December 1, 2023

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

Re: K230391
Trade/Device Name: BD MiniDraw™ Capillary Blood Collection System with BD MiniDraw™ SST™ Capillary Blood Collection Tube
Regulation Number: 21 CFR 862.1675
Regulation Name: Blood Specimen Collection Device
Regulatory Class: Class II
Product Code: JKA
Dated: October 31, 2023
Received: October 31, 2023

Dear Katherine Lemus:

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,

Marianela Perez-torres -S

Marianela Perez-Torres, Ph.D
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K230391

Device Name
BD MiniDraw™ Capillary Blood Collection System with BD MiniDraw™ SST™ Capillary Blood Collection Tube

Indications for Use *(Describe)*
BD MiniDraw™ Capillary Blood Collection System with BD MiniDraw™ SST™ Capillary Blood Collection Tube is used to collect, separate, transport, and store capillary blood samples from individuals 18 years and older. The system is comprised of a capillary blood collection tube and the BD MiniDraw™ Finger Sleeve that is intended for use by a trained healthcare worker.

BD MiniDraw™ Capillary Blood Collection System with BD MiniDraw™ SST™ Capillary Blood Collection Tube is intended for sample collection used in the measurement of Alkaline Phosphatase (ALKP), Alanine Aminotransferase (ALT), Sodium (Na), Chloride (Cl), Albumin (ALB), Blood Urea Nitrogen (BUN), Calcium (Ca), Creatinine (CREAT), Total Bilirubin (TBIL), Total Protein (TP), High Density Lipoprotein (HDL), Low Density Lipoprotein (LDL), Total Cholesterol (CHOL), and Triglycerides (TRIG).

BD MiniDraw™ SST™ Capillary Blood Collection Tube is not intended for use with other parameters/analytes.

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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510(K) SUMMARY

Device Name:

BD MiniDraw™ Capillary Blood Collection System with BD MiniDraw™ SST™ Capillary Blood Collection Tube

Summary Preparation Date:

11/28/2023

Submitted by:

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

Phone: (201) 847-6800

Contact:

Katherine Kenner Lemus
Staff Regulatory Affairs Specialist
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Proprietary Names:

The BD MiniDraw™ Capillary Blood Collection System with BD MiniDraw™ SST™ Capillary Blood Collection Tube (MiniDraw™ SST™ System) includes the following components:

- BD MiniDraw™ SST™ Capillary Blood Collection Tube (MiniDraw™ SST™ Tube)
- BD MiniDraw™ Finger Sleeve
- BD MiniDraw™ Finger Sizing Tool
- BD MiniDraw™ Capillary Tube Adapter SST™
- BD MiniDraw™ Cap Removal Tool

These devices are components of the BD MiniDraw™ Capillary Blood Collection System.

Common Names:

FDA Product Code Name(s): Tubes, Vials, Systems, Serum Separators, Blood Collection

Regulatory Information

Regulatory information for devices included in this submission is as follows:

Classification Name: Tubes, Vials, Systems, Serum Separators, Blood Collection
Classification Regulation: 21 CFR §862.1675
Regulatory Class: Class II
Panel: Clinical Chemistry
Product Code(s): JKA

Predicate Device

Predicate: K991702 BD Microtainer® SST™

Device Establishment

Becton, Dickinson and Company
Registration Number: 2243072

Performance Standards

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

ASTM D999-08(2015) Standard Test Methods for Vibration Testing of Shipping Containers

ASTM D4728-17 Standard Test Method for Random Vibration Testing of Shipping Containers

ASTM D6653/D6653M-13(2021) Standard Test Methods for Determining the Effects of High Altitude on Packaging Systems by Vacuum Method

ASTM D5276-19 Standard Test Method for Drop Test of Loaded Containers by Free Fall

ASTM D5264-98(2019) Standard Practice for Abrasion Resistance of Printed Materials by the Sutherland Rub Tester

ISO/IEC 15415:2011 Information technology — Automatic identification and data capture techniques — Bar code symbol print quality test specification — Two-dimensional symbols

