboard	No change

1.16 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® EDTA Blood Collection Tubes at time-zero and over the proposed shelf life:

Test	Result
Draw Volume	Pass
X-Value	Pass
Second Stopper Pullout	Pass
Stopper/Shield Separation	Pass
Stopper Leakage	Pass
Resistance to Breakage during Drop Testing	Pass
Resistance to Breakage During Centrifugation	Pass
Ship Testing for Functional Performance of Packaging Materials	Pass

The BD Vacutainer® EDTA Blood Collection Tubes met all non-clinical testing requirements at time-zero and over the product shelf life, demonstrating that the device functions as designed. These performance tests demonstrate that the modifications to the device do not impact its safety or effectiveness and that the subject BD Vacutainer® EDTA Blood Collection Tubes continue to perform as intended.

1.17 Performance Testing – Animal Summary

No animal studies were performed in support of this submission.

1.18 Performance Testing – Clinical Summary

The suitability of the BD Vacutainer® EDTA Blood Collection Tubes for collection of clinical samples was demonstrated through testing performed internally and externally which demonstrated clinical equivalency to the venous comparator tube by performing the following studies: Method Comparison (Clinical Equivalence), Precision, Within-Tube Type Stability, and Shelf Life. Testing was performed on identified analytes (i.e., White Blood Cell Count (WBC), Red Blood Cell Count (RBC), Hemoglobin, Hematocrit, Platelet Count, Neutrophil %, Lymphocyte %, Monocyte %, Eosinophil %, Basophil %, Mean Corpuscular Hemoglobin, Mean Corpuscular Hemoglobin Concentration, Mean Corpuscular Volume, and Red Cell Distribution Width."

Method Comparison

This study was performed to evaluate Clinical Equivalence between the evaluate the performance of BD Vacutainer® EDTA Blood Collection Tubes against legally marketed comparator tubes., for the analytes identified above. This assessment considered whether the

mean and the two one-sided 95% Confidence Limits of the paired sample biases were within the Clinical Acceptance Limits (CALs).

Clinical equivalency was demonstrated for all hematology parameters for each tube comparison except Hgb, PLT, and WBC at the low medically relevant points on two instruments. For these three analytes the mean bias was within the predefined clinical acceptance limits, but exceeded the confidence interval. The observed non-equivalence is clinically acceptable, as the number of data points at the low medically relevant points were insufficient to adequately power the analysis.

Lot to Lot Variability

This study was performed to evaluate non-inferiority of the BD Vacutainer® K_2EDTA tube for repeatability (within tube) and reproducibility (lot-to-lot and tube-to-tube) variation using hematology parameters identified above.

Performance of the BD Vacutainer® K_2EDTA Tubes with Hemogard™ closure for repeatability, lot-to-lot variation and tube-to-tube variation showed non-inferiority for all tube comparisons for the hematology parameters tested on two instrument platforms when compared with a comparator device.

Within-Tube Type Stability

This study evaluated within-tube type stability of BD Vacutainer® EDTA Blood Collection Tubes by comparing samples taken from the same subject in the candidate tubes at various identified time points and storage conditions.

All analytes demonstrated stability at 12- and 24-hours storage Room Temperature, 24 hours Refrigerated, 24 hours Room Temperature followed by 24 hours Refrigerated.

Shelf-Life

The purpose of this study was to evaluate product shelf-life by evaluating evaluate Shelf-Life performance (11+1 months or 10+1 months from date of manufacture) of BD Vacutainer® K_2EDTA and K_3EDTA Blood Collection Tubes with Hemogard™ closure and Conventional closure, respectively, in comparison with recently manufactured BD Vacutainer® K_2EDTA and K_3EDTA Blood Collection Tubes for selected hematology test parameters.

Real time clinical stability testing performed using clinical samples demonstrated a shelf life of 11 months for BD Vacutainer® K_2EDTA Blood Collection Tubes and 10 months for BD Vacutainer® K_3EDTA Blood Collection Tubes.

1.19 Conclusion

The technical performance characteristics of the subject device are unchanged. The proposed BD Vacutainer® EDTA Blood Collection Tubes and predicate device of the same name have the same intended use, principle of operation, and technological characteristics. Non-Clinical and Clinical Performance Testing sufficiently support the determination that the changes made to the

BD Vacutainer® EDTA Blood Collection Tubes do not raise any new concerns of safety or effectiveness. Based on information provided in this submission the proposed device is substantially equivalent to the predicate device.