JUL 2 9 2002

K022130

J. 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

510(k) Summary Of Safety and Effectiveness

I. General Information

This Summary of Safety and Effectiveness information is being submitted in accordance with the requirements of the SMDA of 1990 and 21 § 807.92

Establishment:

- Address: BD VACUTAINER Systems, Preanalytical Solutions
  1 Becton Drive, MC 300
  Franklin Lakes, NJ 07417-1885
- Registration Number: 2243072
- Contact Person: Jing Zhang
  Manager Regulatory Affairs
  Telephone No.:(201) 847-4717
  Fax No. (201) 847-4858
- Date of Summary: July 24, 2002

Device

- Trade Name: BD Vacutainer™ PLUS PST II™ Tube
- Classification Name: Tubes, Vials, Systems, Serum Separators, Blood Collection
- 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™ PLUS PST II™ Tubes are sterile, plastic, evacuated blood collection tubes. The Vacutainer™ PLUS PST II™ Tube consists of: (1) a closure assembly, (2) an inert acrylic gel mechanical barrier, and (3) a lithium heparin coated plastic tube. The specimen is centrifuged and the barrier material forms at the plasma interface, mechanically separating the plasma from cells. The plasma portion is used for clinical laboratory assays involving the use of patient plasma. The benefits of a plastic tube decrease the occurrence of accidental breakage increases the safety of laboratory personnel and reduces the necessity of repeat specimens.

- Intended Use:

  The BD Vacutainer™ PLUS PST II™ Tube is a lithium heparin coated plastic evacuated blood collection tube that provides a means of collecting, transporting and processing blood in a closed tube. Blood collected in a Vacutainer™ PLUS PST II™ Tube is used for clinical laboratory assays involving the use of patient plasma.

- Claims:

  The PLUS PST II™ Tube: (1) provides improved plasma quality vs. the BD Vacutainer™ Brand PLUS PST™ Plasma Separation Tube; (2) provides selected analyte stability up to twenty-four hours after centrifugation; and (3) provides stability for up to two hours after centrifugation for the following cardiac analytes: troponin I, creatine kinase MB fraction (CKMB), and myoglobin.

- Synopsis of Test Methods and Results

  Clinical evaluations were performed to determine the safety and efficacy of the BD Vacutainer™ PLUS PST II™ Tube. The BD Vacutainer™ PLUS PST II™ Tube was compared to the currently marketed BD Vacutainer™ Brand PLUS PST™ Plasma Separation Tube. The results of the clinical evaluation demonstrated that the BD Vacutainer™ PLUS PST II™ Tube provides clinically equivalent chemistry analyte results when compared to the BD Vacutainer™ Brand PLUS PST™ Plasma Separation Tube.

- Substantial Equivalence

Based on a comparison of the device features, materials, and intended use, the BD Vacutainer™ PLUS PST II™ Tube are substantially equivalent to the commercially available predicate device. The only difference between the predicate Vacutainer™ PLUS PST™ Tubes and the Vacutainer™ PLUS PST II™ Tubes is the acrylic gel material. The predicate device, K number, and clearance date are identified below:

Manufacturer	Predicate Device	K-Number	Clearance Date
BD VACUTAINER™ Systems	VACUTAINER™ Brand PST™ PLUS Tube	K945952	1/18/95

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUL 2 9 2002

Mr. Jing Zhang
Manager, Regulatory Affairs
Becton, Dickinson and Company
1 Becton Drive, MC 300
Franklin Lakes, NJ 07417-1885

Re: k022130
Trade/Device Name: BD Vacutainer™ Plus PST II™ Tube
Regulation Number: 21 CFR 862.1675
Regulation Name: Blood specimen collection device
Regulatory Class: Class II
Product Code: JKA
Dated: June 28, 2002
Received: July 1, 2002

Dear Mr. Zhang:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), 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 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); 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.

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" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

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

B. INDICATIONS FOR USE

510(k) Number (if known): K022130

Device Name: BD Vacutainer™ PLUS PST II™ Tube

Indications for Use:

The BD Vacutainer™ PLUS PST II™ Tube is a lithium heparin coated plastic evacuated blood collection tube that provides a means of collecting, transporting and processing blood in a closed tube. Blood collected in a Vacutainer™ PLUS PST II™ Tube is used for clinical laboratory assays involving the use of patient plasma.

(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)

Jean Cooper

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K022130