DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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September 23, 2016

BECTON, DICKINSON AND COMPANY
BRANDEN REID
STAFF REGULATORY AFFAIRS SPECIALIST
1 BECTON DRIVE
FRANKLIN LAKES NJ 07417

Re: K160657
Trade/Device Name: BD Vacutainer® Barricor™ Lithium Heparin Plasma Blood Collection Tube
Regulation Number: 21 CFR 862.1675
Regulation Name: Blood specimen collection device
Regulatory Class: II
Product Code: JKA
Dated: August 23, 2016
Received: August 24, 2016

Dear Branden Reid:

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 (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. 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 Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Katherine Serrano -S

For: Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K160657

Device Name
BD Vacutainer® Barricor™ Lithium Heparin Plasma Blood Collection Tube

Indications for Use *(Describe)*
BD Vacutainer® Barricor™ Lithium Heparin Plasma Blood Collection Tubes (BD Barricor™ Tubes) are used to collect, separate, process, transport, and store venous blood samples for use in chemistry determinations, therapeutic drug monitoring, and zinc testing in plasma for in vitro diagnostic use. It is used in settings where a venous blood sample is collected by a trained healthcare worker.

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
21 CFR 807.92(c)

BD Vacutainer® Barricor™ Lithium Heparin^{N} Plasma Blood Collection Tube

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Submitter Information	Submitter Name:	Becton, Dickinson and Company
	Submitter Address:	1 Becton Drive Franklin Lakes, NJ 07417
	Contact Person:	Branden Reid, Ph.D. branden.reid@bd.com 201-847- 7378 (phone) 201-847- 5307 (fax)
	Date of Preparation:	September 21, 2016

Device Information	Trade Name:	BD Vacutainer® Barricor™ Lithium Heparin^{N} Plasma Blood Collection Tube
	Common Name:	Blood Collection Tube
	Classification Name:	Blood Specimen Collection Device (21 CFR 862.1675)
	Classification:	Class II
	Product Code:	JKA

Predicate Device	Trade Name:	Vacutainer® Brand PST™ Plasma Separator Tube
	Common Name:	Blood Collection Tube
	Classification Name:	Blood Specimen Collection Device (21 CFR 862.1675)
	Classification:	Class II
	Product Code:	JKA

Device Description

The BD Vacutainer® Barricor™ Lithium Heparin^{N} Plasma Blood Collection Tubes (BD Barricor™ Tubes) are sterile (interior), single-use, evacuated blood collection tubes for collecting, separating, processing, transporting, and storing lithium heparin plasma in a closed tube. These products are comprised of a plastic tube containing a mechanical separator (in place of gel), a low-zinc stopper and a plastic BD Hemogard™ color-coded Lime Green safety-engineered shield. The interior of the BD Barricor™ Tube is spray coated with a lithium heparin anticoagulant. Tube stopper and mechanical separator are lubricated with silicone based surfactant to facilitate product assembly. The BD Barricor™ Tubes contain less than 50 µg/L of zinc to enable zinc testing. These tubes are available in 13x75mm and 13x100mm configurations with various nominal draw volumes ranging from 3.0mL to 5.5mL.

The BD Barricor™ Blood Collection Tube is designed to be compatible with current phlebotomy and clinical laboratory practice. It employs a novel separation technology, a mechanical separator, which remains stable in its initial position, to enable the blood to be filled via current methods and subsequently creates a stable, robust barrier during processing. The mechanical separator is comprised of two materials of different densities - an elastomer and a higher density base material.

In its resting position, the diameter of the mechanical separator is greater than that of the tube. The resulting friction from this interface allows the separator to maintain its position and orientation prior to blood collection and permits filling of the tube. Under centrifugation, the force applied on the separator will correctly orient the separator and allows it to move within the tube. While immersed in the collected sample, the differential buoyancy of the two materials will stretch the separator enabling the passage of cellular content and appropriate positioning of the separator between the cell column and plasma sample. When centrifugation stops, the mechanical separator returns to its original shape to form a barrier between the plasma sample (at the top), which is subsequently available for analysis, and the sedimented cells below.

