510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY

I Background Information:

A 510(k) Number

K230493

B Applicant

Becton Dickinson and Company

C Proprietary and Established Names

BD MiniDraw Capillary Blood Collection System with BD MiniDraw H&H Capillary Blood Collection Tube

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
GIM	Class II	21 CFR 862.1675 - Blood Specimen Collection Device	CH - Clinical Chemistry

II Submission/Device Overview:

A Purpose for Submission:

New Device

B Measurand:

Not applicable – blood collection system

C Type of Test:

Not applicable

Food and Drug Administration 10903
New Hampshire Avenue
Silver Spring, MD 20993-0002
www.fda.gov

III Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) for Use:

The BD MiniDraw Capillary Blood Collection System with BD MiniDraw Hemoglobin & Hematocrit (H&H) Capillary Blood Collection Tube with K2EDTA is used to collect, anticoagulate, transport, and store capillary whole blood samples from individuals 18 years and older. The System is comprised of a capillary blood collection tube and a BD MiniDraw Finger Sleeve that are intended for use by a trained healthcare worker.

BD MiniDraw Capillary Blood Collection System with BD MiniDraw H&H Capillary Blood Collection Tube is intended for sample collection used in the measurement of Hemoglobin (HgB) & Hematocrit (HCT), when analyzed on Sysmex XN-Series systems.

The BD MiniDraw Capillary Blood Collection System with BD MiniDraw H&H Capillary Blood Collection Tube is not intended for use with other parameters.

C Special Conditions for Use Statement(s):

Rx - For Prescription Use Only

D Special Instrument Requirements:

Sysmex XN-Series (K112605)

IV Device/System Characteristics:

A Device Description:

The BD MiniDraw Capillary Blood Collection System with BD MiniDraw H&H Capillary Blood Collection Tube (MiniDraw H&H System) is designed to collect, anticoagulate, transport, and store capillary blood samples from adults 18 years and older for measurement of hemoglobin and hematocrit requiring whole blood. The system is comprised of a capillary blood collection tube and a Finger Sleeve that is intended for use by trained healthcare workers in ancillary healthcare facilities (e.g., retail pharmacies, clinics), clinical laboratory use environments. It is intended to be used with Sysmex XN-Series Analyzers.

The BD MiniDraw Capillary Blood Collection System with BD MiniDraw H&H Capillary Blood Collection Tube (MiniDraw H&H System) is intended to collect a whole blood specimen from a finger and deliver an anticoagulated sample for measurement of hemoglobin and hematocrit. The BD MiniDraw H&H Capillary Blood Collection Tube is comprised of three main blood path contacting parts: a collector, cap with integrated lid, and container. The collector is methylmethacrylate acrylonitrile butadiene styrene (MABS) and only used during the sample collection. The cap with integrated lid is polypropylene and thermoplastic elastomer, and

the container is polypropylene. The BD MiniDraw H&H Capillary Blood Collection Tube (MiniDraw H&H Tube) contains K2EDTA for anticoagulation of whole blood samples. The tube has a unique barcode that links the tube with the patient.

The MiniDraw H&H 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 in K223243) and three accessories: BD MiniDraw Finger Sizing Tool, BD MiniDraw Capillary Tube Adapter H&H, and BD MiniDraw Cap Removal Tool.

Model Numbers

Product/Component	**SKU #**	**Final Device Name**
Overall System	N/A	BD MiniDraw Capillary Blood Collection System
Blood Collection Tube	366603	BD MiniDraw H&H Capillary Blood Collection Tube
Tube Adapter	366619	BD MiniDraw Capillary Tube Adapter H&H
Finger Sizing Tool	366617	BD MiniDraw Finger Sizing Tool
Finger Sleeve	366613	BD MiniDraw Finger Sleeve, Small
	366614	BD MiniDraw Finger Sleeve, Medium
	366615	BD MiniDraw Finger Sleeve, Large
	366616	BD MiniDraw Finger Sleeve, Extra Large
De-capping Tool	366618	BD MiniDraw Cap Removal Tool

B Principle of Operation:

The blood collection tube attaches to the BD MiniDraw Finger Sleeve to enable placement of the system on the patient's finger during sample collection. The BD MiniDraw H&H Capillary Blood Collection Tube contains K2EDTA for anticoagulation of whole blood samples.

