March 13, 2026

Becton, Dickinson and Company
Matthew Tennen
Staff Regulatory Affairs Specialist
1 Becton Dr.
Franklin Lakes, New Jersey 07417

Re: K252040
Trade/Device Name: BD Vacutainer® Plasma Separator Tubes (PST™), BD Vacutainer® Sodium Heparin Blood Collection Tubes
Regulation Number: 21 CFR 862.1675
Regulation Name: Blood specimen collection device
Regulatory Class: Class II
Product Code: JKA, GIM
Dated: February 13, 2026
Received: February 13, 2026

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and 21 CFR 820.70) and document changes and approvals in the Medical Device File (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 Management System Regulation (QMSR) (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,

PAULA V. CAPOSINO -S

Paula Caposino, Ph.D.
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)*
K252040

Device Name
• BD Vacutainer® Plasma Separator Tubes (PST™)
• BD Vacutainer® Sodium Heparin Blood Collection Tubes

Indications for Use *(Describe)*
• BD Vacutainer® Plasma Separator Tubes (PST™)

The BD Vacutainer® Plasma Separator Tubes (PST™) are evacuated, sterile, single-use, in vitro diagnostic medical devices. They are intended to be used by healthcare professionals for the collection, containment, and transport of human venous blood specimens, and the subsequent separation and storage of plasma for in vitro diagnostic testing.
BD Vacutainer® Plasma Separator Tubes (PST™) are used for testing chemistry analytes in plasma samples.

• BD Vacutainer® Sodium Heparin Blood Collection Tubes

The BD Vacutainer® Sodium Heparin Blood Collection Tube is a sterile, single-use, in vitro diagnostic medical device for the collection, containment, transport of human venous blood specimens, and the subsequent separation of plasma by centrifugation, for in vitro diagnostic testing. It is used in settings where a venous blood specimen is collected by a healthcare professional.
The BD Vacutainer® Sodium Heparin Blood Collection Tube is used for testing lithium.

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.

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Table of Contents

List of Tables

1 510(K) SUMMARY

1.1 Device Name

BD Vacutainer® Plasma Separator Tubes (PST™)

BD Vacutainer® Sodium Heparin Blood Collection Tubes

1.2 Summary Preparation Date:

Tuesday, March 12, 2026

1.3 Submitted by:

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

Phone: (201) 847-6800

1.4 Contact:

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Staff Regulatory Affairs Specialist,
BD Specimen Management, Regulatory Affairs
Email: Matthew.B.Tennen@bd.com
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1.5 Alternate Contact:

Nathan Carrington
Vice President,
BD Specimen Management, Regulatory Affairs
Email: Nate.Carrington@bd.com
Phone: (317) 280-0921

1.6 Proprietary Name:

- BD Vacutainer® Plasma Separator Tubes (PST™),
- BD Vacutainer® Sodium Heparin Blood Collection Tubes

1.7 Common or Usual Names:

BD Plasma Tubes

BD Vacutainer® Plasma Separator Tube (PST™) Blood Collection Tubes

1.8 Regulatory Information

Classification Name: Tubes, Vacuum Sample, With Anticoagulant. Vials, systems, serum separators, blood collection
Classification Regulation: 21 CFR § 862.1675
Regulatory Class: Class II
Product Code: JKA, GIM

1.9 Predicate Device

BD Vacutainer® Brand PLUS PST™ Plasma Separator Tube (K945952)

BD Vacutainer® Brand Plus Sodium Heparin Tube (K944566)

1.10 Device Establishment

Becton, Dickinson and Company

1.11 Registration Number:

2243072

1.12 Performance Standards:

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)].

ISO 11137-2 Third edition 2013-06 [Including AMD1:2022] Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose [Including Amendment 1 (2022)]

ISO 11137-3:2017 Sterilization of health care products - Radiation - Part 3: Guidance on dosimetric aspects of development, validation and routine control.

ISO 11737-1:2018 Sterilization of health care products - Microbiological methods - Part 1: Determination of a population of microorganisms on products.

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.

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 Indications for Use

BD Vacutainer® Plasma Separator Tubes (PST™)

The BD Vacutainer® Plasma Separator Tubes (PST™) are evacuated, sterile, single-use, in vitro diagnostic medical devices. They are intended to be used by healthcare professionals for the collection, containment, and transport of human venous blood specimens, and the subsequent separation and storage of plasma for in vitro diagnostic testing.

BD Vacutainer® Plasma Separator Tubes (PST™) are used for testing chemistry analytes in plasma samples.