ASTM F1886/F1886M-16 Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection

ISO 11607-1 Second edition 2019-02 Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems

ASTM F1980-21 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices

ISO 10993-1:2018 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process

EN ISO 10993-2:2006 Biological evaluation of medical devices - Part 2: Animal welfare requirements

ISO 10993-4:2017 Biological evaluation of medical devices – Part 4: Selection of tests for interactions with blood

ISO 10993-5:2009 Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity

ISO 10993-10:2010 Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization

ISO 10993-12:2012 Biological evaluation of medical devices – Part 12: Sample preparation and reference materials

ISO 10993-17:2002 Biological evaluation of medical devices – Part 17: Establishment of allowable limits for leachable substances

ISO 10993-18:2020 Biological evaluation of medical devices – Part 18: Chemical characterization of materials

ISO 10993-23:2021, Biological Evaluation of Medical Devices - Part 23: Tests for irritation

Intended Use

BD MiniDraw™ Capillary Blood Collection System with BD MiniDraw™ SST™ Capillary Blood Collection Tube is used to collect, separate, transport, and store capillary blood samples from individuals 18 years and older. The system is comprised of a capillary blood collection tube and the BD MiniDraw™ Finger Sleeve that are intended for use by a trained healthcare worker.

BD MiniDraw™ Capillary Blood Collection System with BD MiniDraw™ SST™ Capillary Blood Collection Tube is intended for sample collection used in the measurement of Alkaline Phosphatase (ALKP), Alanine Aminotransferase (ALT), Sodium (Na), Chloride (Cl), Albumin (ALB), Blood Urea Nitrogen (BUN), Calcium (Ca), Creatinine (CREAT), Total Bilirubin (TBIL), Total Protein (TP), High Density Lipoprotein (HDL), Low Density Lipoprotein (LDL), Total Cholesterol (CHOL), and Triglycerides (TRIG).

BD MiniDraw™ SST™ Capillary Blood Collection Tube is not intended for use with other parameters/analytes.

Device Description

The BD MiniDraw™ Capillary Blood Collection System family of devices is a capillary blood collection solution designed to collect, separate, transport, and store capillary blood samples from a finger stick that are clinically equivalent to both capillary and venous comparator tubes. The system is designed to standardize the capillary blood collection procedure, thereby allowing users who are trained to use the subject device, but who may not otherwise have been trained in phlebotomy, to collect fingerstick capillary blood samples. The BD MiniDraw™ Capillary Blood Collection System is intended to be used by trained healthcare workers in ancillary healthcare facilities and clinical use environments (e.g., retail pharmacies, clinics).

The BD MiniDraw™ Capillary Blood Collection System with BD MiniDraw™ SST™ Capillary Blood Collection Tube (MiniDraw™ SST™ System) is a subset of components in the BD MiniDraw™ Capillary Blood Collection System. It is intended to collect a whole blood specimen from a finger and deliver a serum sample for measurement of specific analytes listed in the Indication for Use. The BD MiniDraw™ SST™ Capillary Blood Collection Tube (MiniDraw™ SST™ Tube) contains a silica-based clot activator solution and a gel that creates a barrier between serum and cells during centrifugation. The tube has a unique barcode that links the tube with the patient.

The MiniDraw™ SST™ Tube is designed to be used in combination with the BD MiniDraw™ Finger Sleeve (available in four sizes), the BD Microtainer® Contact-Activated Lancet (clearance K223243), and three accessories; BD MiniDraw™ Finger Sizing Tool, BD MiniDraw™ Capillary Tube Adapter SST™ and BD MiniDraw™ Cap Removal Tool.

Substantial Equivalence

A comparison of the proposed and predicate device is provided in Table 1.

A discussion of equivalence between the subject device and the predicate device is provided in Table 2.