V Substantial Equivalence Information:

A Predicate Device Name(s):
BD Microtainer Map Microtube For Automated Process, Model 363706

B Predicate 510(k) Number(s):
K093972

C Comparison with Predicate(s):

Device & Predicate Device(s):	K230493	K093972
Device Trade Name	BD MiniDraw Capillary Blood Collection System with BD MiniDraw H&H Capillary Blood Collection Tube	BD Microtainer MAP Microtube for Automated Process
General Device Characteristic Similarities		

Device & Predicate Device(s):	K230493	K093972
Intended Use/Indications For Use	The BD MiniDraw Capillary Blood Collection System with BD MiniDraw Hemoglobin & Hematocrit (H&H) Capillary Blood Collection Tube with K2EDTA is used to collect, anticoagulate, transport, and store capillary whole blood samples from individuals 18 years and older. The System is comprised of a capillary blood collection tube and a BD MiniDraw Finger Sleeve that are intended for use by a trained healthcare worker. BD MiniDraw Capillary Blood Collection System with BD MiniDraw H&H Capillary Blood Collection Tube is intended for sample collection used in the measurement of Hemoglobin (HgB) & Hematocrit (HCT), when analyzed on Sysmex XN-Series systems. The BD MiniDraw Capillary Blood Collection System with BD MiniDraw H&H Capillary Blood Collection Tube is not intended for use with other parameters.	Bd microtainer map microtube for automated process with K2EDTA is used to collect, anticoagulate, transport, and store skin puncture blood specimens for measurement of the following hematological parameters. White blood cells (WBC), red blood cells (RBC), hemoglobin (HgB), hematocrit (HCT), mean corpuscular volume (MCV), mean corpuscular hemoglobin (MCH), mean corpuscular hemoglobin concentration (MCHC), platelets, 5-part white blood cell (WBC) differentials (neutrophils, lymphocytes, monocytes, eosinophils, basophils), reticulocytes and whole blood lead testing
Single Use	Yes	Yes
Sterility	Non-sterile	Non-sterile
Sample Type	Capillary	Capillary
Additive	K2EDTA, Spray dried	K2EDTA, Spray dried
Container Design	Flat bottomed with rounded recessed plug	Flat bottomed with rounded recessed plug
General Device Characteristic Differences		
Intended Population	Adults – individuals aged 18 and older, limited by correct fit of the Finger Sleeve	General Use – all populations
Intended Use Environment	Ancillary healthcare facilities, clinical laboratory environments	Clinical laboratory environments
Analytes	Hemoglobin and Hematocrit	Hematology Analytes and Lead

Device & Predicate Device(s):	K230493	K093972
Materials	Container: Polypropylene Collector: methylAcrylonitrileButedieneStyrene (mABS) Cap: Polypropylene + Thermoplastic elastomer (TPE) Finger Sleeve: Polypropylene + colorant	Container: Polypropylene Collector: Polypropylene Cap: High Density Polyethylene and TPE Finger Sleeve: Not applicable
Container Dimensions	13x40mm	9x40mm
Finger Sleeve	Yes	Not applicable
Compatibility with Automated Processing	Compatible through use of BD MiniDraw™ Capillary Tube Adapter H&H	Compatible
Finger Sizing Tool	Yes	Not applicable
Cap Removal Tool	Yes	Not applicable
Shelf-Life	9 months	18 months

VI Standards/Guidance Documents Referenced:

