December 20, 2023

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

Re: K230855
Trade/Device Name: BD Vacutainer® Serum Separator (SST™) Blood Collection Tubes
Regulation Number: 21 CFR 862.1675
Regulation Name: Blood Specimen Collection Device
Regulatory Class: Class II
Product Code: JKA
Dated: November 16, 2023
Received: November 17, 2023

Dear Matthew Tennen:

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,

Lindsey M. Coe -S

for Paula Caposino, PhD
Acting Division Deputy 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)*
K230855

Device Name
BD Vacutainer® Serum Separator (SST™) Blood Collection Tubes

Indications for Use *(Describe)*
The BD Vacutainer® Serum Separator (SST™) Blood Collection Tube is a sterile, single use tube used for the collection, containment, transport, and centrifugation of venous blood specimens to obtain and store serum for in vitro diagnostic testing. It is used in settings where a venous blood specimen is collected by a trained healthcare professional. The BD Vacutainer® Serum Separator (SST™) Blood Collection Tube is used for clinical laboratory testing in chemistry and for the monitoring of certain therapeutic drugs.

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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5 510(K) SUMMARY K230855

5.1 Device Name

BD Vacutainer® Serum Separator (SST™) Blood Collection Tubes

5.2 Summary Preparation Date:

Date: November 13, 2023

5.3 Submitted by:

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

Phone: (201) 847-6800

5.4 Contact:

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5.5 Alternate Contact:

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Director Regulatory Affairs
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5.6 Proprietary Name:

BD Vacutainer® Serum Separator (SST™) Blood Collection Tubes

5.7 Common or Usual Names:

Serum Separator Blood Collection Tube

5.8 Regulatory Information

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

5.9 Predicate Device

BD Vacutainer® PLUS SST™ Tube (K023075)

5.10 Device Establishment

Becton, Dickinson and Company

5.11 Registration Number:

2243072

5.12 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: 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 14971:2019 Medical Devices – Application of risk management to medical devices

5.13 Intended Use

The BD Vacutainer® Serum Separator (SST™) Blood Collection Tube is a sterile, single use tube used for the collection, containment, transport, and centrifugation of venous blood specimens to obtain and store serum for in vitro diagnostic testing. It is used in settings where a venous blood specimen is collected by a trained healthcare professional. The BD Vacutainer® Serum Separator (SST™) Blood Collection Tube is used for clinical laboratory testing in chemistry and for the monitoring of certain therapeutic drugs.

5.14 Device Description

BD Vacutainer® Serum Separator (SST™) Blood Collection Tubes are sterile blood collection tubes which use a controlled vacuum to pull a specific volume of blood into the tube. Each BD Vacutainer® Serum Separator (SST™) Blood Collection Tube consists of 1) a plastic tube manufactured from PET (polyethylene terephthalate), 2) a BD Hemogard™ cap assembly or Conventional rubber stopper with lubricant, 3) an inert polymer separator gel, and 4) a clot activator.

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® Serum Separator (SST™) Blood Collection Tube	Predicate Device - BD Vacutainer® SST Plus Tubes (K023075)	Comparison
Indications for Use	The BD Vacutainer® Serum Separator (SST™) Blood Collection Tube is a sterile, single use tube used for the collection, containment, transport, and centrifugation of venous blood specimens to obtain and store, serum for in vitro diagnostic testing. It is used in settings where a venous blood specimen is collected by a trained healthcare professional. The BD Vacutainer® Serum Separator (SST™) Blood Collection Tube is used for clinical laboratory testing in chemistry and for the monitoring of certain therapeutic drugs.	The Vacutainer™ PLUS SST™ Tube is a plastic evacuated blood collection tube with silica clot activator and gel that provides a means of collecting, transporting, separating, and processing blood in a closed tube. Blood collected in a Vacutainer™ PLUS SST Tube is primarily used for clinical laboratory testing in chemistry using patient serum but may be used for other assays requiring serum specimens as determined by the laboratory. In addition, the Vacutainer™ PLUS SST™ Tube is compatible with many commonly used therapeutic drugs therefore suitable for therapeutic drug monitoring (TDM). Blood can be collected, processed, and stored in a Vacutainer™ PLUS SST™ tube for at least 24 hours for therapeutic drug monitoring without large losses in recovery	There are minor changes to the indications for use wording to best align with the appropriate use of the product and available testing. The closed tube reference was removed as the processing and testing of the samples within the tube is dependent on the laboratory testing being performed. These changes do not result in a new intended use for the subject device.
Intended Population	General Use	General Use	Identical
Evacuated Blood Collection Tube	Yes	Yes	Identical
Tube Dimension	13 x 75 mm, 13 x 100 mm, 16 x 100 mm 16 x 125 mm	13 x 75 mm, 13 x 100 mm, 16 x 100 mm 16 x 125 mm	Identical
Tube Draw volumes	3.5mL, 4.0mL, 5.0mL, 7.5mL, 8.5mL, and 10mL	3.5mL, 4.0mL, 5.0mL, 7.5mL, 8.5mL, and 10mL	Identical
Sample Type	Serum	Serum	Identical

