April 10, 2026

Becton, Dickinson and Company
Alexandra Kirby
Staff Regulatory Affairs Specialist
1 Becton Drive
Franklin Lakes, New Jersey 07417 USA

Re: K252378
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: July 30, 2025
Received: July 30, 2025

Dear Alexandra Kirby:

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 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (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 ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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,

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)*
K252378

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 Albumin (ALB), Alkaline Phosphatase (ALKP), Alanine Aminotransferase (ALT), Aspartate Aminotransferase (AST), Blood Urea Nitrogen (BUN), Calcium (Ca), Chloride (Cl), Creatinine (CREAT), Glucose (GLU), Potassium (K), Sodium (Na), 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.

1 510(K) SUMMARY

1.1 510(k) Number

K252378

1.2 Device Name

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

1.3 Summary Preparation Date

April 9, 2026

1.4 Submitted by

Becton, Dickinson and Company
1 Becton Drive
Franklin Lakes, NJ 07417-1885
Phone: (201) 847-6800

1.5 Contact

Alexandra Kirby
Staff Regulatory Affairs Specialist
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1.6 Alternate Contact

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1.7 Proprietary Name

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

- BD® MiniDraw™ SST™ Capillary Blood Collection Tube (BD® MiniDraw™ SST™ Tube)
- BD® MiniDraw™ Finger Sleeve
- BD® MiniDraw™ Finger Sizing Tool

- BD® MiniDraw™ Capillary Tube Adapter SST™
- BD® MiniDraw™ Cap Removal Tool

1.8 Common or Usual Names

Product code JKA device name: Tubes, Vials, Systems, Serum Separators, Blood Collection

1.9 Regulatory Information

Regulatory information for the BD® MiniDraw™ SST™ Tube, BD® MiniDraw™ Finger Sleeve, BD® MiniDraw™ Finger Sizing Tool, and BD® MiniDraw™ Cap Removal Tool is below:

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

1.10 Predicate Device

BD® MiniDraw™ SST™ System (K230391)

1.11 Device Establishment

Becton, Dickinson and Company

1.12 Registration Number

2243072

1.13 Performance Standards

ISO 20916:2019 In vitro diagnostic medical devices – Clinical performance studies using specimens from human subjects – Good study practice

ISO 14155:2011 Clinical investigation of medical devices for human subjects – Good clinical practice

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

ANSI/AAMI/IEC 62366-1:2015+AMD1:2020 Medical devices – Part 1: Application of usability engineering to medical devices

ANSI AAMI HE75:2009/(R)2018 Human factors engineering – Design of medical devices

ASTM D4169-22 Standard Practice for Performance Testing of Shipping Containers and Systems

ASTM D999-08(2023) Standard Test Methods for 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(2023) 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

ASTM F1886/F1886M 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

1.14 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 Albumin (ALB), Alkaline Phosphatase (ALKP), Alanine Aminotransferase (ALT), Aspartate Aminotransferase (AST), Blood Urea Nitrogen (BUN), Calcium (Ca), Chloride (Cl), Creatinine (CREAT), Glucose (GLU), Potassium (K), Sodium (Na), 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.

1.15 Intended Use

A blood specimen collection device is a device intended for medical purposes to collect and to handle blood specimens and to separate serum from non-serum (cellular) components prior to further testing. This generic type of device may include blood collection tubes, vials, systems, serum separators, blood collection trays, or vacuum sample tubes.

1.16 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.

1.17 Non-Clinical Bench Testing and Packaging Testing

Non-Clinical Bench Testing activities for the BD® MiniDraw™ SST™ System were carried out by BD to evaluate the performance and safety of the devices through functional testing conducted over the course of the product shelf-life. Non-Clinical Bench Testing includes packaging testing and functional (mechanical product) testing.

For Packaging testing, BD previously provided packaging ship testing and packaging material accelerated aging testing and BD successfully completed real-time aging Packaging testing to support the proposed shelf-life of the device.

For Functional Testing, BD previously provided non-clinical bench testing data and BD successfully completed the non-clinical bench testing to support the proposed shelf-life of the device.

1.18 Clinical Performance Testing

The clinical performance evaluation of the BD® MiniDraw™ SST™ System was based on applicable standards and guidance documents. Studies were performed internally at BD's Franklin Lakes laboratory, externally at multiple sites, or at some combination of internal and external sites.

Clinical performance testing was performed to demonstrate that blood specimens collected in BD® 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,

Venous Surrogate, and Shelf-Life. Data generated from the studies were compared to the pre-defined acceptance criteria. Testing was performed for aspartate aminotransferase (AST), potassium (K), and glucose (Glu) analytes.

1.19 Substantial Equivalence

1.19.1 Comparison Tables

A comparison between the subject and predicate devices is provided in Table 1. The differences between the subject and predicate devices are summarized in Table 2.