- CLSI GP34-A, Validation and Verification of Tubes for Venous and Capillary Blood Specimen Collection; Approved Guidance
- CLSI GP39-A6, Tubes and Additives for Venous Blood Specimen Collection; Approved Standard – Sixth Edition.
- CLSI EP05-A3, Evaluation of Precision of Quantitative Measurement Procedures
- 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

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:

a. Lot-to-Lot Precision Study

This study was conducted to evaluate the performance of BD MiniDraw Capillary Blood Collection System with BD MiniDraw H&H Capillary Blood Collection Tube (BD MiniDraw H&H System) compared to BD Microtainer Microtube for Automated Processes (BD MAP EDTA) and Greiner Vacuette Blood Collection Tube with K2EDTA (Greiner Vacuette EDTA) for repeatability (total), lot-to-lot and tube-to-tube variation for hematology parameters: Hemoglobin (HgB) and Hematocrit (HCT). This study was conducted at a single site. Blood from 57 subjects was collected into the study tubes, which consisted of three lots of each tube type. Samples were tested for the HgB and HCT within 4 hours of collection at room temperature on the Sysmex XN-1000 (Sampling Module XN-10). Performance of the BD MiniDraw H&H System for between-lot variation and between-tube variation showed non-inferiority for all tube comparisons for Hemoglobin (HgB) and Hematocrit (HCT) tested the Sysmex XN-1000 when compared with the comparator device.

Variance Components and Confidence Intervals (CI)

Analyte	Mean	Variance Component	SD (95% CI)	%CV (95% CI)
HCT (%)	42.23	Between-Lot	0.6 (0, 0.13)	0.1 (0, 0.3)
		Between-Tube	0.31 (0.28, 0.34)	0.7 (0.7, 0.8)
		Total	0.31 (0.26, 0.38)	0.7 (0.6, 0.9)
HGB (g/dL)	14.29	Between-Lot	0.03 (0, 0.04)	0.2 (0, 0.3)
		Between-Tube	0.09 (0.08, 0.1)	0.6 (0.6, 0.7)
		Total	0.09 (0.08, 0.11)	0.6 (0.5, 0.8)

b. Operator-to-Operator Precision Study

This study was conducted to evaluate operator variability of the BD MiniDraw H&H System compared to BD MAP EDTA and Greiner Vacuette EDTA for Hemoglobin (HgB) and Hematocrit (HCT). A total of 198 participants were enrolled in the study. Blood was collected from the same participant into the capillary (BD MiniDraw H&H and BD MAP EDTA) and venous (Greiner Vacuette EDTA) study tubes, on the same occasion, in randomized collection order. For each participant, two trained health care workers (e.g., pharmacists, pharmacy technicians) collected one BD MiniDraw H&H System each, and two phlebotomists each collected one venous tube (Greiner Vacuette EDTA) by venipuncture and one capillary tube (BD MAP EDTA). Testing for HgB and HCT was performed on the Sysmex XN-1000. Performance of the BD MiniDraw H&H System for between-operator variation showed non-inferiority for all tube comparisons for Hemoglobin (HgB) and Hematocrit (HCT) tested the Sysmex XN-1000 when compared with the comparator device.

Operator to Operator Variance Components and Confidence Intervals (CI)

Analyte	Mean	Variance Component	SD (95% CI)	%CV (95% CI)
HCT (%)	41.56	Between-operator	0.73 (0.62, 0.94)	1.9 (1.5, 2.8)
HGB (g/dL)	14.08	Between-operator	0.23 (0.19, 0.31)	1.8 (1.4, 2.6)

2. Linearity:

Not applicable

3. Analytical Specificity/Interference:

Not applicable

4. Assay Reportable Range:

Not applicable

5. Traceability, Stability, Expected Values (Controls, Calibrators, or Methods):

a. Shelf-Life Stability

Shelf-life stability studies were conducted by using BD MiniDraw H&H Tubes at 9 (+1) months from date of manufacture, compared with MiniDraw H&H Tubes that were recently manufactured. The studies were conducted by testing Hemoglobin and Hematocrit parameters. Forty-three apparently healthy subjects 18 years of age or older were enrolled in this study. The results showed that the shelf-life for the BD MiniDraw H&H Tubes is 9 months when stored at 4–25 °C.

