July 17, 2023

Becton, Dickinson and Company
Angela Mariani
Senior Staff Regulatory Affairs Specialist
1 Becton Drive
Franklin Lakes, New Jersey 07417

Re: K213953
Trade/Device Name: BD Vacutainer® Trace Element K2EDTA Tubes, BD Vacutainer® Trace Element Serum Tubes
Regulation Number: 21 CFR 862.1675
Regulation Name: Blood Specimen Collection Device
Regulatory Class: Class II
Product Code: JKA
Dated: March 28, 2023
Received: March 29, 2023

Dear Angela Mariani:

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,

Marianela Perez-torres -S

Marianela Perez-Torres, PhD
Acting 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)*
K213953

Device Name
BD Vacutainer® Trace Element K2EDTA Tube and BD Vacutainer® Trace Element Serum Tube

Indications for Use *(Describe)*
BD Vacutainer® Trace Element Serum Tubes and BD Vacutainer® Trace Element K2EDTA Tubes are plastic, evacuated, sterile, single use, in vitro diagnostic medical devices. They are intended to be used in settings where venous blood specimens are collected by trained healthcare professionals for the collection, transportation, and processing of blood in a closed tube. Blood collected in the BD Vacutainer® Trace Element Serum Tubes and BD Vacutainer® Trace Element K2EDTA Tubes are used for trace element testing (e.g., Arsenic, Cadmium, Chromium, Copper, Lead, Manganese, Mercury, Selenium, and Zinc).

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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 K213953

1.1 Device Name:

BD Vacutainer® Trace Element K_2EDTA Tubes and,

BD Vacutainer® Trace Element Serum Tubes

1.2 Summary Preparation Date:

July 7, 2023

1.3 Submitted by:

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

Phone: (201) 847-6800

1.4 Contact:

Angela M Mariani
Senior Staff Regulatory Affairs Specialist
email: angela.mariani@bd.com

Phone: (201) 847-6800
Work: (240) 704-3084

1.5 Alternate Contact:

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

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

1.6 Proprietary Names:

BD Vacutainer® Trace Element K_2EDTA Tubes and,

BD Vacutainer® Trace Element Serum Tubes

1.7 Common or Usual Names:

Tubes, Vials, Systems, Serum Separators, Blood Collection

1.8 Regulatory Information

Classification Name: Tubes, Vials, Systems, Serum Separators, Blood Collection
Classification Regulation: 21 CFR § 862.1675
Regulatory Class: Class II
Product Code: JKA

1.9 Predicate Device

BD Vacutainer® Trace Element Serum Plus Tube and BD Vacutainer® Trace Element K_2EDTA Plus Tube (K041071)

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® Trace Element Serum Tubes and BD Vacutainer® Trace Element K_2EDTA Tubes are plastic, evacuated, sterile, single use, in vitro diagnostic medical devices. They are intended to be used in settings where venous blood specimens are collected by trained healthcare professionals for the collection, transportation, and processing of blood in a closed tube. Blood collected in the BD Vacutainer® Trace Element Serum Tubes and BD Vacutainer® Trace Element K_2EDTA Tubes are used for trace element testing (e.g., Arsenic, Cadmium, Chromium, Copper, Lead, Manganese, Mercury, Selenium, and Zinc).

1.14 Device Description

The BD Vacutainer® Trace Element K_2EDTA Tube is an evacuated plastic blood collection tube. It consists of closure assembly, a plastic tube, and EDTA coating (dipotassium) and is available in two draw sizes, 6 mL (13 x 100 mm) and 3 mL (13 x 75 mm). The plastic tube is manufactured from PET (polyethylene terephthalate) plastic, which enhances user safety and disposal because of the reduced risk of tube breakage and the use of incineration as a method of disposal compared to glass. The EDTA anticoagulant coating is spray-dried on the walls of the tube in the dipotassium (K_2) form.

The BD Vacutainer® Trace Element Serum Tube is also an evacuated plastic blood collection tube consisting of a closure assembly, a plastic tube and contains a silica clot activator additive which is spray-dried on the interior walls of the tube. It is available in one draw size, 6 mL (13 x 100 mm). The plastic tube is manufactured from PET (polyethylene terephthalate) plastic.

All of these plastic tubes are closed with a BD Hemogard™ Closure, which consists of a rubber stopper and protective plastic shield to help reduce user exposure to blood. The stopper/closures are color coded to reflect the intended use (Royal Blue for trace element tubes).

1.15 Substantial Equivalence

The subject and predicate device are substantially equivalent as described in Table 1.