Table 1: Substantial Equivalence Comparison

Characteristic	Subject Device MiniDraw™ SST™ System	Predicate BD Microtainer® SST™ K991702	Comparison
Indications for Use	BD MiniDraw™ Capillary Blood Collection System with BD MiniDraw™ SST™ Capillary Blood Collection Tube is used to collect, separate, transport, and store capillary blood samples from individuals 18 years and older. The system is comprised of a capillary blood collection tube and the BD MiniDraw™ Finger Sleeve that is intended for use by a trained healthcare worker. BD MiniDraw™ Capillary Blood Collection System with BD MiniDraw™ SST™ Capillary Blood Collection Tube is intended for sample collection used in the measurement of Alkaline Phosphatase (ALKP), Alanine Aminotransferase (ALT), Sodium (Na), Chloride (Cl), Albumin (ALB), Blood Urea Nitrogen (BUN), Calcium (Ca), Creatinine (CREAT), Total Bilirubin (TBIL), Total Protein (TP), High Density Lipoprotein (HDL), Low Density Lipoprotein (LDL), Total Cholesterol (CHOL), and Triglycerides (TRIG). BD MiniDraw™ SST™ Capillary Blood Collection Tube is not intended for use with other parameters/analytes.	The MICROTAINER® Brand Chemistry Tubes with MICROGARD™ Closures are intended to collect, transport and store skin puncture blood specimens for chemistry determination requiring serum or heparinized plasma.	Both devices are intended to collect, transport and store blood for testing serum for chemistry analytes. MiniDraw™ SST™ System is intended for capillary blood collection for chemistry determinations requiring serum. It is not intended for those determinations requiring heparinized plasma.

Characteristic	Subject Device MiniDraw™ SST™ System	Predicate BD Microtainer® SST™ K991702	Comparison
Intended Population	Adults – individuals aged 18 and older, limited by correct fit of the Finger Sleeve	General Use – all populations	Use of the MiniDraw™ is limited to individuals aged 18 and older whose finger measurements match the available sizes of Finger Sleeves
Intended Use Environment	Ancillary healthcare facilities, clinical and laboratory environments	Clinical and laboratory environments	MiniDraw™ SST™ System adds ancillary healthcare facility use environment
Intended User	Trained Healthcare Workers: phlebotomists, clinicians, pharmacists, pharmacy technicians, and other healthcare workers trained in the use of the device	Trained Healthcare Workers: phlebotomists and clinicians	MiniDraw™ SST™ System adds pharmacists, pharmacy technicians, and other healthcare workers trained in the use of the device
Analytes	Alkaline Phosphatase (ALKP), Alanine Aminotransferase (ALT), Sodium (Na), Chloride (Cl), Albumin (ALB), Blood Urea Nitrogen (BUN), Calcium (Ca), Creatinine (CREAT), Total Bilirubin (TBIL), Total Protein (TP), High Density Lipoprotein (HDL), Low Density Lipoprotein (LDL), Total Cholesterol (CHOL), and Triglycerides (TRIG)	Chemistry analytes	MiniDraw™ SST™ System tests for labeled subset of analytes in the predicate devices.

Characteristic	Subject Device MiniDraw™ SST™ System	Predicate BD Microtainer® SST™ K991702	Comparison
Single Use	Yes	Yes	Identical
Sterility	Non-sterile	Non-sterile	Identical
Centrifugation	Cap Down	Cap Up	MiniDraw™ SST™ System is intended for centrifugation when oriented with the cap down (reverse centrifugation).
Sample Type	Capillary	Capillary	Identical
Additive	Clot activator and gel separator	Clot activator and gel separator	Identical
Materials	Container: Polypropylene Collector: methylAcrylonitrileButedieneStyrene (mABS) Cap: Polypropylene + Thermoplastic elastomer (TPE) Finger Sleeve: Polypropylene + colorant	Container: Polypropylene Collector: Polypropylene Cap: High Density Polyethylene Finger Sleeve: N/A	MiniDraw™ SST™ System uses various different materials.
Container Design	Flat bottomed with rounded recessed plug	Flat Bottomed with rounded recessed plug	Identical
Container Dimensions	13x40mm	9x40mm	Varies by product
Finger Sleeve	Yes	N/A	MiniDraw™ SST™ System introduces use of the Finger Sleeve
Finger Sizing Tool	Yes	N/A	MiniDraw™ SST™ System introduces use of the finger sizing tool