b. Shelf-Life Stability (Additive)

Additive Shelf-life stability studies were conducted by using BD MiniDraw H&H Tubes at 12 (+1) and 14 (+1) months from date of manufacture, compared with MiniDraw H&H Tubes that were recently manufactured. The studies were conducted by testing K2EDTA in BD MiniDraw H&H Tubes. Thirty BD MiniDraw H&H Tubes containing K2EDTA anticoagulant for each lot were tested in this study. The results showed that EDTA amount is within acceptable limits to achieve functional blood to additive ratio for BD MiniDraw H&H Tubes at 14 months.

c. Within-Tube Stability

Within-Tube Stability was evaluated by using BD MiniDraw H&H System for Hemoglobin and Hematocrit. Storage conditions included: 4 hours at room temperature (23–27°C), 36 and 48 hours stored refrigerated (2–8°C). Seventy-eight apparently healthy subjects 18 years of age or older, were enrolled in this study. Testing for the Hemoglobin and Hematocrit parameters was performed on the Sysmex XN-1000 (Sampling Module XN-10). The within-tube stability showed that the samples are stable at 4 hours when stored at room temperature (23–27°C), and 48 hours when stored refrigerated at 2–8°C.

d. Sample Transport Stability

Sample Transport Stability was evaluated by using BD MiniDraw H&H System to characterize the effects that extreme storage and transport conditions have on sample quality and the physical integrity of the H&H Tube. Transport conditions included: 48 hours at Refrigerated Temperature Storage (2–8°C); 4 hours at Room Temperature Storage (20–24°C); 4 and 48 hours at High Temperature, High Humidity Storage (38–42°C) / 90%RH. Testing for the Hemoglobin and Hematocrit parameters was performed on the Sysmex XN-1000 (Sampling Module XN-10). The transport stability study demonstrated that there is no impact to physical tube integrity or sample stability when stored and transported in accordance with product labeling (48 hours at Refrigerated Temperature Storage (2–8°C); 4 hours at Room Temperature Storage (20–24°C); 4 hours at High Temperature, High Humidity Storage (38–42°C) / 90%RH).

6. Detection Limit:

Not applicable

7. Assay Cut-Off:

Not applicable

B Comparison Studies:

1. Method Comparison with Predicate Device:

The method comparison study was conducted at two clinical testing sites including 126 subjects 18 years of age or older collected from five representative collection sites. Participants were enrolled at various collection sites representative of the ancillary health care site of the intended use environment to enroll patient populations. Blood was collected from each participant into the capillary (BD MiniDraw H&H System and BD MAP EDTA) study tubes. Samples were tested for the Hemoglobin (HgB) and Hematocrit (HCT) analytes on Sysmex XN-1000 (Sampling Module XN-10). Deming or Passing Bablok Regression was used to estimate average differences between the evaluation tube (BD MiniDraw H&H System) and the comparator tube (BD MAP EDTA) at medically relevant points for each analyte.

The results are summarized in the following table:

Regression Parameter Estimates – BD MiniDraw™ H&H System vs BD MAP EDTA

Parameter	N	Intercept (95% CI)	Slope (95% CI)	Correlation Coefficient
HCT	117	0.2 (-0.73, 0.91)	1 (0.98, 1.03)	0.979
HGB	117	0.1 (-0.07, 0.23)	1 (0.99, 1.01)	0.982

The result demonstrated that the BD MiniDraw H&H System demonstrated the substantial equivalent performance for the tested parameters (HGB and HCT) compared to the BD MAP EDTA.

