October 31, 2024

Becton Dickinson and Company
Joseph Basore
Staff Regulatory Affairs Specialist
1 Becton Drive
Franklin Lakes, New Jersey 07417

Re: K240455
Trade/Device Name: BD Vacutainer Citrate Blood Collection Tubes
Regulation Number: 21 CFR 862.1675
Regulation Name: Blood Specimen Collection Device
Regulatory Class: Class II
Product Code: GIM
Dated: February 15, 2024
Received: October 1, 2024

Dear Joseph Basore:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K240455

Device Name

BD Vacutainer® Citrate Blood Collection Tubes

Indications for Use *(Describe)*

The BD Vacutainer® Citrate Blood Collection Tube (0.109M buffered sodium citrate) is a sterile, single use tube used for the collection, containment, transport, and centrifugation of venous blood specimens to obtain plasma for in vitro diagnostic testing. It is used in settings where a venous blood sample is collected by a trained healthcare worker. The BD Vacutainer® Citrate Blood Collection Tube is used for clinical laboratory testing in coagulation.

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.

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1 510(K) SUMMARY

1.1 Device Name

BD Vacutainer® Citrate Blood Collection Tubes

1.2 Summary Preparation Date:

Date: February 15, 2024

1.3 Submitted by:

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

Phone: (201) 847-6800

1.4 Contact:

Joseph Basore, Ph.D., RAC
Staff Regulatory Affairs Specialist
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1.5 Alternate Contact:

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VP, Regulatory Affairs
email: Nate.Carrington@bd.com

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1.6 Proprietary Name:

BD Vacutainer® Citrate Blood Collection Tubes

1.7 Common or Usual Names:

BD Citrate 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

BD Vacutainer Safety Coagulation Tube (K013971)

1.10 Device Establishment

Becton, Dickinson and Company

1.11 Registration Number:

2243072

1.12 Performance Standards:

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".

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

EN ISO 14971:2019 Medical Devices – Application of risk management to medical devices.

1.13 Indications for Use

The BD Vacutainer® Citrate Blood Collection Tube (0.109M buffered sodium citrate) is a sterile, single use tube used for the collection, containment, transport, and centrifugation of venous blood specimens to obtain plasma for in vitro diagnostic testing. It is used in settings where a venous blood sample is collected by a trained healthcare worker. The BD Vacutainer® Citrate Blood Collection Tube is used for clinical laboratory testing in coagulation.

1.14 Device Description

BD Vacutainer® Citrate Blood Collection Tubes (BD Citrate Tubes) are available in plastic configurations and contain a liquid additive. Tubes include a color-coded BD Hemogard™ Closure and are comprised of an inner and outer tube to maintain the draw volume and liquid additive. Refer to Table 1 for unique product configurations. Tube stoppers are lubricated with silicone to facilitate stopper insertion. The buffered sodium citrate solution provides an anticoagulated specimen when used in accordance with the instructions for use. The tubes are compatible with the BD Vacutainer® Blood Collection Needles, Blood Collection Sets, Transfer Devices, Holders and Adaptors.

Table 1: BD Citrate Tubes Configurations

Catalog #	Size (diameter x length in mm)	Draw Volume (mL)	Closure Assembly	Material (Inner/Outer)	Additive	Shelf Life
363083	13 x 75	2.7 ± 10% (2.43 -2.97)	BD Hemogard™ (Light Blue) and Stopper (Light Blue)	Polypropylene/ Polyethylene Terephthalate (PET)	0.109 M (3.2%) Buffered Sodium Citrate	9 months
366560						
363080		1.8 ± 10% (1.62 -1.98)	BD Hemogard™ (Translucent) and Stopper (Light Blue)			6 months