BD Vacutainer® Sodium Heparin Blood Collection Tubes

The BD Vacutainer® Sodium Heparin Blood Collection Tube is a sterile, single-use, in vitro diagnostic medical device for the collection, containment, transport of human venous blood specimens, and the subsequent separation of plasma by centrifugation, for in vitro diagnostic testing. It is used in settings where a venous blood specimen is collected by a healthcare professional.

The BD Vacutainer® Sodium Heparin Blood Collection Tube is used for testing lithium.

1.14 Device Description

BD Vacutainer® Plasma Separator Tubes (PST™) and BD Vacutainer® Sodium Heparin 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® Plasma Separator Tube (PST™) and BD Vacutainer® Sodium Heparin 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, and 3) a spray-dried anti-coagulated formulated from lithium or sodium heparin. The BD Vacutainer® Plasma Separator Tubes (PST™) additionally include an inert polymer separator gel.

1.15 Substantial Equivalence

The subject and predicate devices are substantially equivalent as described in Table 1 and Table 2

Table 1: Substantial Equivalence Comparison: BD Vacutainer® Plasma Separator Tubes (PST™)

Characteristic	Subject Device - •BD Vacutainer® Plasma Separator Tubes (PST™)	Predicate Device - VACUTAINER® BRAND PLUS PST™ PLASMA SEPARATION TUBE (K945952)	Comparison
Indications for Use	The BD Vacutainer® Plasma Separator Tubes (PST™) are evacuated, sterile, single-use, in vitro diagnostic medical devices. They are intended to be used by healthcare professionals for the collection, containment, and transport of human venous blood specimens, and the subsequent separation and storage of plasma for in vitro diagnostic testing. BD Vacutainer® Plasma Separator Tubes (PST™) are used for testing chemistry analytes in plasma samples.	The Vacutainer® Brand PLUS PST™ Plasma Separator Tube is an evacuated blood collection tube which provides a means of collecting, separating, transporting and processing venous blood in a closed plastic tube system. Blood collected in a PST™ tube is used for clinical laboratory assays involving the use of patient plasma.	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.
Product Code	JKA (tubes, vials, systems, serum separators, blood collection), GIM (tubes, vacuum sample, with anticoagulant)	JKA (tubes, vials, systems, serum separators, blood collection)	Product Code GIM is being added as it indicates the use of an anticoagulant and is appropriate to describe the plasma tubes.
Classification Number	21 CFR § 862.1675	21 CFR § 862.1675	Identical
Intended Population	General Use	General Use	Identical
Evacuated Blood Collection Tube	Yes	Yes	Identical
Tube Dimension	13 x 75 mm, 13 x 100 mm	13 x 75 mm, 13 x 100 mm 16 x 100 mm	Identical to 2 of the 3 sizes of the predicate.
Tube Draw volumes	3 mL, 3.5mL, and 4.5mL	3 mL, 3.5mL, 4.5mL and 8mL	Identical to 3 of the 4 predicate volumes

Characteristic	Subject Device - •BD Vacutainer® Plasma Separator Tubes (PST™)	Predicate Device - VACUTAINER® BRAND PLUS PST™ PLASMA SEPARATION TUBE (K945952)	Comparison
Sample Type	Plasma	Plasma	Identical
Plasma Separator	Barrier Gel	Barrier Gel	Identical
Gel Quantity	0.9-1.0 g	0.9-1.75 g	Identical to each size offering available.
Additive Type	Lithium Heparin	Lithium Heparin	Identical
Additive Application/Quantity	Lithium Heparin Spray Dried Additive amount ranges from 56-83 I.U.	Lithium Heparin Spray Dried Additive amount ranges from 56-126 I.U.	Identical to each model offering available.
Tube Material	PET (polyethylene terephthalate) plastic	PET (polyethylene terephthalate) plastic	Identical
Tube Closure	BD Hemogard™ Light Green with Dark Grey Stopper	BD Hemogard™ Light Green with Dark Grey Stopper Conventional stopper: Light Green	Identical to each model offering available.
Sterilization Method	Gamma Irradiation	Gamma Irradiation	Identical
Sterility Assurance Level (SAL)	10^{-3}	10^{-3}	Identical

Characteristic	Subject Device - •BD Vacutainer® Plasma Separator Tubes (PST™)	Predicate Device - VACUTAINER® BRAND PLUS PST™ PLASMA SEPARATION TUBE (K945952)	Comparison
Shelf Life	12 months	12-16 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.