Table 1: Substantial Equivalence Comparison

Characteristic	BD Vacutainer® Trace Element K_2EDTA Tubes and BD Vacutainer® Trace Element Serum Tubes (K213953)	BD Vacutainer® Trace Element Serum Plus Tubes and BD Vacutainer® Trace Element K_2EDTA Tubes (K041071)	Comparison
Indications for Use	BD Vacutainer® Trace Element Serum Tubes and BD Vacutainer® Trace Element K_2EDTA Tubes are plastic, evacuated, sterile, single use, in vitro diagnostic medical devices. They are intended to be used in settings where venous blood specimens are collected by trained healthcare professionals for the collection, transportation, and processing of blood in a closed tube. Blood collected in the BD Vacutainer® Trace Element Serum Tubes and BD Vacutainer® Trace Element K_2EDTA Tubes are used for trace element testing (e.g., Arsenic, Cadmium, Chromium, Copper, Lead, Manganese, Mercury, Selenium, and Zinc).	The BD Vacutainer® Trace Element Serum Plus Tube and BD Vacutainer® Trace Element K_2EDTA Tube and are plastic evacuated blood collection tubes that provide a means of collecting, transporting, and processing blood in a closed tube. Blood collected in the BD Vacutainer® Trace Element Serum Plus Tube and BD Vacutainer® Trace Element K_2EDTA Tube is used for trace element testing (e.g., Arsenic, Cadmium, Calcium, Chromium, Copper, Iron, Lead, Magnesium, Manganese, Mercury, Selenium, and Zinc).	The indications for use of the subject device is identical to the cleared indication for the predicate device except that the subject device indication 1) reduces the indication scope to remove Calcium, Iron, and Magnesium from trace element testing because they are not present in the blood in trace amounts, and 2) includes additional information related to the intended use setting and intended user of the devices. The subject indication is intended to be cleared for a subset of the previously cleared predicate trace element indication. These minor changes do not result in a new intended use of the subject device.
Evacuated Blood Collection Tube	Yes	Yes	Identical

Characteristic	BD Vacutainer® Trace Element K_2EDTA Tubes and BD Vacutainer® Trace Element Serum Tubes (K213953)	BD Vacutainer® Trace Element Serum Plus Tubes and BD Vacutainer® Trace Element K_2EDTA Tubes (K041071)	Comparison
Tube Dimensions and Draw Volume	BD Vacutainer® Trace Element Serum Tube: 13 x 100 mm, 6 mL BD Vacutainer® Trace Element K_2EDTA Tube: 13 x 100 mm, 6 mL and 13 x 75 mm, 3 mL	BD Vacutainer® Trace Element Serum Plus Tube: 13 x 100mm, 6 mL BD Vacutainer® Trace Element K_2EDTA Tube: 13 x 100mm, 6 mL	The predicate tubes were only available in 13 x 100mm 6 mL draw volumes. The proposed devices include a product line extension to include a 13 x 75mm 3 mL draw volume version of the BD Vacutainer® Trace Element K_2EDTA Tube to meet customer needs. This product line expansion does not raise new questions of safety and effectiveness.
Sample Type	BD Vacutainer® Trace Element Serum Tube: Serum BD Vacutainer® Trace Element K_2EDTA Tube: Whole Blood	BD Vacutainer® Trace Element Serum Plus Tube: Serum BD Vacutainer® Trace Element K_2EDTA Tube: Whole Blood	Identical
Additive Type	BD Vacutainer® Trace Element Serum Tube: Serum Clot Activator BD Vacutainer® Trace Element K_2EDTA Tube: K_2EDTA	BD Vacutainer® Trace Element Serum Plus Tube: Serum Clot Activator BD Vacutainer® Trace Element K_2EDTA Tube: K_2EDTA	Identical
Additive Application/Quantity	BD Vacutainer® Trace Element Serum Tube: Spray Dried Silica Additive BD Vacutainer® Trace Element K_2EDTA Tube: K_2EDTA Spray Dried 10.8 mg, 13 x 100 mm, 6 mL 5.4 mg, 13 x 75 mm, 3 mL	BD Vacutainer® Trace Element Serum Plus Tube: Spray Dried Silica Additive BD Vacutainer® Trace Element K_2EDTA Tube: K_2EDTA Spray Dried 10.8 mg, 13 x 100 mm, 6 mL	The new 3mL K_2EDTA Trace Element tube has a lower quantity of K_2EDTA, but an identical additive-to-blood ratio. This product line expansion does not raise new questions of safety and effectiveness.
Tube Material	PET (polyethylene terephthalate) plastic	PET (polyethylene terephthalate) plastic	Identical
Tube Closure	BD Hemogard™ /Royal Blue	BD Hemogard™ /Royal Blue	Identical

Characteristic	BD Vacutainer® Trace Element K_2EDTA Tubes and BD Vacutainer® Trace Element Serum Tubes (K213953)	BD Vacutainer® Trace Element Serum Plus Tubes and BD Vacutainer® Trace Element K_2EDTA Tubes (K041071)	Comparison
Sterilization Method	Gamma Irradiation	Gamma Irradiation	Identical
Sterility Assurance Level (SAL)	10^{-6}	10^{-6}	Identical
Shelf Life	6 mL BD Vacutainer® Trace Element Serum Tube and 6mL BD Vacutainer® Trace Element K_2EDTA Tube 12 months 3 mL BD Vacutainer® Trace Element K_2EDTA Tube 10 months	12 months	Shelf-life durations are based on test data currently available and additional testing is ongoing to support future shelf-life extensions. This difference does not raise new 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

1.16 Substantial Equivalence Discussion

Intended Use

The intended use of the subject BD Vacutainer® Trace Element K_2EDTA Tubes and BD Vacutainer® Trace Element Serum Tubes is substantially equivalent to the prior cleared indications for use of the BD Vacutainer® Trace Element Serum Plus Tubes and BD Vacutainer® Trace Element K_2EDTA Tubes under K041071. They are intended to be used for the collection, transportation, and processing of blood in a closed tube for trace element testing.