Characteristic	Subject Device MiniDraw™ SST™ System	Predicate BD Microtainer® SST™ K991702	Comparison
Cap Removal Tool	Yes	N/A	MiniDraw™ SST™ System introduces use of the cap removal tool
Shelf-Life	9 months	15 months	Varies by Product

Table 2: Substantial Equivalence Discussion

Difference	Substantial Equivalence to the Predicate
Intended Use/Included Analytes/Panels	Both the subject and predicate device are intended to collect, transport and store capillary blood for analysis. The intended use statement for the predicate refers to "skin prick" collection instead of "capillary" but these are understood to be equivalent. MiniDraw™ SST™ System is intended for a narrower subset of targeted analytes than the BD Microtainer® SST™ (i.e., chemistry). The selection of analytes included in this submission are supported by clinical testing which demonstrates that the results are clinically equivalent. Because the proposed list of analytes is considered to be a subset of those cleared for use with the predicate device, this is not considered to be a new intended use.
Intended Population	Intended for adult individuals aged 18 and older and whose fingers fit in one of the four finger sleeve sizes.
Addition of Ancillary Healthcare Facility Use Environments	MiniDraw™ SST™ System is intended for use in laboratory and clinical use environments. Blood collection may also occur at ancillary healthcare facilities (e.g., retail pharmacies, retail clinics). This does not change the primary use of the device or the intended patient population and so this use environment does not result in a new intended use. Whether the intended trained user is capable of using the device appropriately has been validated (via Human Factors and Clinical testing).

Difference	Substantial Equivalence to the Predicate
Intended User	The device is designed for users who may not have been previously trained in phlebotomy but who are trained in the correct use of the MiniDraw™ SST™ System (i.e., pharmacists, pharmacy technicians, and other healthcare workers trained in the use of the device). Ultimately, the users of both the subject and predicate devices post-training are considered to be "trained healthcare workers," so this difference is not considered a new intended use. The workflow steps of the subject device have been designed and carefully evaluated to ensure no new serious adverse events or use-related hazards that may negatively impact the overall benefit-risk profile of capillary blood collection devices were introduced when used by the intended users described in this submission. Human factors testing and clinical evaluations performed with the targeted user groups demonstrated no increase in risk of errors in the handling and processing of capillary blood samples (i.e., centrifuging, storage and transport) and there was no observed increase in erroneous downstream test results.
Reverse Centrifugation	MiniDraw™ SST™ Tube is designed to be centrifuged in the cap down position so that the gel separator and clot are centrifuged into the cap, which is removed and discarded prior to testing, maximizing the serum quantity available for sampling and reducing the possibility of probe contamination during testing. Regardless of the orientation during centrifugation, the assessment of appropriate gel formation, clot separation, and absence of leakage during centrifugation/handling are not new questions of safety or effectiveness.
Materials	The BD MiniDraw™ SST™ Capillary Blood Collection Tube container is made from polypropylene the same as the predicate. The other materials used in the components of the subject device differ. The collector of the predicate is also made of polypropylene as it is molded in a single piece, and the collector of the MiniDraw™ SST™ Tube is made from mABS which is a clearer plastic material intended to enhance blood visualization during collection. The cap on the MiniDraw™ SST™ Tube is made from Polypropylene and TPE to ensure seal integrity during reverse centrifugation. The BD MiniDraw™ Finger Sleeve, which does not have a matching analog from the predicate device, is made from polypropylene mixed with colorants that were found to be both appropriate for the intended use of the device and compatible with biocompatibility considerations. The assessment of whether these materials do not negatively impact device performance nor have any negative effects on clinical results are not new questions of safety or effectiveness. Non-Clinical Performance testing, Clinical testing, and Biocompatibility testing demonstrated the devices perform as intended.