Additive Type	BD Vacutainer® Serum Separator (SST™): Silica clot activator	BD Vacutainer® Serum Separator (SST™): Silica clot activator	Identical
Additive Application/Quantity	Clot Activator Spray Dried Clot Activator amounts range from 2.1-4.3 mg/mL.	Clot Activator Spray Dried Clot Activator amounts range from 2.1-4.3 mg/mL.	Identical
Tube Material	PET (polyethylene terephthalate) plastic	PET (polyethylene terephthalate) plastic	Identical
Tube Closure	BD Hemogard™ / Gold cap with red stopper Conventional stopper: Red/Grey	BD Hemogard™ / Gold cap with red stopper Conventional stopper: Red/Grey	Identical
Sterilization Method	Gamma Irradiation	Gamma Irradiation	Identical
Sterility Assurance Level (SAL)	13x75mm Hemogard™/ 10^{-3} 13x100mm Hemogard™/ 10^{-3} or 10^{-6} 16x100mm Conventional/ 10^{-3} 16x125mm Conventional/ 10^{-3}	13x75mm Hemogard™/ 10^{-3} 13x100mm Hemogard™/ 10^{-3} 16x100mm Conventional/ 10^{-3} 16x125mm Conventional/ 10^{-3}	BD sterilizes the tubes at 10^{-3} or 10^{-6} based on size and configuration. Sterilization of some products at a different SAL does not raise any new questions of safety or effectiveness.
Shelf Life	10 to 12 months	12 months	Shelf-life durations are based on aged test data currently available. The tubes have demonstrated they maintain appropriate functionality over the stated shelf life. This difference does not raise new questions of safety or effectiveness.
Packaging	Unit – tube and closure Shelf – shrink wrapped polystyrene tray	Unit – tube and closure Shelf – shrink wrapped polystyrene tray	Identical

	Case – corrugated cardboard	Case – corrugated cardboard	

5.16 Substantial Equivalence Discussion

Intended Use/Indications for Use

The indications for use of the subject BD Vacutainer® Serum Separator (SST™) Blood Collection Tubes is considered the same as the previously cleared indications for use of the BD Vacutainer® Serum Separator (SST™) Blood Collection Tube under K023075. They are both intended to be used for the collection, transportation, separating, and processing blood in a tube for the testing of chemical analytes and for the monitoring of certain therapeutic drugs.

Any wording differences are intended to be a minor update to better clarify the products supported by the testing and possible uses in the laboratory setting. 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 identical technological characteristics. They are plastic, evacuated, sterile, single use, in vitro diagnostic medical devices with either gold BD Hemogard™ cap assemblies or Conventional stoppers with red/grey striping. While there have not been a significant number of technological changes, there have been two identifiable changes to the BD SST™ tubes. The first change was a change in the sterility assurance level for one of the tubes. The change in the sterilization assurance level (SAL) to 10^{-6} coincides with additional markets where the product is sold. The second change is relating to the shelf-life of the BD SST™ tubes. Depending on the configuration of the tube, the shelf life can be 10 months for (1 sku 13mm x 100mm) or 12 months (rest of the skus), whereas previously in 510(k), K023075, all tubes had a 12-month shelf life. Since the clearance of the predicate K023075, 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. These changes while different from the predicate submission do not raise new questions of safety or effectiveness and testing has demonstrated no impact to product performance.

5.17 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® Serum Separator (SST™) Blood Collection Tubes at time-zero and over the claimed shelf life: Draw Volume, X-Value, 2nd Stopper Pullout, Stopper/Shield Separation, Stopper Leakage (or blood

pooling), Tube Leakage, Resistance to Breakage During Drop Testing, Resistance to Breakage During Centrifugation, Barrier Formation following Centrifugation, and Barrier Integrity following Simulated Transport. 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 11-16 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 11-13 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 11 months of accelerated aging for SST™ products with a 10 month shelf life; and at least 13 months for SST™ 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.

5.18 Performance Testing – Clinical Summary

Clinical testing was conducted on whole blood collected in the subject device BD Vacutainer® Serum Separator (SST™) 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 confirmed the devices' clinical equivalence for chemistry analytes and in therapeutic drug monitoring (TDM) using these tubes. 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 multiple BD Vacutainer® Serum Separator Blood Collection Tubes (BD SST™) in comparison with a similarly marketed serum separator tube and demonstrate Within Tube Stability (WTS) for select routine and special chemistry analytes, therapeutic drugs, and select cardiac markers. Results were analyzed and found to be clinically acceptable when used under the conditions described in the Instructions for Use.

- Repeatability/Reproducibility: These studies evaluated the clinical performance of BD Vacutainer® Serum Separator (SST™) Blood Collection Tubes in comparison with a similarly marketed serum separator tube for selected chemistry analytes and therapeutic drugs for repeatability (within tube) by testing each tube in duplicate, as well as lot-to-lot reproducibility and tube-to-tube reproducibility by testing two tubes per lot per subject across 3 lots on two different instrument platforms. Results were analyzed and found to be clinically acceptable when used under the conditions described in the Instructions for Use.

- Shelf-Life: This study evaluated the performance of BD Vacutainer® Serum Separator Tubes (BD SST™) at the end of shelf life (EOSL) in comparison with BD SST™ Tubes that were recently manufactured for selected chemistry analytes and therapeutic drugs. Three lots for

each SKU of EOSL tubes were evaluated in this study. Results were analyzed and found to be clinically acceptable when used under the conditions described in the Instructions for Use

Results based on pre-determined acceptance criteria demonstrated the BD Vacutainer® Serum Separator (SST™) Blood Collection Tube are suitable for use evaluating chemistry analytes and in therapeutic drug monitoring (TDM) testing.

5.19 Conclusion

The proposed BD Vacutainer® Serum Separator (SST™) Blood Collection 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® Serum Separator (SST™) Blood Collection Tubes. Based on information provided in this submission the proposed device is substantially equivalent to the predicate device.