February 2, 2024

Becton, Dickinson and Company
Brice Biggins
Sr. Regulatory Affairs Specialist, SM
1 Becton Drive
Franklin Lakes, New Jersey 07417

Re: K231373
Trade/Device Name: BD Vacutainer® K_2 EDTA Blood Collection Tubes
Regulation Number: 21 CFR 862.1675
Regulation Name: Blood Specimen Collection Device
Regulatory Class: Class II
Product Code: JKA, GIM
Dated: January 4, 2024
Received: January 4, 2024

Dear Brice Biggins:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Paula V. Caposino -S

Paula Caposino, Ph.D.
Acting Deputy Division Director
Division of Chemistry and Toxicology 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)*
K231373

Device Name
BD Vacutainer® K2 EDTA Blood Collection Tubes

Indications for Use *(Describe)*
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.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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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."

5. 510(K) SUMMARY K231373

5.1 Device Name

BD Vacutainer® K_2 EDTA Blood Collection Tubes

5.2 Summary Preparation Date:

Date: 12/22/2023

5.3 Submitted by:

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

Phone: (201) 847-6800

5.4 Contact:

Brice Biggins
Senior Regulatory Affairs Specialist, SM
Phone: (410) 456-3633
email: Brice.Biggins@bd.com

5.5 Alternate Contact:

Matthew Trachtenberg
Director Regulatory Affairs, SM
email: Matthew_Trachtenberg@BD.com
Phone: (201) 847-6337

5.6 Proprietary Names:

BD Vacutainer® K_2 EDTA Blood Collection Tubes

5.7 Common or Usual Names:

EDTA Blood Collection Tubes

5.8 Regulatory Information:

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

5.9 Predicate Device(s):

K981013 Vacutainer® Brand Plus Tube with EDTA Anticoagulant

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 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

5.13 Intended 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."

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 1.

Table 1. Substantial Equivalence Comparison

Characteristic	Subject Device BD Vacutainer® K_2 EDTA Blood Collection Tubes	Predicate Device Vacutainer® Brand Plus Tube with EDTA Anticoagulant K981013	Comments
Indication 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.	The Vacutainer® Brand PLUS (plastic) Tube with EDTA anticoagulant 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.[1]	The intended use of the subject device is the same as the predicate with regard to the claims for collection, and transportation of blood for in vitro diagnostic use, with the subject device providing additional clarity on certain information consistent with current best practices. The addition of HbA1c is not considered a new intended use because the subject and predicate devices are both intended for determination of analytes in whole blood. HbA1c is a diagnostic test completed on a venous whole blood sample. Therefore, the subject and predicate devices have the same intended use.
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	The additional sizes do not raise different questions of safety or effectiveness.

[1] This represents a subset of the indications for use of the predicate device subject to review by CDRH and does not include indications for use subject to review by CBER.

Draw Volume	2, 3, 4, 6, 10 mL	6 mL	The additional draw volumes do not raise different questions of safety or effectiveness.
Tube Material	Plastic	Plastic	Identical
Tube Closure	Hemogard™ Safety Closure	Hemogard™ Safety Closure	Identical
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
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 intended use of the subject device is the same as the predicate with regard to the claims for collection and transportation of blood for in vitro diagnostic use. The subject device provides additional clarity on certain information consistent with current best practices (e.g., containment, preservation). The addition of HbA1c testing is not considered a new intended use because the subject and predicate devices are both intended for determination of analytes in whole blood. The proposed indication for use is equivalent to the indication cleared under K981013 except for explicitly stating for use with HbA1C testing. Despite this difference in the indications for use statements, the intended use for both the subject and predicate device is to provide a whole blood specimen for diagnostic evaluation. HbA1c is a diagnostic test completed on human venous whole blood sample.

Therefore, using K981013 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 K981013 have similar technological characteristics. They both use K_2 EDTA anticoagulant that has been spray dried onto a sterile evacuated plastic tube and closed with a Hemogard™ closure.
Differences and justification that they do not raise different questions of safety and effectiveness are described below:

Draw Volume and Tube Dimensions: Regarding differences in tube draw volumes (and the associated tube dimensions necessary to accommodate higher draw volumes), evaluation of an appropriate vacuum in the tube to meet the labeled draw volume, and of clinical studies to confirm appropriate blood to additive ratios are not new, and so do not result in 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® K2 EDTA Blood Collection Tubes at time-zero and over the shelf life: Draw Volume, X-Value, Second Stopper Pullout, Stopper/Shield Separation, Stopper Leakage, Tube Leakage and Resistance to Breakage during Drop Testing. 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_2 EDTA products with a 16-month shelf life; at least 13 months for K_2 EDTA 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® K2 EDTA 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 HbA1C with the distribution of subjects selected to be approximately representative of the general US population.

Results based on pre-determined acceptance criteria demonstrated the BD Vacutainer® K2 EDTA Blood Collection Tubes are suitable for use in HbA1C testing.

5.19 Conclusion

The technical performance characteristics of the subject device are unchanged. The BD Vacutainer® K2 EDTA Blood Collection Tubes and predicate device of the same name have the same intended use and any differences in technological characteristics do not raise different questions of safety and effectiveness. Non-Clinical and Clinical Performance Testing supports the determination that the subject BD K_2 EDTA Tubes continue to perform as intended. Based on information provided in this submission the subject device is substantially equivalent to the predicate device.