November 27, 2023

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

Re: K230493
Trade/Device Name: BD MiniDraw Capillary Blood Collection System with BD MiniDraw H&H Capillary Blood Collection Tube
Regulation Number: 21 CFR 862.1675
Regulation Name: Blood specimen collection device
Regulatory Class: Class II
Product Code: GIM
Dated: February 22, 2023
Received: February 23, 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.

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,

Min Wu -S

Min Wu, Ph.D.
Branch Chief
Division of Immunology and Hematology 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)*
K230493

Device Name
BD MiniDraw™ Capillary Blood Collection System with BD MiniDraw™ H&H Capillary Blood Collection Tube

Indications for Use *(Describe)*
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.

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

Summary Preparation Date:

11/27/2023

Submitted by:

Becton, Dickinson and Company
1 Becton Drive
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Phone: (201) 847-6800

Contact:

Katherine Kenner Lemus
Staff Regulatory Affairs Specialist
Email: katherine.lemus@bd.com

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Proprietary Names:

The BD MiniDraw™ Capillary Blood Collection System with BD MiniDraw™ H&H Capillary Blood Collection Tube (MiniDraw™ H&H System) is including the following devices:

- BD MiniDraw™ H&H Capillary Blood Collection Tube (MiniDraw™ H&H Tube)
- BD MiniDraw™ Finger Sleeve
- BD MiniDraw™ Finger Sizing Tool
- BD MiniDraw™ Capillary Tube Adapter H&H
- 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, Vacuum Sample, With Anticoagulant

Regulatory Information

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

Classification Name: Tubes, Vacuum Sample, With Anticoagulant
Classification Regulation: 21 CFR §862.1675
Regulatory Class: Class II
Panel: Clinical Chemistry
Product Code: GIM

Predicate Device

Predicate: K093972 BD Microtainer® Microtube for Automated Process (MAP)

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

The BD MiniDraw™ Capillary Blood Collection System with BD MiniDraw™ Hemoglobin & Hematocrit (H&H) Capillary Blood Collection Tube with K_2EDTA 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.

Device Description

The 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 and is clinically equivalent to capillary and venous comparator tubes for both analytes. 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 and laboratory use environments. It is intended to be used with Sysmex XN – Series™ Analyzers.

The 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 (MiniDraw™ H&H Tube) contains K_2EDTA 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 K223243) and three accessories; BD MiniDraw™ Finger Sizing Tool, BD MiniDraw™ Capillary Tube Adapter H&H, and BD MiniDraw™ Cap Removal Tool.

Substantial Equivalence

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

A discussion of equivalence between the subject and predicate device is provided in Table 3

Table 1: Substantial Equivalence Comparison

Characteristic	Subject Device MiniDraw™ EDTA System	Predicate BD Microtainer® MAP K093972	Comparison
Indications for Use	The BD MiniDraw™ Capillary Blood Collection System with BD MiniDraw™ Hemoglobin & Hematocrit (H&H) Capillary Blood Collection Tube with K_2EDTA 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 K_2EDTA is used to collect, anticoagulate, transport and store skin puncture blood specimens for measurement of the following hematology 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.	Both devices are intended to collect, transport and store capillary blood for testing whole blood for hematocrit and hemoglobin. MiniDraw™ H&H System is intended for use exclusively with the Sysmex XN - Series™ Analyzers. MiniDraw™ H&H System is not intended for other parameters.
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

Characteristic	Subject Device MiniDraw™ EDTA System	Predicate BD Microtainer® MAP K093972	Comparison
Intended Use Environment	Ancillary healthcare facilities, clinical and laboratory environments	Clinical and laboratory environments	MiniDraw™ H&H System adds ancillary healthcare facility use environments
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, clinicians	MiniDraw™ H&H System adds pharmacists, pharmacy technicians, and other healthcare workers trained in the use of the device
Analytes	Hemoglobin and Hematocrit	Hematology Analytes and Lead	MiniDraw™ H&H System is not intended for other parameters except for hemoglobin and hematocrit.
Single Use	Yes	Yes	Identical
Sterility	Non-sterile	Non-sterile	Identical
Sample Type	Capillary	Capillary	Identical
Additive	K_2EDTA, Spray dried	K_2EDTA, Spray dried	Identical
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: 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™ EDTA System introduces use of the Finger Sleeve

