



January 19, 2024

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

Re: K231237

Trade/Device Name: BD Vacutainer® Fluoride Blood Collection Tubes
Regulation Number: 21 CFR 862.1675
Regulation Name: Blood specimen collection device
Regulatory Class: Class II
Product Code: JKA, GIM
Dated: December 21, 2023
Received: December 21, 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 (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

Indications for Use

510(k) Number (if known)
K231237

Device Name
BD Vacutainer® Fluoride Blood Collection Tubes

Indications for Use (Describe)

BD Vacutainer® Fluoride Blood Collection Tubes are evacuated, sterile, single use, in vitro diagnostic medical devices available with Sodium Fluoride/Potassium Oxalate or Sodium Fluoride/Na₂EDTA. They are intended to be used by trained healthcare professionals for the collection, containment, preservation, transportation, and centrifugation of venous blood specimens as required for in vitro diagnostic testing. Plastic BD Vacutainer® Fluoride Blood Collection Tubes are used to collect whole blood for the generation of plasma samples.

Blood collected in BD Vacutainer® Fluoride Blood Collection Tubes containing Sodium Fluoride/Potassium Oxalate are used for glucose and lactate determinations. Blood collected in BD Vacutainer® Fluoride Blood Collection Tubes containing Sodium Fluoride/Na₂EDTA are used for glucose determinations.

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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510(K) SUMMARY K231237

1.1 Device Name

BD Vacutainer® Fluoride Blood Collection Tubes

1.2 Summary Preparation Date:

January 19, 2024

1.3 Submitted by:

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1.4 Contact:

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1.6 Proprietary Names:

BD Vacutainer® Fluoride Blood Collection Tubes

1.7 Common or Usual Names:

Tubes, Vacuum Sample, With Anticoagulant

1.8 Regulatory Information

Classification Name: Tubes, Vacuum Sample, With Anticoagulant
Classification Regulation: 21 CFR § 862.1675

Regulatory Class: Class II
Product Code: GIM/JKA

1.9 Predicate Device

BD Vacutainer® Plus Blood Collection Tubes containing Potassium Oxalate / Sodium Fluoride (K901449)

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/(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 Third edition 2013-06-01 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

1.13 Intended Use

BD Vacutainer® Fluoride Blood Collection Tubes are evacuated, sterile, single use, in vitro diagnostic medical devices available with Sodium Fluoride/Potassium Oxalate or Sodium Fluoride/Na₂EDTA. They are intended to be used by trained healthcare professionals for the collection, containment, preservation, transportation, and centrifugation of venous blood

specimens as required for in vitro diagnostic testing. Plastic BD Vacutainer® Fluoride Blood Collection Tubes are used to collect whole blood for the generation of plasma samples.

Blood collected in BD Vacutainer® Fluoride Blood Collection Tubes containing Sodium Fluoride/Potassium Oxalate are used for glucose and lactate determinations. Blood collected in BD Vacutainer® Fluoride Blood Collection Tubes containing Sodium Fluoride/Na₂EDTA are used for glucose determinations.

1.14 Device Description

The BD Vacutainer® Fluoride Blood Collection Tubes are evacuated, sterile, single use, Class II in vitro diagnostic medical devices regulated under 21 CFR § 862.1675 for blood specimen collection devices, and product code GIM for tubes, vacuum sample, with anticoagulant. The tubes are intended to be used in settings where venous blood samples would be collected by trained healthcare professionals for the collection, containment, preservation, transportation, and centrifugation of blood in a closed tube.

BD Vacutainer® Fluoride Blood Collection Tubes are available in a plastic configuration containing various additive combinations in a blended powder mixture. The blended powder mixture contains sodium fluoride, which acts as an antiglycolytic agent. The plastic tube configurations also include various additives which provide an anticoagulated specimen when used according to the instructions for use. Tubes include a Gray color-coded BD Hemogard™ Closure indicative of the Fluoride additive. Tube stoppers are lubricated with silicone to facilitate stopper insertion.

1.15 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® Fluoride Blood Collection Tubes	Predicate Device: BD Vacutainer® Plus Blood Collection Tubes containing Potassium Oxalate / Sodium Fluoride (K901449)	Comparison
Indications for Use	<p>BD Vacutainer® Fluoride Blood Collection Tubes are evacuated, sterile, single use, in vitro diagnostic medical devices available with Sodium Fluoride/Potassium Oxalate or Sodium Fluoride/Na₂EDTA. They are intended to be used by trained healthcare professionals for the collection, containment, preservation, transportation, and centrifugation of venous blood specimens as required for in vitro diagnostic testing. Plastic BD Vacutainer® Fluoride Blood Collection Tubes are used to collect whole blood for the generation of plasma samples.</p> <p>Blood collected in BD Vacutainer® Fluoride Blood Collection Tubes containing Sodium Fluoride/Potassium Oxalate are used for glucose and lactate determinations. Blood collected in BD Vacutainer® Fluoride Blood Collection Tubes containing Sodium Fluoride/Na₂EDTA are used for glucose determinations.</p>	<p>The BD Vacutainer® Fluoride Tubes are intended to provide a means of collecting, transporting, separating, and processing blood in a closed tube.</p>	<p>The intended use of the subject device is the same as the predicate with regard to the claims for collection, transportation, and separating (centrifugation) of blood for in vitro diagnostic use, with the subject device’s Indications for Use providing additional clarity on certain information consistent with current best practices. The addition of a specific reference to lactate is not considered a new intended use because the subject and predicate devices are both intended for determination of analytes in the blood that are stabilized by the glycolytic inhibition associated with the Fluoride additive present in the tubes.</p>
Intended Population	General Use – all populations	General Use – all populations	Identical
Evacuated Blood Collection Tube	Yes	Yes	Identical