Intended Use/ Indications for Use

The BD Vacutainer® Barricor™ Lithium Heparin^{N} Plasma Blood Collection Tubes (BD Barricor™ Tubes) are used to collect, separate, process, transport and store venous blood samples for use in chemistry determinations, therapeutic drug monitoring (TDM), and zinc testing in plasma for in vitro diagnostic use. It is used in settings where a venous blood sample is collected by a trained healthcare worker.

Technological Characteristics

The technological characteristics of the subject device are equivalent to that of the predicate device with respect to blood collection and processing. The BD Barricor™ Tube utilizes the same family of component materials as the predicate, the Vacutainer® Brand PST™ Plasma Separator Tube (BD PST™ Tube), with the following exceptions: the use of a mechanical separator (in place of gel), a low zinc rubber stopper is utilized, PET is used for the tube material instead of glass, the proposed device has a sterility acceptance limit of $SAL10^{-6}$, and the proposed device utilizes shrink-wrapped polystyrene tray for shelf level packaging. The mechanical separator and low zinc stopper of the BD Barricor™ Tube improves sample stability, centrifugation time, enables zinc testing, and eliminates test interferences due to gel adsorption (e.g., some therapeutic drug assays).

Table 1: Comparison to Predicate Device

KEY PARAMETERS		PROPOSED DEVICE	PREDICATE DEVICE (K954592)
PRODUCT NAME		BD Barricor™ Tube	BD PST™ Tube
INTENDED USE/INDICATIONS FOR USE		BD Vacutainer® Barricor™ Lithium Heparin^{N} Plasma Blood Collection Tubes (BD Barricor™ Tubes) are used to collect, separate, process, transport, and store venous blood samples for use in chemistry determinations, therapeutic drug monitoring, and zinc testing in plasma.	The VACUTAINER® Brand PST™ Plasma Separation Tube is and evacuated blood collection tube. Blood collected into a PST™ Tube is used for clinical laboratory assays involving patient plasma.
DESIGN/FUNCTION	Evacuated blood collection tube	✓	✓
	Anticoagulation	✓	✓
	Separate plasma from other blood components	Plasma with barrier	Plasma with barrier
Tube Components Comparison			
TUBE DIMENSION	13x75, 13x100 mm	✓	✓
DRAW VOLUME		3.0mL - 5.5mL	4.0mL – 9.5mL
CLOSURE	Hemogard™ safety closure	✓	✓
TUBE STOPPER	Rubber	Halobutyl rubber – low zinc	Compression Molded Rubber
LUBRICANT	Silicone-based formulation	Tube Stopper and Separator	Tube Stopper
TUBE MATERIAL		Polyethylene Teraphthalate (PET)	Glass
BARRIER		Mechanical separator	Gel
CLOT ACTIVATOR	Silica+hemo-repellent surfactant	N/A	N/A

KEY PARAMETERS		PROPOSED DEVICE	PREDICATE DEVICE (K954592)
ANTICOAGULANT	Lithium Heparin	✓	✓
STERILITY ASSURANCE LEVEL (SAL)		10^{-6}	10^{-3}
TUBE SHELF LIFE		18 months at 4 – 25°C	12 months at 4 – 25°C
TUBE STERILITY	Sterile	✓	✓
STERILE METHOD	Irradiation	✓	✓
INJECTION MOLDING		✓	✓
RUBBER MOLDING		✓	✓
BARRIER INSERTION		Mechanical separator insertion	Gel dispense
INTERIOR COATING OF ADDITIVE	Spray coated and Dried	✓	✓
TUBE EVACUATION VIA VACUUM CHAMBER		✓	✓
SHELF LEVEL		Shrink-wrapped polystyrene tray	Printed shelf carton
CASE LEVEL	Corrugated cardboard	✓	✓

Clinical Performance

Clinical testing was conducted on blood collected in both the proposed device and the comparator device for a representative panel of routine and special chemistry analytes, and representative therapeutic drugs using both apparently healthy and diseased subject populations. Clinical equivalence was established per CLSI GP-34A guideline (Validation and Verification of Tubes for Venous and Capillary Blood Specimen Collection).