1.15 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® Citrate Blood Collection Tubes	Predicate Device: BD Vacutainer® Safety Coagulation Tube (K013971)	Comments
Indications for use	The BD Vacutainer® Citrate Blood Collection Tube (0.109M buffered sodium citrate) is a sterile, single use tube used for the collection, containment, transport, and centrifugation of venous blood specimens to obtain plasma for in vitro diagnostic testing. It is used in settings where a venous blood sample is collected by a trained healthcare worker. The BD Vacutainer® Citrate Blood Collection Tube is used for clinical laboratory testing in coagulation.	BD Vacutainer® Safety Coagulation tube is a plastic evacuated blood collection tube that provides a means of collecting, transporting and processing blood in a closed tube. The buffered sodium citrate additive provides an anticoagulated specimen that may be used for clinical laboratory coagulation assays. The benefits of a safety plastic coagulation tube with Hemogard™ Safety Closure Assembly are: • Reduced risk of specimen tube breakage • Reduced exposure to blood by laboratory personnel and to minimize blood splatter during stopper removal. These benefits lead to increased safety of laboratory personnel and reduced necessity of repeat specimen collection.	There are minor changes to the indications for use wording to best align with the appropriate use of the product and available testing. The benefits/safety statements for use of plastic tubes over glass tubes have been removed. These changes do not result in a new intended use for the subject device.
Product Code	GIM (Tubes, Vacuum Sample, With Anticoagulant)	JKA (Tubes, Vials, Systems, Serum Separators, Blood Collection)	GIM indicates the use of an anticoagulant and so is more appropriate to describe the BD Citrate Tubes.
Regulation	21 C.F.R. § 862.1675	21 C.F.R. § 862.1675	Identical
Intended Population	General Use – all populations	General Use – all populations	Identical
Evacuated Blood Collection Tube	Yes	Yes	Identical
Clot/Anticoagulation	Anti-coagulation	Anti-coagulation	Identical

Characteristic	Subject Device: BD Vacutainer® Citrate Blood Collection Tubes	Predicate Device: BD Vacutainer® Safety Coagulation Tube (K013971)	Comments
Tube Material	Plastic inner and outer tubes	Plastic inner and outer tubes	Equivalent; the product has undergone like for like changes in some materials since the initial FDA clearance in 2001. These differences do not raise different questions of safety or effectiveness.
Tube Size	13 x 75 mm	13 x 75 mm	Identical
Draw Volume	1.8 mL or 2.7 mL	1.8 mL or 2.7 mL	Identical
Blood to Additive Ratio	9 to 1	9 to 1	Identical
Additive	0.109M (3.2%) sodium citrate	0.109M (3.2%) sodium citrate	Identical
Closure Type/Color	2.7mL: Hemogard™ light blue cap and blue stopper 1.8mL: Hemogard™ Translucent cap and blue stopper	2.7mL: Hemogard™ light blue cap and blue stopper 1.8mL: Hemogard™ Translucent cap and blue stopper	Equivalent; the product has undergone like for like changes in some materials since the initial FDA clearance in 2001. These differences do not raise different questions of safety or effectiveness.
Tube Evacuation	Vacuum Chamber	Vacuum Chamber	Identical
Sterilization Method	Gamma Irradiation	Gamma Irradiation	Identical
Sterility Assurance Level (SAL)	10^{-3}	10^{-3}	Identical
Shelf Life	2.7 mL: 9 months 1.8 mL: 6 months	2.7 mL: 9 months 1.8 mL: 6 months	Identical

1.16 Substantial Equivalence Discussion

Intended Use/Indications for Use

The BD Vacutainer® Citrate Blood Collection Tubes includes the same intended use of evacuated blood containers for collection, separation, processing and storage of venous blood as the predicate device (K013971). The proposed indications for use statement is the same as the prior indications for use statement with slightly different wording to best align with the appropriate use of the product and therefore does not result in a new intended use.

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 worker. Therefore, using K013971 as the predicate satisfies the FDA's requirements regarding intended use.