Table 2: Substantial Equivalence Comparison: BD Vacutainer® Sodium Heparin Blood Collection Tubes

Characteristic	Subject Device - BD Vacutainer® Sodium Heparin Blood Collection Tube	Predicate Device – VACUTAINER® BRAND PLUS SODIUM HEPARIN TUBE (K944566)	Comparison
Indications for Use	The BD Vacutainer® Sodium Heparin Blood Collection Tube is a sterile, single use, in vitro diagnostic medical device for the collection, containment, transport of human venous blood specimens, and the subsequent separation of plasma by centrifugation, for in vitro diagnostic testing. It is used in settings where a venous blood specimen is collected by a healthcare professional. The BD Vacutainer® Sodium Heparin Blood Collection Tube is used for testing lithium.	The VACUTAINER® Brand PLUS Sodium Heparin Tube is an evacuated blood collection tube which provides a means of collecting, anticoagulating, transporting, and processing venous blood in a closed plastic tube system. Blood collected in a Sodium Heparin Tube is used for clinical laboratory assays using plasma.	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.
Product Code	JKA (tubes, vials, systems, serum separators, blood collection), GIM (tubes, vacuum sample, with anticoagulant)	JKA (tubes, vials, systems, serum separators, blood collection)	Product Code GIM is being added as it indicates the use of an anticoagulant and is appropriate to describe the plasma tubes.
Classification Number	21 CFR § 862.1675	21 CFR § 862.1675	Identical
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	13 x 75 mm, 13 x 100 mm, 16 x 100 mm	Identical
Tube Draw volumes	4 mL, 6 mL, and 10 mL	2 mL, 4 mL, 6 mL, and 10 mL	Identical to 3 of the 4 volumes of the predicate.
Sample Type	Plasma	Plasma	Identical

Characteristic	Subject Device - BD Vacutainer® Sodium Heparin Blood Collection Tube	Predicate Device – VACUTAINER® BRAND PLUS SODIUM HEPARIN TUBE (K944566)	Comparison
Additive Type	Sodium Heparin	Sodium Heparin	Identical
Additive Application/Quantity	Sodium Heparin Spray Dried Additive amount ranges from 75-158 USP Units/mL	Sodium Heparin Spray Dried Additive amount ranges from 33-158 I.U.	Identical for the models of product in scope. There is no longer a 2mL draw option available of the product which accounts for the alteration in the low range of the additive.
Tube Material	PET (polyethylene terephthalate) plastic	PET (polyethylene terephthalate) plastic	Identical
Tube Closure	BD Hemogard™ Green cap with Dark Grey stopper Conventional stopper: Green	BD Hemogard™ Green cap with Dark Grey stopper Conventional stopper: Green	Identical
Sterilization Method	Gamma Irradiation	Gamma Irradiation	Identical
Sterility Assurance Level (SAL)	10^{-3}	10^{-3}	Identical
Shelf Life	16-17 months	16-18 months	Shelf-life durations are based on aged test data currently available. The tubes have

Characteristic	Subject Device - BD Vacutainer® Sodium Heparin Blood Collection Tube	Predicate Device – VACUTAINER® BRAND PLUS SODIUM HEPARIN TUBE (K944566)	Comparison
			demonstrated they maintain appropriate functionality over the stated shelf life. This difference does not raise new questions of safety or effectiveness.

1.16 Substantial Equivalence Discussion

Intended Use/Indications for Use

The indications for use of the subject BD Vacutainer® Plasma Separator Tube (PST™) and BD Vacutainer® Sodium Heparin Blood Collection Tube are considered the same as the previously cleared indications for use of the BD Vacutainer® Plasma Separator Tubes (PST™) under K945952 and BD Vacutainer® Plus Sodium Heparin Blood Collection Tubes under K944566. All devices are intended to be used for the collection, containment, and transport of human venous blood specimens and the subsequent separation and storage of plasma for in vitro diagnostic testing.

The subject device indications for use statements are almost identical to the predicate indications for use statements. The subject indications for use statements make minor adjustments to the language to align with current expectations for the content of indications for use statements and remove the closed tube phrase. The closed tube indication has been removed because the handling and test method of a tube is determined by the laboratory, which may not require the tube to be closed. This change does not represent a change in intended use; rather it allows for the test laboratory to determine the appropriate configuration of the tube (closed or open) for its systems and methods, consistent with current practices. 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 criterion for a determination 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 light green or green BD Hemogard™ cap assemblies or green Conventional stoppers. The subject and predicate devices are available with various tube dimensions and draw volume configurations. The subject and predicate devices include the same gel quantities (PST™ only) and use the same quantity and type of spray dried heparin additives to prevent sample coagulation.

Changes to shelf life of the tubes offered are subject to the shelf life testing available. These changes are supported with non-clinical and analytical/clinical data provided within this submission and do not raise new questions of safety or effectiveness, and testing has demonstrated no impact to product performance.

