JUN 17 1998

K981013

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:** Eileen Schweighardt
  Regulatory Affairs Manager
  Telephone no.: 201 - 847 - 4570
  Facsimile no.: 201 - 847 - 4858
- **Date of Summary:** March, 1998

Device Name:

- **Trade Name:** VACUTAINER® Brand PLUS Tube
  with EDTA Anticoagulant and
  VACUTAINER® Brand PLUS Serum Tube
- **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

Substantial Equivalence Declaration: The term "Substantial Equivalence" is 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 apporval or reclassification.

• Device Description

The VACUTAINER® Brand PLUS Tube with EDTA and the VACUTAINER PLUS Serum Tube are evacuated plastic blood collection tubes for collecting, transporting and processing blood in a closed plastic tube. The VACUTAINER® Brand PLUS Tube with EDTA consists of closure assembly, a plastic tube and EDTA coating (dipotassium). The VACUTAINER PLUS Serum Tube consists of closure assembly, a plastic tube and silica clot activator.

The standard closure assembly is a basic rubber stopper. The tubes are also available with the VACUTAINER® Hemogard Closure Assembly, which consists of a rubber stopper and protective plastic shield to reduce user exposure to blood. The Hemogard closure assembly, intended to reduce user exposure to blood, was described in 510(k) Premarket Notification K945952 that received FDA clearance on January 18, 1995. All stopper/closures are color coded to reflect additive type (see the chart **VACUTAINER® Tube Stopper/Closure Color Code Cross Reference** located in the Product Insert, Attachment D)

• Intended Use

The VACUTAINER® Brand PLUS Tube with EDTA anticoagulant and the VACUTAINER Brand PLUS Serum Tube are evacuated blood collection tubes which provides a means collecting, transporting and processing blood in a closed plastic tube. Blood collected in a tube containing EDTA anticoagulant, VACUTAINER® Brand PLUS Tube with EDTA anticoagulant, is used primarily for clinical laboratory hematology studies. The VACUTAINER® Brand PLUS Serum Tube containing Silica activator is used primarily in clinical laboratory testing for chemistry assays.

In addition, the blood collected and processed in the VACUTAINER® Brand PLUS with EDTA anticoagulant and the VACUTAINER® Brand PLUS Serum Tube can be used immunohematology testing including ABO grouping, Rh typing and antibody screening which requires red cells and plasma or serum.

• Synopsis of Test Methods and Results

Clinical testing to evaluate the effectiveness of the tube for the additional Indications for Use described in premarket notification was performed. The results of the clinical evaluation demonstrate that the VACUTAINER® Brand PLUS (plastic) EDTA and PLUS Serum tubes provide equivalent results compared to the VACUTAINER® Brand (glass) Serum and EDTA tubes for immunohematology testing including ABO Grouping, Rh typing and antibody screening which requires red cells and plasma or serum.

• Substantial Equivalence

Becton Dickinson VACUTAINER Systems believes that the VACUTAINER® Brand PLUS Tube with EDTA and VACUTAINER® Brand PLUS Serum Tube 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 Serum Tube	Not Applicable	Pre-Amendment Device and, therefore, exempt from premarket notification requirements according to the MDA of 1976.
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.

Eileen Schweighardt

Eileen Schweighardt
Regulatory Affairs Manager
Regulatory Affairs Department

March 16, 1998
Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUN 17 1998

Ms. Eileen Schweighardt
Regulatory Affairs Manager
Becton Dickinson VACUTAINER Systems
1 Becton Drive
Franklin Lakes, New Jersey 07417

Re: K981013
VACUTAINER Brand (PLUS) Plastic Blood Collection Tube with EDTA Anticoagulant and VACUTAINER Brand PLUS (Plastic) Serum Tube
Regulatory Class: II
Product Code: JKA
Dated: March 17, 1998
Received: March 18, 1998

Dear Ms. Schweighardt:

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 regulated by CDRH 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. You may, therefore, market the device, subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act). The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration.

In addition, we have determined that your indications for use which includes immunohematology testing for ABO grouping, Rh typing and antibody screening are subject to regulation by the Center for Biologics(CBER).

Our substantially equivalent determination does not apply to the indications for use regulated by CBER. CBER is reviewing BK980011 for the immunohematology claims. For information on applicable Agency requirements for marketing this product, we suggest you contact:

Mary Gustafson
HFM-370, Room 200 N. Woodmont
Center for Biologics Evaluation and Research
Food and Drug Administration, Rockville, MD 20852
(301) 827-3524

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 Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (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 section 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device indicated for uses regulated by CDRH in your 510(k) premarket notification although we recommend that you first contact Ms. Kochman from CBER at (301) 827-3524 before marketing your product with the immunohematology claims regulated by CBER. An FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market, but it does not mean that FDA approves your device. Therefore, you may not promote or in any way represent your device or its labeling as being approved by FDA. If you desire specific advice for your device on the labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), promotion, or advertising, please contact the Office of Compliance, Promotion and Advertising Policy Staff (HFZ-302) 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,

S Dutman

Steven I. Gutman, MD, MBA
Director
Division of Clinical
Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K981013

Device Name: VACUTAINER® Brand PLUS Tube with EDTA Anticoagulant and VACUTAINER® Brand PLUS Serum Tube

Indications for Use:

The VACUTAINER® Brand PLUS (plastic) Tube with EDTA and VACUTAINER® Brand Serum Tube are evacuated blood collection tubes 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 PLUS EDTA and PLUS Serum tubes can be used for immunohematology testing including ABO Grouping, Rh typing and antibody screening which requires red cells and plasma or serum.

(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 K981013