Characteristic	Subject Device: BD Vacutainer® Fluoride Blood Collection Tubes	Predicate Device: BD Vacutainer® Plus Blood Collection Tubes containing Potassium Oxalate / Sodium Fluoride (K901449)	Comparison
Tube Dimensions, Material, and Draw Volume	BD Vacutainer® Sodium Fluoride / Potassium Oxalate Tubes: 13 x 75 mm, plastic, 2.0 mL 13 x 75 mm, plastic, 4.0 mL 13 x 100 mm, plastic, 6.0 mL BD Vacutainer® Sodium Fluoride / Na ₂ EDTA Tube: 13 x 75 mm, plastic, 2.0 mL	BD Vacutainer® Sodium Fluoride / Potassium Oxalate Tubes: 13 x 75 mm, plastic, 2.0 mL	The additional options for tube dimensions and draw volume do not raise different questions of safety and effectiveness as described below.
Sample Type	Plasma	Whole Blood Plasma	Identical
Additive Type, Application, and Concentration	Sodium Fluoride / Potassium Oxalate: 2.5 mg/mL / 2mg/mL, powder Sodium Fluoride / Na ₂ EDTA: 1.5 mg/mL / 3 mg/mL, powder	Sodium Fluoride / Potassium Oxalate: 2.5 mg/mL / 2mg/mL, powder	The additional additive configuration does not raise different questions of safety and effectiveness as described below.
Tube Closure/Color	BD Hemogard™ / Gray	BD Hemogard™ / Gray	Identical
Sterilization Method	Gamma Irradiation	Gamma Irradiation	Identical
Sterility Assurance Level (SAL)	10 ⁻³	10 ⁻³	Identical
Shelf Life	Varies by configuration	12 months	The shelf life is established based on available shelf-life testing so difference in shelf-life do not raise different questions of safety and effectiveness.

Characteristic	Subject Device: BD Vacutainer® Fluoride Blood Collection Tubes	Predicate Device: BD Vacutainer® Plus Blood Collection Tubes containing Potassium Oxalate / Sodium Fluoride (K901449)	Comparison
Packaging	Tray: 100 tubes Case: 1000 tubes (10x100)	Tray: 100 tubes Case: 1000 tubes (10x100)	Identical

1.16 Substantial Equivalence Discussion

Intended Use

The intended use of the subject device is the same as the predicate with regard to the claims for collection, transportation, and separating (centrifugation) of blood for in vitro diagnostic use. The subject device's Indications for Use provide additional clarity on the specimen type: venous whole blood collection for the generation of plasma. These clarifying statements do not alter the intended use of the device.

The subject device's Indications for Use statement makes reference to glucose and lactate determinations, while the predicate's Indications for Use statement only references the determination of glucose. The intended use for the subject and predicate devices are the same because both are intended for determination of analytes in the blood that are stabilized by the glycolytic inhibition associated with the Fluoride additive present in both tubes. Both the subject and predicate devices include an anticoagulant that can produce either a whole blood sample, or following centrifugation, a plasma sample.

The additional analyte determinations and sample matrices listed in the Indications for Use have been fully validated through clinical testing as compared to currently marketed comparator devices.

Therefore, the subject and predicate devices have the same intended use.

Technological Characteristics

Both the subject and predicate tubes have similar technological characteristics. They are evacuated, sterile, single use, in vitro diagnostic medical devices with Gray BD Hemogard™ closures. There is no change in sterilization method or sterility assurance level for these tubes. Since the clearance of the predicate K901449, there were additional minor changes. Changes broadly included minimal changes to the Indications for Use statement which does not constitute a new intended use, nor impact the overall diagnostic effect for the claimed uses; and updates to the shelf life based on test data currently available which does not raise different questions of safety or effectiveness. Differences between the subject and predicate and justification why such differences do not raise different questions of safety and effectiveness are described below:

Draw Volume: 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 to clinical studies to confirm appropriate blood to additive ratios are not new, and so do not result in different questions of safety and effectiveness.

Additive: Regarding the new Sodium Fluoride / Na₂EDTA tube configuration, there is an EDTA-based anticoagulant instead of an Oxalate-based anticoagulant in the subject device. Evaluation that the anticoagulant can provide a whole blood or plasma sample, and that it provides acceptable clinical results are not different questions of safety or effectiveness.

Shelf Life: Regarding the varied shelf-life, the shelf life is established based on available shelf-life testing 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.

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® Fluoride Blood Collection 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, and Breakage Resistance During Drop Testing. Additionally, Ship Testing was conducted to assess the functional performance of the packaging materials.

The BD Vacutainer® Fluoride 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 substantial equivalence of the subject device to the predicate device.

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 blood collected in the subject devices (BD Vacutainer® Fluoride Blood Collection 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 based on pre-determined acceptance criteria confirmed the functional clinical equivalence and performance of the BD Vacutainer® Fluoride Blood Collection Tubes in the identification of clinically relevant levels of glucose and lactate.

1.20 Conclusion

The proposed BD Vacutainer® Fluoride Blood Collection Tubes and predicate device have the same intended use, and any technological characteristics that differ from the predicate have been evaluated to demonstrate they do not result in different questions of safety and effectiveness. Non-Clinical and Clinical Performance Testing sufficiently support the determination of substantial equivalence of the BD Vacutainer® Fluoride Blood Collection Tubes. Based on information provided in this submission, the subject device is substantially equivalent to the predicate device.