Representative Analytes in Routine and Special Chemistry and Therapeutic Drug Monitoring (TDM):

For routine and special chemistry determinations, six (6) studies were conducted at multiple sites. A minimum of 86 and up to 104 apparently healthy and diseased population subjects were enrolled per study (for a total of 570 subjects). Blood was collected from each subject into the BD Barricor™ and the BD PST™ tubes in randomized draw order. Tubes were handled and processed per their recommended handling conditions and centrifuged within 2 hours of collection in swing bucket centrifuges (BD Barricor™: for 3 minutes at 4000g and BD PST™ for 10 minutes at 1300g). Plasma samples from the tubes were tested for representative analytes listed in Table 2. Each analyte was tested on two instrument platforms. In addition, contrived specimens were also tested to cover the analytical range for some of the assays. A total of 68 apparently healthy subjects (18 years of age or older) were also

enrolled at the BD Franklin Lakes clinical trial site in order to create abnormally low or high values for one or more of the analytes. Samples prepared were tested at one or more sites for the specified analyte in the 6 studies.

For therapeutic drug monitoring, the performance of the BD Barricor™ Tube for representative therapeutic drugs (see Table 2 for list of therapeutic drugs tested) was evaluated at initial time on two instruments per drug vs. the BD Serum Tubes. A total of 705 adult subjects were enrolled in the study at multiple sites. Blood was collected from each subject into a BD Barricor™ and BD Serum Tube in randomized draw order. Tubes were handled and processed per their recommended handling conditions. BD Serum Tubes were allowed to clot for 60 minutes from the time of blood collection (maximum of 2 hours). All study tubes were then centrifuged in a swing bucket centrifuge at room temperature (BD Barricor™: 3 minutes at 4000g; BD Serum: 10 minutes at 1300g) within two hours of collection. Plasma/serum was either tested on-site for the selected therapeutic drugs or aliquoted from the primary tubes into secondary tubes, frozen, and shipped for testing at a central testing laboratory. In addition, contrived specimens were also tested to cover the assay range for the therapeutic drugs. A total of 25 apparently healthy subjects (18 years of age or older) were also enrolled at the BD Franklin Lakes clinical trial site to create the contrived specimens.

The results from the BD Barricor™ Tube were compared with the results of the BD PST™ Tube for each routine and special chemistry analyte per instrument. For therapeutic drug monitoring, the results from the BD Barricor™ Tube were compared with the results of the BD Serum Tube for each therapeutic drug per instrument. Deming Regression was used for each analyte/therapeutic drug per instrument.

The following information was provided:

- The slope and intercept of the fitted line with 95% confidence intervals.
- The standard error of the estimate.
- The biases with individual 100 (1 – 2α) % confidence intervals (or 2 one-sided 95% limits) calculated from the regression line at medical decision points.

Tube comparisons were evaluated relative to the assigned clinical acceptance limit (CAL) for each analyte/therapeutic drug. When the mean bias and the 95% limit of the comparison were both within the CAL, the results were considered clinically equivalent. If the 95% limit exceeded the CAL, the data were reviewed for clinical acceptability. The BD Barricor™ Tubes demonstrated clinically equivalent or clinically acceptable performance when compared with BD PST™ Tubes for the representative analytes in routine and special chemistry. BD Barricor™ Tubes demonstrated clinically equivalent or clinically acceptable performance for therapeutic drugs when compared with BD Serum Tubes on both instrument platforms.

