FEB 24 1998

K972075

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BECTON DICKINSON

Becton Dickinson and Company
1 Becton Drive
Franklin Lakes, New Jersey 07417
(201) 847-6800

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

I. General Information

This Summary of 510(k) Safety and Effectiveness information is being submitted in accordance with the requirements of the SMDA of 1990 and 21 CFR 807.92

Establishment:

- Address: Becton Dickinson VACUTAINER Systems
  1 Becton Drive
  Franklin Lakes, NJ 07417-1885
- Registration Number: 2243072
- Contact Person: John A. Schalago
  Regulatory Affairs Specialist
  Telephone no.: 201 - 847 - 6280
  Facsimile no.: 201 - 847 - 4858
- Date of Summary: December 4, 1997

Device Name:

- Trade Name: VACUTAINER® Brand PPT™-Plasma Preparation Tube
- Classification Name : Blood Specimen Collection Device
- Classification: Class II
- Performance Standards: None Established under 514 of the Food, Drug and Cosmetic Act
- **Safety and Effectiveness Information Supporting the Substantial Equivalence Determination**

The term, "Substantial Equivalence" used in this 510(k) Premarket Notification, is limited to the definition of Substantial Equivalence as found in the Federal Food, Drug, and Cosmetic Act, as amended and as applied under 21 CFR § 807, Subpart E under which a device can be marketed without pre-market approval or reclassification. A determination of substantial equivalency under this notification is not intended to have any bearing whatsoever on the resolution

of patent infringement suits or any other patent matters. No statements related to or in support of substantial equivalence herein shall be construed as an admission against interest under the US Patent Laws or their application by the courts.

• Device Description

The VACUTAINER® Brand PPT™-Plasma Preparation Tube (blood collection tube containing EDTA Anticoagulant and Gel barrier) is an evacuated plastic blood collection tube for collecting, processing and transporting blood in a closed plastic tube. The VACUTAINER® Brand PPT™ consists of a HEMOGARD® closure assembly, plastic tube (PET), EDTA anticoagulant (dipotassium or tripotassium) and a polymeric gel barrier material.

• Intended Use

The VACUTAINER® Brand PPT™ Plasma Preparation Tube with EDTA anticoagulant and a gel barrier material are evacuated blood collection tubes which provide a means of collecting, processing and transporting blood in a closed plastic tube. When the Tube is used together with VACUTAINER® Brand Needles and Holders, it is a closed system for the collection of venous blood with the same indications identified here.

Blood collected in a tube containing EDTA anticoagulant and gel barrier material is used primarily to provide undiluted plasma for use in molecular diagnostic test methods including but not limited to PCR (Polymerase Chain Reaction) and bDNA (branched DNA). The specimen may also be used for other testing that requires an undiluted plasma sample as determined by the laboratory.

• Synopsis of Test Methods and Results

Six studies were conducted to evaluate the use of the VACUTAINER® Brand PPT™ Tube for molecular diagnostic viral load determinations. Study I evaluated the clinical functional performance of the PPT™ tube as compared to a control device (Terumo Venoject K_3EDTA). Studies II, III, IV, V, and VI were conducted to demonstrate substantial equivalence to the predicate device (PLUS K_2 EDTA). Studies I, III, and IV compared HIV viral loads obtained with the principal device to viral loads obtained with either control or predicate (non-gel separator EDTA) devices. Studies II, V, and VI compared HCV viral loads obtained in the principal device to those obtained in the predicate device.

The clinical functional performance of the VACUTAINER® PPT™ Tube was evaluated using the Roche Amplicor® HIV RT PCR Monitor™ Kit. (Study I) The clinical evaluation compared the VACUTAINER® PPT™ Tube, principal device, to the Terumo Venoject K_3EDTA for 56 HIV-Positive patients. Paired aliquots of undiluted plasma produced in the VACUTAINER® PPT™ tube and Terumo Venoject K_3 EDTA were evaluated for HIV viral load. The PPT™ tube demonstrated clinically equivalent performance compared to the samples produced in the EDTA control tube.