Technological Characteristics

Both the subject and predicate tubes cleared under K013971 use 0.109M buffered sodium citrate anticoagulant to reversibly bind free calcium in the blood and stop the clotting/coagulation cascade. Both the subject and predicate device are comprised of a plastic outer tube and plastic inner tube that helps retain vacuum and enables the different variants of the tubes to be consistent in outer dimension (13 x 75 mm), while having different draw volumes of 1.8 mL and 2.7 mL. Lastly, both the subject and predicate tubes utilize a Hemogard™ Closure Assembly with a rubber stopper and protective plastic shield to reduce user exposure to blood.

Since the clearance of the predicate K013971, there were additional minor changes that individually did not require a new 510(k) submission nor introduce new/modified existing risks, but which have been determined to cumulatively warrant submission of this new 510(k). Changes broadly included label/packaging updates, qualification of additional material suppliers, material discontinuation/replacement/location changes, new/changed manufacturing sites/equipment/processing, minor specification updates, supplier changes, etc. Therefore, the cumulative effect of all changes together has the potential to cause technological differences between the subject and predicate tubes that were addressed through performance testing. These technological differences do not raise new questions of safety and effectiveness and were not made with the intent to improve the safety and or effectiveness of the 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® Citrate Blood Collection Tubes at time-zero and over the proposed shelf life:

Table 3: Non-Clinical Performance Testing Results

Test	Results
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
Moisture Lost	Pass
Ship Testing for Functional Performance of Packaging Materials	Pass

The BD Vacutainer® Citrate 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. Therefore, these performance tests demonstrate substantial equivalence of the subject devices to the predicate devices.

1.18 Performance Testing – Clinical Summary

Clinical testing was conducted on whole blood collected in the subject device, BD Citrate Tubes, and a similar comparator tube 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' clinical equivalence for coagulation parameters. A summary of the clinical studies completed is included below:

- Clinical Equivalence and Within-Tube Stability: The purpose of these studies was to evaluate the Clinical Equivalence of the BD Citrate Tubes in comparison with a similar comparator citrate tube, and to demonstrate Within-Tube Stability (WTS), for representative selected plasma coagulation test parameters (i.e., Prothrombin Time [PT], Activated Partial Thromboplastin Time [aPTT], International Normalized Ratio [INR], D-Dimer, Anti-Factor Xa). Clinical equivalence was demonstrated for all tube comparisons.

- Shelf-Life: This study evaluated the performance of BD Citrate Tubes at the end of shelf-life (EOSL) in comparison with BD Citrate Tubes that were recently manufactured for selected plasma coagulation test parameters (i.e., Prothrombin Time [PT], Activated Partial Thromboplastin Time [aPTT], International Normalized Ratio [INR], D-Dimer, Anti-Factor Xa). The results support the proposed shelf-life for the selected plasma coagulation test parameters.

- Repeatability/Reproducibility: This study evaluated the performance of BD Citrate Tubes in comparison to a similar comparator citrate anticoagulant tube for within tube repeatability (by testing tubes in duplicate), tube to tube reproducibility (by testing two tubes within each lot) and lot to lot reproducibility (by testing three lots of tubes) for selected plasma coagulation test parameters (i.e., Prothrombin Time [PT], Activated Partial Thromboplastin Time [aPTT], International Normalized Ratio [INR], D-Dimer, Anti-Factor Xa). The evaluation passed the non-inferiority criterion for all tube comparisons, based on the ratios appropriate to the data structure for the selected coagulation analytes when compared with a similar comparator citrate anticoagulant tube.

1.19 Conclusion

The known differences between the BD Vacutainer® Citrate Blood Collection Tubes (subject device) and predicate device have been identified and the rationale to support substantial equivalence has been provided. The proposed subject device and predicate device have the same intended use, principle of operation, and technological characteristics. Non-Clinical and Clinical Performance testing demonstrates that the subject device meets applicable performance requirements. Therefore, the differences between the subject device and the predicate device do not raise different questions of safety and effectiveness. In conclusion, the subject device is substantially equivalent to the predicate device.