Table 2: Routine and Special Chemistry Analytes and Therapeutic Drugs Tested at Initial Time	
Routine Chemistry	Albumin (ALB), Alanine Aminotransferase (ALT), Alkaline Phosphatase (ALKP), Amylase(AMY), Aspartate Aminotransferase (AST), Direct Bilirubin (DBIL), Total Bilirubin (TBIL), Blood Urea Nitrogen (BUN), Calcium (CA), Carbon Dioxide (CO_2), Chloride (CL), Cholesterol (CHOL), Creatine Kinase (CK), Creatinine(CREAT), Gamma-glutamyltransferase (GGT), Glucose (GLU), High density lipoprotein (HDL), Iron (FE), Lactate dehydrogenase (LDH), Low density lipoprotein (LDL), Lipase (LIP), Magnesium (MG), Phosphorus (PHOS), Potassium (K), Sodium (NA), Total Protein (TP), Triglycerides (TRIG), Uric Acid (UA)
Special Chemistry	Anemia panel: Ferritin, Folate, Vitamin B12 (Vit B12) Hormones: Free Triiodothyronine (Free T3), Total Triiodothyronine (Total T3), Free Thyroxine (Free T4), Total Thyroxine (Total T4), Thyroid Simulating Hormone (TSH), Cortisol, Estradiol, Follicle Stimulating Hormone (FSH) , β Human Chorionic Gonadotropin (βhCG), Luteinizing Hormone (LH), Progesterone, Testosterone Cardiac Markers: Creatine Kinase-MB Fraction (CKMB) Troponin I (TnI), Troponin T (TnT) Cancer Marker: Total Prostate Specific Antigen (Total PSA) Specific Proteins: Complement C3 (C3), Immunoglobulin A (IgA), Immunoglobulin G (IgG), Immunoglobulin M (IgM), C-Reactive Protein (CRP), Haptoglobin (HAP), Transferrin Autoantibody: Rheumatoid Factor (RF)
Therapeutic Drugs	Acetaminophen (ACET), Carbamazepine (CBZ), Digoxin (DIG), Phenytoin (PHT), Valproic Acid (VPA), Vancomycin (VANCO), and Salicylate (ASA)

Repeatability, Lot-to-Lot Variation, and Tube-to-Tube Variation Using Representative Chemistry Analytes and Therapeutic Drugs:

Two studies were conducted to assess the repeatability, lot-to-lot variation, and tube-to-tube variation in BD Barricor™ Tubes. The study designs included three lots each of BD Barricor™ and BD PST™/BD Serum Tubes and duplicate tubes from each lot.

Study 1 evaluated the BD Barricor™ Tube performance for representative routine and special chemistry analytes and Study 2 assessed performance for representative therapeutic drugs.

In Study 1, within-tube repeatability, lot-to-lot, and tube-to-tube variation for representative analytes (see Table 3) were investigated in the BD Barricor™ Tube in comparison to the BD PST™ Tube. A total of 35 subjects were enrolled. After centrifugation, all tubes from 20 subjects were tested in duplicate on two different instruments at initial time (0hr) for all routine and special chemistry analytes listed in Table 3. All tubes from an additional 10 subjects were tested in duplicate on two different instruments for Testosterone only; all tubes from the remaining 5 subjects were tested in duplicate on two different instruments for PSA only.

Similarly, in Study 2, within-tube repeatability, lot to lot variation, and tube-to-tube variation for representative therapeutic drugs (see Table 3) were investigated in the BD Barricor™ Tube in comparison to the BD Serum Tube. Fifty subjects were enrolled of which only 41 completed the study. Contrived specimens prepared from 20 subjects were tested for Carbamazepine, Digoxin, and Phenytoin, and contrived specimens prepared from another 21 subjects were tested for Acetaminophen and Vancomycin. Each sample was tested in duplicate on two different instrument platforms to compare the total tube variability in the evaluation and control tubes.

Acceptance criteria: For each routine and special chemistry analyte, the ratio of the total variability [Standard deviation (SD)] for BD Barricor™ to the total variability (SD) for BD PST™ did not exceed 2.0 with 95% confidence. For each therapeutic drug, the ratio of the total variability [standard deviation (SD)] for BD Barricor™ to the total variability (SD) for BD Serum did not exceed 2.0 with 95% confidence.