Table 1. Substantial Equivalence Comparison

Characteristic	Subject Device BD® MiniDraw™ SST™ System (K252378)	Predicate Device BD® MiniDraw™ SST™ System (K230391)	Comments
Intended Use	A blood specimen collection device is a device intended for medical purposes to collect and to handle blood specimens and to separate serum from non-serum (cellular) components prior to further testing. This generic type of device may include blood collection tubes, vials, systems, serum separators, blood collection trays, or vacuum sample tubes.	Same as subject device	Identical
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 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),	The subject device includes the same analytes as the predicate device except that the subject device includes AST, K, and Glu. This difference does not raise new questions of safety or effectiveness because it is supported by clinical testing, which demonstrates that the results are clinically equivalent.

Characteristic	Subject Device BD® MiniDraw™ SST™ System (K252378)	Predicate Device BD® MiniDraw™ SST™ System (K230391)	Comments
	BD® MiniDraw™ Capillary Blood Collection System with BD® MiniDraw™ SST™ Capillary Blood Collection Tube is intended for sample collection used in the measurement of Albumin (ALB), Alkaline Phosphatase (ALKP), Alanine Aminotransferase (ALT), Aspartate Aminotransferase (AST), Blood Urea Nitrogen (BUN), Calcium (Ca), Chloride (Cl), Creatinine (CREAT), Glucose (GLU), Potassium (K), Sodium (Na), 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.	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.	
Intended Population	Adults – individuals aged 18 and older, limited by correct fit of the BD® MiniDraw™ Finger Sleeve	Same as subject device	Use of the BD® MiniDraw™ SST™ System is limited to individuals aged 18 and older whose finger measurements match the available sizes of BD® MiniDraw™ Finger Sleeves.
Intended Use Environment	Ancillary healthcare facilities, clinical and laboratory environments, and other environments where a trained individual is present.	Same as subject device	BD® MiniDraw™ SST™ System adds ancillary healthcare facility use environment and other environments where a trained individual is present.
Intended User	Trained Healthcare Workers: phlebotomists, clinicians, pharmacists, pharmacy technicians, and other	Same as subject device	BD® MiniDraw™ SST™ System adds pharmacists, pharmacy technicians, and other individuals trained in the use of the device.

Characteristic	Subject Device BD® MiniDraw™ SST™ System (K252378)	Predicate Device BD® MiniDraw™ SST™ System (K230391)	Comments
	individuals trained in the use of the device		
Analytes	Albumin (ALB), Alkaline Phosphatase (ALKP), Alanine Aminotransferase (ALT), Aspartate Aminotransferase (AST), Blood Urea Nitrogen (BUN), Calcium (Ca), Chloride (Cl), Creatinine (CREAT), Glucose (GLU), Potassium (K), Sodium (Na), Total Bilirubin (TBIL), Total Protein (TP), High Density Lipoprotein (HDL), Low Density Lipoprotein (LDL), Total Cholesterol (CHOL), and Triglycerides (TRIG).	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).	The subject device includes the same analytes as the predicate device except that the subject device includes AST, K, and Glu. This difference does not raise new questions of safety or effectiveness it is supported by clinical testing, which demonstrates that the results are clinically equivalent.
Single Use	Yes	Same as subject device	Identical
Sterility	Non-sterile	Same as subject device	Identical
Centrifugation	Cap Down	Same as subject device	Identical
Sample Type	Capillary	Same as subject device	Identical
Additive	Clot activator and gel separator	Same as subject device	Identical
Materials	Container: Polypropylene Collector: methylAcrylonitrileButedieneStyrene (mABS) Cap: Polypropylene + Thermoplastic elastomer (TPE) Finger Sleeve: Polypropylene + colorant	Same as subject device	Identical
Container Design	Flat bottomed with rounded recessed plug	Same as subject device	Identical
Container Dimensions	13x40 mm	Same as subject device	Identical
Finger Sleeve	Yes	Same as subject device	Identical

Characteristic	Subject Device BD® MiniDraw™ SST™ System (K252378)	Predicate Device BD® MiniDraw™ SST™ System (K230391)	Comments
Finger Sizing Tool	Yes	Same as subject device	Identical
Use of Tube Adapter	Compatible	Same as subject device	Identical
Cap Removal Tool	Yes	Same as subject device	Identical

Table 2. Differences Between the BD® MiniDraw™ SST™ System and Predicate Device

Difference	Substantial Equivalence to the Predicate
Indications for Use / Analytes	The subject device includes the same analytes as the predicate device except that the subject device also includes AST, K, and Glu. This submission seeks to add AST, K, and Glu to the subject BD® MiniDraw™ SST™ System indications for use, which is supported by clinical testing demonstrating that the results are clinically equivalent.
Shelf-Life	Shelf-life durations are based on test data currently available. This difference does not raise new questions of safety or effectiveness because testing data and subsequent shelf-life claims can differ between products.

1.19.2 Conclusion

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