Substantial equivalence between the principal device and the predicate device (VACUTAINER® Brand PLUS EDTA) was demonstrated for the determination of viral loads using the Roche Amplicor® HIV RT PCR Monitor™ Test Kit, (Studies III and IV), the Amplicor® HCV RT PCR Monitor™ Test Kit (Studies V and VI), and for the Chiron Quantiplex HCV-RNA (branched DNA) assay (Study II).

Two HIV clinical evaluations (Study III and Study IV) compared viral load measurements of paired PPT™/EDTA samples from HIV positive subjects. Each study evaluated the viral load of plasma produced from forty (40) HIV positive subjects. The samples were evaluated using the Roche Amplicor® HIV RT PCR Monitor™ Kit. The results of HIV viral load determinations demonstrated statistically and clinically equivalent results between the principal and predicate devices.

The VACUTAINER® Brand PPT™ Tube was also evaluated for HCV viral load determinations, by b-DNA and PCR. For Study II, a total of forty-nine (49) paired samples were collected from twenty-four (24) HCV negative and twenty-five (25) HCV positive subjects and evaluated using the Chiron Quantiplex HCV RNA Assay. The VACUTAINER® Brand PPT™ Tube, principal device, demonstrated equivalent results to the VACUTAINER® Brand PLUS Tube with EDTA for both negative and positive HCV samples.

For Studies V and VI, paired PPT™/EDTA samples were collected from a total of sixty-five (65) HCV-positive patients and were evaluated for HCV viral load using the Roche Amplicor® HCV RT PCR Monitor™ Test Kit. Viral load measurements of paired HCV samples were compared and results indicated that viral load results obtained from plasma produced in the VACUTAINER® Brand PPT™ Tube are equivalent to those obtained with the VACUTAINER® Brand PLUS Tube with EDTA.

• Substantial Equivalence

Becton Dickinson VACUTAINER Systems believes that the VACUTAINER® Brand PPT™ Tube is substantially equivalent to two commercially available blood collection tubes. Clinical testing which demonstrated equivalent performance and effectiveness and comparisons of the Principal and Predicate device characteristics and manufacturing process supports the determination of substantial equivalence. The predicate devices, manufacturer, K number and clearance date are identified below:

Manufacturer	Predicate Device	K-Number	Clearance Date
VACUTAINER Systems	VACUTAINER® Brand PLUS Tube with EDTA Anticoagulant	K953463	9/20/95
VACUTAINER Systems	VACUTAINER™ Brand PST™ Tube	K945952	1/18/95

John A. Schalago
Regulatory Affairs Specialist
Regulatory Affairs Department

December 4, 1997
Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Becton Dickinson Vacutainer Systems and Labware
John A. Schalago
Regulatory Affairs Specialist
1 Beckton Drive
Franklin Lakes, NJ 07417

FEB 06 2015

Re: K972075
Trade/Device Name: VACUTAINER Brand PPT Plasma Preparation Tubes
Regulation Number: 21 CFR 862.1675
Regulation Name: Blood specimen collection device
Regulatory Class: Class II
Product Code: PJE
Dated: December 4, 1997
Received: December 5, 1997

Dear Mr. Schalago:

This letter corrects our substantially equivalent letter of February 24, 1998.

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.

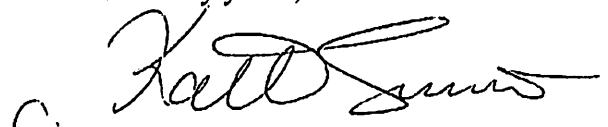
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

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 regulation (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" (21CFR 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,



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

510(k) Number (if known): K972075

Device Name: VACUTAINER® Brand PPT™ Plasma Preparation Tubes

Indications for Use:

The VACUTAINER® Brand PPT™ Plasma Preparation Tube with EDTA anticoagulant and a gel barrier material are evacuated blood collection tubes which provide a means of collecting, processing and transporting blood in a closed plastic tube. When the Tube is used together with VACUTAINER® Brand needles and holders, it is a closed system for the collection of venous blood with the same indications identified here.

Blood collected in a tube containing EDTA anticoagulant and gel barrier material can be primarily used to provide undiluted plasma for use in molecular diagnostic test methods; including but not limited to Polymerase Chain Reaction (PCR) and branched-DNA (bDNA). The specimen may also be used for other testing that requires an undiluted plasma sample as determined by the laboratory.

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K972075

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter Use ____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)