The subject device indication for use is for a subset of the previously cleared predicate trace element indications. The subject indication for use statement reduces the scope of trace elements to remove Calcium, Iron, and Magnesium from trace element testing because they are not present in the blood in trace amounts. In addition to this change, there is a minor language change in the subject indications for use which expands on the cleared indication for use to better clarify the intended setting and user of the devices, e.g., to be in settings where venous blood samples would be collected by trained healthcare professionals. These minor changes do not result in a new intended use of the subject device.

Both the subject and predicate device have the same intended use and substantially similar indications for use, meeting the first criteria for a finding of substantial equivalence.

Technological Characteristics

Both the subject and predicate tubes have similar technological characteristics. They are plastic, evacuated, sterile, single use, in vitro diagnostic medical devices with Royal Blue BD Hemogard™ closures. There is no change in sterilization method or sterility assurance level for these tubes.

The subject BD Vacutainer® Trace Element Serum Tubes and predicate tubes are available in 6 mL draw volumes and contain the same quantity of spray dried silica additive to ensure clot formation.

The one minor change to the technological characteristics is the introduction of a 3 mL draw BD Vacutainer® Trace Element K_2EDTA Tube as an extension to the BD Trace Element Tube line. This new tube size does not introduce any new questions of safety or effectiveness. The additive types and application methods are unchanged. In alignment with this new size offering, the K_2EDTA blood-to-additive ratio for the tubes, which is related to the draw volume to ensure adequate anticoagulation of the sample, remains unchanged. This is technologically equivalent and allows for testing on an anticoagulated sample.

Furthermore, performance testing demonstrates that the modifications do not impact the safety or effectiveness of the device over the indicated shelf life and that the subject BD Trace Element tubes continue to perform as intended.

Principles of Operation

Both the subject and predicate tubes are used for the collection of venous whole blood for trace element testing. BD Vacutainer® Trace Element K_2EDTA Tubes are designed to provide an anticoagulated sample for trace element testing and BD Vacutainer® Trace Element Serum Tubes are designed to ensure clot formation for trace element testing on serum. The principles of operation are unchanged compared to the predicate device.

1.17 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® Trace Element K_2EDTA Tubes and BD Vacutainer® Trace Element Serum Tubes at time-zero and over the proposed shelf life: Draw Volume, X-Value, Second Stopper Pullout, Stopper/Shield Separation, Stopper Leakage, Tube Leakage, Breakage Resistance During Centrifugation, Breakage Resistance During Drop Testing, and Trace Metal Content Testing. Additionally, Ship Testing was conducted to assess the functional performance of the packaging materials.

The BD Vacutainer® Trace Element K_2EDTA Tubes and BD Vacutainer® Trace Element Serum 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 substantial equivalence of the subject devices to the predicate devices.

1.18 Performance Testing – Animal Summary

No animal studies were performed in support of this submission.

1.19 Performance Testing – Clinical Summary

Clinical testing was conducted on whole blood collected in the subject devices (BD Vacutainer® Trace Element K_2EDTA Tubes and BD Vacutainer® Trace Element Serum Tubes) and a legally marketed comparator device to demonstrate Clinical Equivalence. Additional clinical testing was completed to evaluate Within-Tube Stability, Shelf-Life Performance, and Repeatability/Reproducibility. Clinical testing results confirmed the devices' functional clinical equivalence in the identification of clinically relevant levels of Arsenic, Cadmium, Chromium, Copper, Lead, Manganese, Mercury, Selenium, and Zinc using these tubes.

Results based on pre-determined acceptance criteria demonstrated the BD Vacutainer® Trace Element K_2EDTA Tubes and BD Vacutainer® Trace Element Serum Tubes are suitable for use in trace element testing.

1.20 Conclusion

The technical performance characteristics of the subject device are unchanged. The proposed BD Vacutainer® Trace Element K_2EDTA Tubes and BD Vacutainer® Trace Element Serum Tubes and predicate devices have the same intended use, principle of operation, and technological characteristics. Non-Clinical and Clinical Performance Testing sufficiently support the determination of substantial equivalence of the BD Vacutainer® Trace Element K_2EDTA Tubes and BD Vacutainer® Trace Element Serum Tubes. Based on information provided in this submission the proposed device is substantially equivalent to the predicate device.