Characteristic	Subject Device MiniDraw™ EDTA System	Predicate BD Microtainer® MAP K093972	Comparison
Compatibility with Automated Processing	Compatible through use of BD MiniDraw™ Capillary Tube Adapter H&H	Compatible	The MiniDraw™ H&H Tube is compatible with a tube adapter while the BD Microtainer® MAP tube has a built-in extension.
Finger Sizing Tool	Yes	N/A	MiniDraw™ H&H System introduces use of the finger sizing tool
Cap Removal Tool	Yes	N/A	MiniDraw™ H&H System introduces use of the cap removal tool
Shelf Life	9 months	18 months	Varies by Product

Table 2: Substantial Equivalence Discussion

Difference	Substantial Equivalence to the Predicate
Intended Use/Included Analytes	Both the subject and predicate devices are intended to collect, anticoagulate, transport and store capillary blood. The intended use statement for the predicate refers to "skin prick" collection instead of "capillary" but this is a semantic difference. Both the MiniDraw™ H&H System and BD Microtainer® MAP are intended for analysis of whole blood analytes including hemoglobin and hematocrit, and so the subset of analytes covered by the subject vs predicate device is not considered a new intended use**.** Further, the selection of analytes included in this submission are supported by clinical testing which demonstrate the results are clinically equivalent. Because the proposed list of analytes of the subject device are considered to be a subset of those evaluated from a whole blood sample, this is not considered to be a new intended use.
Intended Population	Intended for adult individuals aged 18 and older. Use of the system is dependent upon the correct fit of the Finger Sleeve, not on the demographic of the patient population. This device is not intended for pediatric populations and if the patient's fingers do not fit in one of the four Finger Sleeve sizes, the MiniDraw™ H&H System should not be used. Because this proposed intended population of the subject device 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.

Difference	Substantial Equivalence to the Predicate
Addition of Ancillary Healthcare Facility Use Environments	MiniDraw™ H&H 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).
Intended User	The device is designed for users who may have not been previously trained in phlebotomy but who are trained in the correct use of the MiniDraw™ H&H System (e.g., 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 operators 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., storage and transport) and there was no observed increase in erroneous downstream test results.
Materials	The BD MiniDraw™ H&H 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™ H&H Tube is made from mABS which is a clearer plastic material intended to enhance blood visualization during collection. The cap on the MiniDraw™ H&H Tube is made from Polypropylene instead of HDPE to allow for the hinge feature of the cap design. 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 negatively impact device performance or 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.
Container Dimensions	The MiniDraw™ H&H System is a subset of component devices that are intended to be used together during capillary blood collection and laboratory analysis. The container dimensions of the MiniDraw™ H&H Tube are designed for optimal functioning of the device and an optional tube adapter is available to enable automated processing. The combination of the MiniDraw™ H&H Tube with the BD MiniDraw™ Capillary Tube Adapter H&H results in a device that matches the container dimensions of the BD MAP EDTA which has a built-in extender by design. Thus, tube dimensional differences do not raise new questions of safety or effectiveness.

Difference	Substantial Equivalence to the Predicate
Combination Devices and Accessories	The MiniDraw™ H&H 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 H&H 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. The MiniDraw™ H&H Tube is compatible with a tube adapter while the BD Microtainer® MAP tube has a built-in extension and so the adapter is not a separate component. The form factor of the MiniDraw™ H&H Tube with the Tube Adapter is consistent with the form factor of the BD Microtainer® MAP tube with the built-in extender to make automated sampling 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. The combination of the tube and tube adapter result in a sample configuration that is optimized for the Sysmex XN – Series™ analyzers which the MiniDraw™ H&H is intended to be used with.
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 3. 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 performance testing n Table 4 was 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 Method Description	Outcome
Cap Lid Closure Force	Pass
Accidental Drop Seal	Pass
Transit Vibration Seal	Pass
Cap / Container Pull-Off	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
EDTA Adapter Retention Force	Pass
Sysmex Barcode Scan	Pass
Barcode Label Sutherland Rub Test	Pass

The 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. These performance tests demonstrate that the modifications to the device do not impact its safety or effectiveness and that the subject MiniDraw™ H&H System continue to perform as intended.