2. Matrix Comparison:

A capillary vs. venous matrix comparison study consisting of 117 normal and pathological paired capillary K2EDTA whole blood and venous K2EDTA whole blood specimens were used. Paired specimens collected from the same individuals were assayed in duplicate on the Sysmex XN-1000 to compare performance between capillary whole blood samples and venous whole blood samples, and the results were analyzed for Hemoglobin (HgB) and Hematocrit (HCT). The test result for each parameter was compared between venous and capillary blood to determine if there were any differences. The investigation found no statistical or clinical differences using venous or capillary blood for the analytes Hemoglobin (HgB) and Hematocrit (HCT). The result demonstrates the comparable performance characteristics for K2EDTA capillary and K2EDTA venous whole blood samples and the venous whole blood is acceptable for use in tube-specific clinical assessments (i.e., shelf-life and lot-to-lot precision studies).

C Clinical Studies:

1. Clinical Sensitivity:
   Not applicable

2. Clinical Specificity:

   Not applicable

3. Other Clinical Supportive Data (When 1. and 2. Are Not Applicable):

   A. Functional Testing

   Functional testing was conducted to evaluate the performance and safety for BD MiniDraw Capillary Blood Collection System with BD MiniDraw H&H Capillary Blood Collection Tube (BD MiniDraw H&H System) over the course of the product shelf-life.

   Functional testing included:

   - Cap Lid Closure Force
   - Accidental Drop Seal
   - Transit Vibration Seal
   - Cap/Container Pull-Off
   - Tube to Collector Pull-Off Force
   - Latch Press Force
   - Tube to Collector Axial Removal Force
   - Pivot Attachment Force
   - Collector to Finger Cuff Snap De-Latch
   - Friction Retention
   - EDTA Adapter Retention Force
   - Sysmex Barcode Scan
   - Barcode Label Sutherland Rub Test

   The result demonstrates that the BD MiniDraw H&H System met all non-clinical testing requirements at time-zero and over the product shelf-life, demonstrating that the device functions as designed.

   B. Package Testing

   Package testing was conducted to ensure that the packaging assembly for the BD MiniDraw H&H System provides adequate protection to the products during shipping and handling.

   Package testing included:

   - Packaging Ship Testing
   - Packaging Material Accelerated Aging

   Packaging Ship Testing: This study was conducted to ensure that the packaging assembly for the BD MiniDraw H&H System provides adequate protection to the products during shipping

and handling. Samples are stressed mechanically and thermally based on what the packaging is likely to experience during shipping and handling. Samples are visually inspected, thermally conditioned, ship tested, and then visually inspected again. The results met the acceptance criteria of no damage to packaging, no damage to contents, and all labeling information legible before and after conditioning.

Packaging Material Accelerated Aging: This study was conducted to ensure that the packaging materials for the BD MiniDraw H&H System provide adequate protection to the products over the intended shelf-life. Samples were visually inspected at T=0, aged at 60°C and 30% RH, and visually inspected at timepoints equivalent to 6+1 months, 12+1 months, and 18+1 months of real-time aging to support the proposed 3-month shelf-life. The results met the acceptance criteria of no damage to packaging, no damage to contents, and all labeling information legible before and after conditioning.

C. Human Factors/Usability Evaluation

This study was conducted to demonstrate that the BD MiniDraw H&H System can be used by the intended users (i.e., registered nurses, phlebotomists, medical technologists, retail pharmacists, and retail pharmacy technicians) without serious use errors or problems for the intended use and under the expected use conditions. A total of 45 users were formally trained in the use of the BD MiniDraw H&H System before being asked to perform simulated blood collections on a mannequin hand. The study results demonstrate that those untrained in phlebotomy perform as well as those trained in phlebotomy in the use of the BD MiniDraw H&H System after undergoing training.

D. Biocompatibility

An assessment of biocompatibility risks for BD MiniDraw H&H System 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.

D. Clinical Cut-Off:

Not applicable

E. Expected Values/Reference Range:

Not applicable

VIII Proposed Labeling:

The labeling supports the finding of substantial equivalence for this device.

IX Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.