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 Vacutainer® Plasma Blood Collection Tubes continue to perform as intended.

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, and supplier changes.

1.17 Performance Testing – Bench Summary

Benchtop testing was conducted to evaluate the following attributes of the BD Vacutainer® Plasma Separator Tube (PST™) and BD Vacutainer® Sodium Heparin Blood Collection Tube over shelf life: Draw Volume, X-Value, Second Stopper Pullout, Stopper/Shield Separation, Stopper Leakage, Tube Leakage, and Resistance to Breakage during Centrifugation and Drop Testing. Stopper/Shield Separation Testing was only applicable to products with a Hemogard™ shield component. PST™ products, which contain a gel component, were also evaluated for Barrier Formation during Centrifugation and Barrier Integrity after 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 manufactured to meet specifications under a Manufacturing Work Order and labeled as "Investigational Use Only." All testing was 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 dosage. Shelf life testing leveraged both accelerated and real-time aging. Accelerated aging occurred by subjecting devices to storage at 40°C and 50% Relative Humidity (RH) to age devices between 13 to 18 months (1 month beyond the claimed shelf life, depending on the SKU) according to the Arrhenius equation. Real-time aging subjected devices to storage at 25°C and 50% RH over 13 to 18 months. Test intervals were selected as at least 13 months of accelerated aging for BD Plasma Tube products with a 12 month shelf life; and up to 18 months for BD Plasma Tube products with a 17 month shelf life. Real time aging studies were completed to confirm all accelerated aging data, and both sets of aging results are presented in the bench testing report.

These performance tests demonstrate substantial equivalence of the subject devices to the predicate devices.

1.18 Performance Testing – Analytical/Clinical Summary

Analytical testing was conducted on plasma collected in the subject devices, BD Vacutainer® Plasma Separator Tubes (PST™) and BD Vacutainer® Sodium Heparin Blood Collection Tubes, and similar comparator tubes to demonstrate analytical equivalence ("method comparison study" is the term FDA uses for this; internally BD has designated it "clinical equivalence"). Additional analytical testing was completed to evaluate Within-Tube Stability, Shelf-Life Performance, and Repeatability/ Reproducibility. Analytical test results confirmed the devices' equivalence for general chemistry analytes. A summary of the analytical studies completed is included below:

- Method Comparison (Clinical Equivalence) and Within-Tube Stability SUST074, SUST094, and SUST076: The purpose of these studies was to evaluate the Clinical Equivalence of multiple BD Vacutainer® Plasma Blood Collection Tubes in comparison with a similarly marketed plasma tubes and demonstrate Within Tube Stability (WTS) for select routine and special chemistry analytes and select cardiac markers. Results were analyzed and found to be clinically acceptable when used under the conditions described in the Instructions for Use. When using BD Vacutainer® Sodium Heparin Blood Collection Tubes for testing lithium, separation of plasma from the cells and subsequent testing should take place within 2 hours of collection. BD Vacutainer® Plasma Separator Tubes (PST™) claim analyte stability as supported by analytical/clinical results and as indicated in the instructions for use.

- Shelf-Life: This study, SUST079, evaluated the performance of BD Vacutainer® Plasma Separator Tube (PST™) and BD Vacutainer® Sodium Heparin Blood Collection Tube at the end of shelf life (EOSL) in comparison with BD Vacutainer® Plasma Separator Tube (PST™) and BD Vacutainer® Sodium Heparin Blood Collection Tube that were recently manufactured for selected chemistry analytes. Three lots for each SKU of EOSL tubes were evaluated in this study. Results were analyzed and established the analytical/clinical shelf-life performance for the BD Vacutainer® Plasma Separator Tube (PST™) and BD Vacutainer® Sodium Heparin Blood Collection Tube.

- Repeatability/Reproducibility: This study, SUST075, evaluated the clinical performance of BD Vacutainer® Plasma Separator Tube (PST™) and BD Vacutainer® Sodium Heparin Blood Collection Tube in comparison with similarly marketed plasma tubes for selected chemistry analytes 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.

1.19 Conclusion

The proposed BD Vacutainer® Plasma Separator Tube (PST™) and BD Vacutainer® Sodium Heparin Blood Collection Tube and predicate devices have the same intended use, principle of operation, and technological characteristics. Non-Clinical and Analytical/Clinical Performance Testing sufficiently support the determination of substantial equivalence of the BD Vacutainer® Plasma Separator Tube (PST™) and BD Vacutainer® Sodium Heparin Blood Collection Tube. Changes made to these tubes do not raise any new questions of safety or effectiveness. Based on information provided in this submission, the proposed device is substantially equivalent to the predicate device.