Performance Testing – Animal Summary

No animal studies were performed in support of this submission.

Performance Testing - Clinical

The clinical performance evaluation of the MiniDraw™ EDTA System was based on applicable standards, guidance documents, statistical evaluation and accepted medical decision levels. Studies were performed internally at BD's Franklin Lakes laboratory, or externally at Babson Diagnostics' laboratory, externally at Research Management, Inc. (RMI) or at some combination of these sites. Clinical performance testing was performed to demonstrate that blood specimens collected in MiniDraw™ EDTA Tube produced test results that are clinically 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 identified analytes (i.e., Hemoglobin (HgB) and Hematocrit (HCT)).

Method Comparison

This study was performed to evaluate Clinical Equivalence between the MiniDraw™ H&H Tube and respective capillary and venous comparator devices, BD Microtainer® Microtube for Automated Processes (BD MAP EDTA) and Greiner Vacuette® Blood Collection Tube with K_2EDTA (Greiner Vacuette EDTA), for the analytes identified above. This assessment considered whether the mean and the two one-sided 95% Confidence Limits of the paired sample biases were within the Clinical Acceptance Limits (CALs).

- **MiniDraw™ H&H Tube vs BD MAP EDTA (Capillary Comparator):** The performance of the MiniDraw H&H Tube was considered clinically equivalent to the BD MAP EDTA for both analytes identified above**.**

- **MiniDraw™ H&H Tube vs Greiner Vacuette EDTA (Venous Comparator):** The performance of the MiniDraw H&H Tube was considered clinically equivalent to the Greiner Vacuette EDTA for both analytes identified above.

Lot to Lot Variability

This study was performed to evaluate non-inferiority of the MiniDraw™ H&H Tube in comparison to respective comparator devices (BD MAP EDTA and Greiner Vacuette EDTA) for total variability (lot-to-lot and within lot) for the analytes identified above.

- **MiniDraw™ H&H Tube vs BD MAP EDTA [Capillary comparator]: This evaluation led to the conclusion that** the MiniDraw™ H&H Tube passed the non-inferiority criterion (which included lot to lot variation and within lot) for the analytes identified above when compared with capillary comparator, BD MAP EDTA.

- **MiniDraw™ H&H Tube vs Greiner Vacuette EDTA [Venous comparator]:** This evaluation led to the conclusion that MiniDraw™ H&H Tube passed the non-inferiority

criterion (which included lot to lot variation and within lot) for all the analytes identified above when compared with venous comparator, Greiner Vacuette EDTA.

Within-Tube Type Stability

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

The MiniDraw™ H&H 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 analytes.

Operator Variability

This study was performed to evaluate operator variability of the MiniDraw™ H&H Tube and respective capillary and venous comparator devices, BD MAP EDTA and Greiner Vacuette EDTA for analytes identified above.

- **MiniDraw™ H&H Tube vs BD MAP EDTA [Capillary comparator]: This evaluation led to the conclusion that** the MiniDraw™ H&H Tube passed the non-inferiority criterion for operator variability for the analytes identified above when compared with capillary comparator, BD MAP EDTA.

- **MiniDraw™ H&H Tube vs Greiner Vacuette EDTA [Venous comparator]:** This evaluation led to the conclusion that MiniDraw™ H&H Tube passed the non-inferiority criterion for operator variability for all the analytes identified above when compared with venous comparator, Greiner Vacuette EDTA.

Shelf-Life

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

Conclusion

The comparison between the proposed device (MiniDraw™ H&H System) and the predicate device (BD MAP EDTA) 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™ H&H 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™ H&H System was compared to the predicate device and the blood collected in each tube was analyzed for identified hemoglobin and hematocrit and produced test results that are considered clinically equivalent to the capillary and venous comparator tubes. The results generated in the clinical performance testing for Method Comparison (Clinical Equivalence), Lot to Lot Variability, Within-Tube Type Stability, Operator Variability and Shelf Life demonstrated appropriate performance.

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