Difference	Substantial Equivalence to the Predicate
Container Dimensions	The container dimensions of the MiniDraw™ SST™ Tube are designed for optimal functioning of the device. For both the subject and predicate capillary devices, use of a tube adapter is common to ensure compatibility with test instruments, and thus tube dimensional differences do not raise new questions of safety or effectiveness.
Combination Devices and Accessories	The MiniDraw™ SST™ System is a subset of component devices that are intended to be used together during capillary blood collection and laboratory analysis. The MiniDraw™ SST™ Tube is designed to be used in combination with the BD MiniDraw™ Finger Sleeve (available in four sizes) and three accessories; BD MiniDraw™ Finger Sizing Tool, BD MiniDraw™ Capillary Tube Adapter SST™ and BD MiniDraw™ Cap Removal Tool. The sample volume and quality requirements exist for a capillary sample regardless of whether a patient's finger is squeezed by the Finger Sleeve or manually. The Finger Sizing Tool is optional as correct sizing of the Finger Sleeve may be assessed with the sleeve itself. Usage of a tube adapter is consistent with the predicate to make automated processing possible. And the requirement to remove the tube cap to access the sample also exists regardless of whether it is removed by hand or with a Cap Removal Tool. Use of the device and accessories do not raise new questions of safety or effectiveness.
Shelf-Life	Shelf-life durations are based on test data currently available. This difference does not raise new questions of safety or effectiveness.

Substantial Equivalence Conclusion

Both the subject and predicate device have the same intended use. The differences between proposed device and predicate device are summarized in Table 2. These differences do not raise any new questions of safety or effectiveness. The differences in technological characteristics were evaluated through performance testing as summarized in the section below.

Biocompatibility Testing

An assessment of biocompatibility risks for the devices included in this submission was performed per FDA Guidance issued September 4, 2020 , Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" and in compliance with the ISO 10993 series of standards. Materials that may come into direct or indirect contact with human body for even transient or limited durations were evaluated to the identified biological endpoints. Results of testing demonstrated that the subject devices are considered safe for use for the proposed intended clinical applications.

Performance Testing – Bench (Non-Clinical Testing)

Non-clinical tests identified in Table 3 were conducted following defined protocols and with established acceptance criteria to evaluate the following attributes of the proposed devices at time-zero and over the proposed shelf life:

Table 3. Non-clinical Testing

Test Description	Result
Cap Lid Closure Force	Pass
Accidental Drop Seal	Pass
Reverse Centrifuge Seal	Pass
Transit Vibration Seal	Pass
Cap / Container Pull-Off	Pass
De-Capping	Pass
Tube to Collector Pull-Off Force	Pass
Latch Press Force	Pass
Tube to Collector Axial Removal Force	Pass
Pivot Attachment Force	Pass
Collector to Finger Cuff Snap De-Latch	Pass
Friction Retention	Pass
Barcode Scan, single automation platform	Pass
Barcode Label Sutherland Rub Test	Pass
Human Factors/Usability Evaluations	Pass

The MiniDraw™ SST™ System 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 that the modifications to the device do not impact its safety or effectiveness and that the subject MiniDraw™ SST™ System continue to perform as intended.

Performance Testing - Clinical

The clinical performance evaluation of the MiniDraw™ SST™ System was based on applicable standards, guidance documents, and statistical analyses at predetermined medical decision levels. Studies were performed at internal and/or external sites. Clinical performance testing was performed to demonstrate that blood specimens collected in MiniDraw™ SST™ Tube produced test results that are substantially equivalent to both the capillary and venous comparator tubes by performing the following studies: Method Comparison (Clinical Equivalence), Lot to Lot Variability, Within-Tube Type Stability, Operator Variability and Shelf-Life. Results were evaluated in accordance with the associated Statistical Analysis Plan for BD MiniDraw™

Capillary Blood Collection System. Data generated from the studies were compared to the pre-defined acceptance criteria.