The acceptance criteria were met for each routine and special chemistry analyte and each therapeutic drug tested on two instrument platforms. Therefore, the variability in the BD Barricor™ Tubes was considered acceptable.

Table 3: Repeatability, Lot-to-Lot Variation, and Tube-to-Tube Variation Using Representative Chemistry Analytes and Therapeutic Drugs

Routine and Special Chemistry	Alanine Aminotransferase (ALT), Bilirubin- Total (TBIL), Calcium (CA), Chloride (CL), Cortisol, Complement C3 (C3), Glucose (GLU), Immunoglobulin G (IgG), Lactate Dehydrogenase (LDH), Phosphorus (PHOS), Potassium (K), Total Protein (TP), Total Thyroxine (Total T4), Testosterone, and Total Prostate Specific Antigen (Total PSA)
Therapeutic Drugs	Acetaminophen (ACET), Carbamazepine (CBZ), Digoxin (DIG), Phenytoin (PHT), and Vancomycin (VANCO)

Within-Tube Stability of Representative Routine and Special Chemistry Analytes and Therapeutic Drugs at Multiple Time Points

Within-tube stability of representative routine and special chemistry analytes in the BD Barricor™ Tube were evaluated at multiple time points with comparison to initial time results. Multiple studies were conducted to assess the within tube stability for representative routine and special chemistry analytes and therapeutic drugs in BD Barricor™ Tubes. Table 4 lists the studies, analytes, and time points. For stability, each analyte was tested on one instrument platform.

Stability for routine and special chemistry analytes (see list in Table 4) was evaluated in Study 1. Specimens from 92 subjects were tested (minimum of 40 subject specimens per analyte were tested). Tubes were tested at initial time and 24 hours (from centrifugation) with storage at room temperature. After the 24-hour test interval, tubes were placed in refrigerated storage (2-8°C) and removed for testing at day 3 (72 hours ±4 hours) and day 7 (168 hours ±4 hours) post centrifugation. Analytes that did not demonstrate stability for 24hrs were tested in a separate study (Study 2). In this follow up study, specimens from 40 subjects were tested at 0, 6 and 12 hours, and another set of 40 subjects were tested at 0 and 18 hours with storage at room temperature.

Stability for C-Reactive Protein (CRP) was evaluated in Study 3. Specimens collected from a minimum of 40 subjects were tested at initial time and 24hrs with storage at room temperature. After 24-hour testing, tubes were placed in refrigerated storage (2-8°C) and removed for testing at day 3 (72 hours ±4 hours) and day 7 (168 hours ±4 hours) post centrifugation.

Stability for βHuman Chorionic Gonadotropin (βhCG) and Total Prostate-Specific Antigen (Total PSA) was evaluated in Study 4. Specimens collected from a minimum of 40 subjects were tested at initial time and 24hrs with storage at room temperature.

Stability for Creatine Kinase-MB Fraction (CKMB), Troponin I (TnI), and Troponin T (TnT), was evaluated in Study 5. Specimens collected from 40 subjects were tested at initial time and 24hrs with storage at room temperature. Stability for therapeutic drugs in the BD Barricor™ Tube was evaluated in Study 6. Specimens from a minimum of 40 subjects were tested for each therapeutic drug (see Table 3 for list of therapeutic drugs) at initial time and 48 hours with room temperature storage, and after an additional 5 days of refrigerated storage (2-8º C) for a total of 7 days (7 d) on one instrument platform per analyte.

For all stability studies, the mean bias (with 95% limits) was calculated for each analyte/therapeutic drug at a given time point (vs.) initial time (0 hr).

