

JUN 17 1997

K971449



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**BECTON  
DICKINSON**

Becton Dickinson VACUTAINER Systems  
1 Becton Drive  
Franklin Lakes, New Jersey 07417  
(201) 847-4500

**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:** April 16, 1997

**Device Name:**

- **Trade Name:** VACUTAINER® Brand Plus Tube  
with EDTA Anticoagulant
- **Classification Name :** Blood Specimen Collection Device
- **Classification:** Class II
- **Performance Standards:** None Established under 514 of  
the Food, Drug and Cosmetic Act

**II. Safety and Effectiveness Information Supporting the Substantial Equivalence Determination**

● **Device Description**

The VACUTAINER® Brand PLUS Tube with EDTA is an evacuated plastic tube for collecting, transmitting and processing blood in a closed plastic tube. The blood collection tube consists of closure assembly, a plastic tube and EDTA coating (dipotassium, K<sub>2</sub>).

The plastic tube is manufactured from PET (Polyethylene terephthalate Plastic and enhances user safety and disposal because of the reduced risk of tube breakage and incineration as a method of disposal. The standard closure assembly is a basic rubber stopper. The tube is also available with VACUTAINER Systems Hemogard™ Closure assembly which is designed to reduce user exposure to blood. The EDTA anticoagulant tube coating is spray coated in a dipotassium (K<sub>2</sub>) form. The EDTA prevents specimen coagulation.

- **Intended Use**

The VACUTAINER® Brand PLUS Tube with EDTA is an evacuated blood collection tube which provides a means of collecting, transporting and processing blood in a plastic tube. Blood collected in a tube containing EDTA anticoagulant is used primarily for clinical laboratory hematology studies but may be used for other whole blood specimens, including but not limited to lead level testing and FEP level testing, as determined by the laboratory.

- **Synopsis of Test Methods and Results**

The VACUTAINER® Brand Plus Tube with EDTA anticoagulant, as described above, is a plastic tube with closure assembly (rubber stopper or HEMOGARD™ Closure). The plastic tube provides enhanced user safety and disposal because of the reduced risk of tube breakage and the use of incineration as a method of disposal. Breakage reduction and enhanced disposal studies and test results were described 510(k) Premarket Notification K901449/A which received FDA clearance on August 9, 1990.

Clinical evaluation of the VACUTAINER® Brand Plus tube with EDTA Anticoagulant was performed to demonstrate device equivalence for FEP and Blood Lead analyses. The VACUTAINER® Brand Plus Plastic Tube with EDTA was compared to VACUTAINER® Brand Glass Tube with EDTA, at initial time and extended tube storage. The VACUTAINER® Brand PLUS Tube with EDTA demonstrated analytically and statistically equivalent results and sample stability. Therefore, Clinical evaluation supports the use of the VACUTAINER® Brand PLUS Tube with EDTA for FEP and Blood Lead analyses.

Additionally, bench testing of three different lots of VACUTAINER® Brand Plus Tube with EDTA was performed to determine the tube lead levels. As identified in the draft product labeling, the maximum limit is 2.5 ug/L (ppb). This maximum lead limit for the Plus plastic tube is significantly lower than the current Center for Disease Control and Prevention decision level of 10 ug/dL or 100 ug/L for toxicity in children. Twenty tubes from each of the three lots were tested according to internal test procedures. The Lead levels were evaluated using Atomic Absorption (AA). The calibration standards used to calibrate the AA had lead concentration levels of 2 and 4 ug/L. The results demonstrated that lead level of all tubes from the three different lots were below 2 ug/L and therefore, support the labeling claim of 2.5 ug/L. The test data and results are maintained on file at Becton Dickinson VACUTAINER Systems, Franklin Lakes, NJ.

● **Substantial Equivalence**

Becton Dickinson VACUTAINER Systems believes that the VACUTAINER® Brand PLUS Tube with EDTA with the expanded Indications for Use is substantially equivalent to a commercially available blood collection tube. Clinical testing, as described in this premarket notification, demonstrates equivalent performance and effectiveness and 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 Tube with EDTA Anticoagulant	Not Applicable	Pre-Amendment Device and, therefore, exempt from premarket notification requirements according to the MDA of 1976.

Also included in this premarket notification, is a description of an incremental packaging modification which occurred prior to the submission of this premarket notification. VACUTAINER Systems determined that the incremental modification did not significantly affect the safety or efficacy of the VACUTAINER® Brand Tube and Brand PLUS Tube, and therefore, did not require a 510(k) premarket notification.

  
John A. Schalago  
Regulatory Affairs Specialist  
Regulatory Affairs Department

April 16, 1997  
Date



JUN 17

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

John A. Schalago  
• Regulatory Affairs Specialist  
Becton Dickinson VACUTAINER Systems  
1 Becton Drive  
Franklin Lakes, New Jersey 07417

Re: K971449  
VACUTAINER® Brand PLUS (Plastic) Blood Collection Tube  
with EDTA Anticoagulant  
Regulatory Class: II  
Product Code: GIM  
Dated: April 16, 1997  
Received: April 21, 1997

Dear Mr. Schalago:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

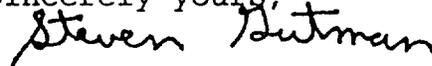
Page 2

Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

\* If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



Steven I. Gutman, M.D., M.B.A.  
Director  
Division of Clinical  
Laboratory Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

510(k) Number (if known): 12971449

Device Name: VACUTAINER® Brand PLUS Tube with EDTA Anticoagulant

Indications for Use:

The VACUTAINER® Brand PLUS (plastic) Tube with EDTA is an evacuated blood collection tube which provide a means of collecting, transporting, separating and processing blood in a 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 as described herein.

Blood collected in a tube containing EDTA Anticoagulant is primarily used for clinical laboratory testing-hematology study using whole blood but may be used for other studies including such studies as testing for lead and FEP analyses, requiring whole blood as determined by the laboratory.

(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)

  
(Division Sign-Off)  
Division of Clinical Laboratory Devices

510(k) Number 12971449