Testing was performed on selected analytes: Alkaline Phosphatase (ALKP), Alanine Aminotransferase (ALT), Sodium (Na), Chloride (Cl), Albumin (ALB), Blood Urea Nitrogen (BUN), Calcium (Ca), Creatinine (CREAT), Total Bilirubin (TBIL), Total Protein (TP), High Density Lipoprotein (HDL), Low Density Lipoprotein (LDL), Total Cholesterol (CHOL), and Triglycerides (TRIG)

Method Comparison

This study was performed to evaluate Clinical Equivalence between the MiniDraw™ SST™ Tube and respective capillary and venous comparator devices, BD Microtainer® SST™ Tubes (BD Microtainer® SST™) and Greiner Bio-One Vacuette® Serum Tubes with Clot Activator and Gel Separator (Greiner Vacuette Serum), for the serum chemistry analytes identified above. This assessment considered whether the mean and 95% Confidence Interval (CI) were within the Clinical Acceptance Limits (CALs).

- **MiniDraw™ SST™ Tube vs BD Microtainer® SST™ (Capillary Comparator):** Comparison of the MiniDraw™ SST™ Tube vs BD Microtainer® SST™ demonstrated clinical equivalence at all medical decision levels for all analytes identified above.

- **MiniDraw™ SST™ Tube vs Greiner Vacuette Serum (Venous Comparator):** Comparison of the MiniDraw™ SST™ Tube vs Greiner Vacuette Serum led to a conclusion that the mean and 95% CI of biases were within CALs identified above

Lot to Lot Variability

This study was performed to evaluate the total variability (lot-to-lot and within lot) of the MiniDraw™ SST™ Tube for the selected chemistry analytes and included testing in comparator devices (BD Microtainer® SST™ and Greiner Vacuette Serum) for . The acceptance criteria were met for each selected analyte, therefore, the lot variability in the MiniDraw™ SST™ Tube was considered acceptable.

Within-Tube Type Stability

This study evaluated within-tube type stability of selected chemistry analytes in the MiniDraw™ SST™ Tube for up to 4 hours at room temperature and up to 48 hours at refrigerated conditions.

The MiniDraw™ SST™ Tube demonstrated within-tube type stability up to 4 hours with room temperature storage and up to 48 hours with refrigerated storage for all evaluated chemistry analytes.

Operator Variability

This study was performed to evaluate operator variability of the MiniDraw™ SST™ Tube for selected serum chemistry analytes. The respective capillary and venous comparator devices, BD Microtainer® SST™ and Greiner Vacuette Serum were also tested in this study. The acceptance criteria were met for each selected analyte, therefore, the operator variability in the MiniDraw™ SST™ Tube was considered acceptable.

Shelf-Life

The purpose of this study was to evaluate product shelf-life by evaluating real time aged 9 (+1) months MiniDraw™ SST™ Tubes in comparison with newly manufactured MiniDraw™ SST™ Tubes. The BD MiniDraw™ SST™ Capillary Blood Collection Tube aged 9(+1) months at both high and low temperature conditions demonstrated clinically equivalent performance when compared with the newly manufactured BD MiniDraw™ SST™ Capillary Blood Collection Tube for the selected serum chemistry analytes identified above that were evaluated in the study.

Conclusion

The comparison between the proposed device (MiniDraw™ SST™ System) and the predicate device (BD Microtainer® SST™) shows that they have the same fundamental technology and technological characteristics and any differences in technology do not raise new questions of safety or effectiveness. The intended use of the MiniDraw™ SST™ System is also considered to be the same as the predicate device.

The performance bench testing based on applicable standards and internal specifications demonstrates that acceptance criteria were met.

During clinical performance testing, the evaluation device, MiniDraw™ SST™ System was compared to the predicate device and the blood collected in each tube was analyzed for identified chemistry analytes and produced test results that are clinically equivalent to both the capillary and venous comparator tubes. The results generated in the clinical performance testing for Method Comparison (Clinical Equivalence), Lot to Lot Variability, Stability, Operator Variability and Shelf-Life demonstrated appropriate performance.

Based on information provided in this submission the MiniDraw™ SST™ System is substantially equivalent to the predicate device.