The mean bias and 95% limits for each comparison were evaluated relative to the Clinical Acceptance Limit (CAL) for each analyte/therapeutic drug. For the within-tube comparison at each time point vs. 0 hr, equivalence was demonstrated when the mean bias and the 95% limits were within the established CAL. If the mean bias of the evaluation was within the CAL but the 95% limit exceeded the CAL, this constituted clinical non-equivalence requiring further interpretation and assessment to determine if the difference was clinically acceptable or not. If the mean bias of the

comparison exceeded the CAL, this constituted clinical non-equivalence. This was considered clinically unacceptable, unless a rationale was provided otherwise.

Within-tube stability was demonstrated in the BD Barricor™ Tube for up to 24hrs with room temperature storage and up to 7 days of refrigerated storage for all routine and special chemistry analytes except Folate, Glucose and CO2. For Folate, stability was established for 24 hours, while Glucose and CO2 demonstrated stability for 18hrs with room temperature storage. Within tube stability was demonstrated for CRP for up to 24hrs with room temperature storage and up to 7 days of refrigerated storage. βhCG, Total PSA, CKMB, TnI, and TnT were only tested for 24hrs at room temperature and demonstrated stability at that time point.

Within tube stability was demonstrated in the BD Barricor™ Tubes for all therapeutic drugs for up to 48 hours of storage at room temperature and up to 7 days of refrigerated storage.

Table 4: Within Tube Stability in Barricor Tube: Study, Analyte, and Time points

Study	Analyte	Time points
1	Routine Chemistry: Albumin (ALB), Alkaline Phosphotase (ALKP), Alanine Aminotransferase (ALT), Amylase (AMY), Aspartate Aminotransferase (AST), Bilirubin –Total (TBIL),Blood Urea Nitrogen (BUN), Calcium (Ca), Carbon Dioxide (CO_2), Chloride (Cl), Cholesterol (Chol), Creatine Kinase (CK), Creatinine (Creat), Gamma-glutamyltransferase (GGT), Glucose (GLU), High-Density Lipoprotein (HDL), Iron (Fe), Lactate Dehydrogenase (LDH), Lipase (Lip), Low-Density Lipoprotein(LDL), Magnesium (Mg), Phosphorus (Phos), Potassium (K), Sodium (Na), , Total Protein (TP), Triglycerides (Trig), and Uric Acid (UA) Special Chemistry: Complement C3 (C3), Cortisol (CORT), Ferritin (FERR), Folate, Follicle Stimulating Hormone (FSH), Free Triiodothyronine (Free T3), Free Thyroxine (Free T4), Haptoglobin (HPT), Immunoglobulin A (IgA), Immunoglobulin G (IgG), Immunoglobulin M (IgM), Luteinizing Hormone (LH), Testosterone, Thyroid Stimulating Hormone (TSH), Total Triiodothyronine (Total T3), Total Thyroxine (Total T4), Transferrin, and Vitamin B 12 (Vit B12)	0hr, 24hrs, 3 days and 7 days
2	Glucose (GLU) and Carbon Dioxide (CO_2)	0 hr, 6 hr and 12 hrs; 0 hr and 18 hrs
3	C-Reactive Protein (CRP)	0 hr, 24 hrs, 3 days and 7 days
4	β Human Chorionic Gonadotropin (βhCG), Total Prostate Specific Antigen (Total PSA)	0 hr and 24 hrs
5	Creatine Kinase MB Fraction (CKMB), Troponin I(TnI), Troponin T(TnT)	0 hr and 24 hrs

6	Therapeutic Drugs: Acetaminophen(ACET), Carbamazepine (CBZ), Digoxin (DIG), Phenytoin (PHT), Salicylate(ASA), Valproic Acid(VPA),and Vancomycin(VANCO)	0 hr, 48 hrs and 7 days

Substantial Equivalence

Based on a comparison of the device design, function, intended use and performance, the BD Barricor™ Tube is as safe, as effective, and performs as well as or better than the predicate device, the BD PST™ Tube. Therefore, the BD Barricor™ Tube is substantially equivalent to the BD PST™ Tube.