K023075

NOV 25 2002

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: Nov. 21, 2002

Device

- Trade Name: BD Vacutainer™ PLUS SST™ 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 SST™ Tubes are sterile, plastic, evacuated blood collection tubes. The Vacutainer™ PLUS SST™ Tube consists of: (1) a closure assembly, (2) an inert polyester gel barrier, (3) silica clot activator, and (4) a silicone surfactant coated plastic tube. The specimen is centrifuged and the barrier material forms at the serum/blood clot interface, mechanically separating the serum from cells. The serum portion is used for clinical laboratory assays involving the use of patient serum.

➢ Intended Use:

The Vacutainer™ PLUS SST™ Tube is a plastic evacuated blood collection tube with silica clot activator and gel that provides a means of collecting, transporting, separating, and processing blood in a closed tube. Blood collected in a Vacutainer™ PLUS SST™ Tube is primarily used for clinical laboratory testing in chemistry using patient serum, but may be used for other assays requiring serum specimens as determined by the laboratory. In addition, the Vacutainer™ PLUS SST™ Tube is compatible with many commonly used therapeutic drugs therefore suitable for therapeutic drug monitoring (TDM). Blood can be collected, processed and stored in a Vacutainer™ PLUS SST™ tube for at least 24 hours for therapeutic drug monitoring without large losses in recovery.

➢ Claims:

Blood can be collected, processed and stored in a Vacutainer™ PLUS SST™ tube for at least 24 hours for therapeutic drug monitoring without large losses in recovery. The storage conditions and time until analysis should be considered when collecting blood in Vacutainer™ PLUS SST™ tubes for TDM. This will ensure specimen integrity is maintained.

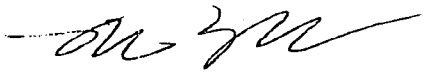
➢ Synopsis of Test Methods and Results:

Clinical evaluations were performed to determine the safety and efficacy of the Vacutainer™ PLUS SST™ Tube. The results of the clinical evaluation demonstrated that blood can be collected, processed and stored in a Vacutainer™ PLUS SST™ tube for at least 24 hours for therapeutic drug monitoring without large losses in recovery. The storage conditions and time until analysis should be considered when collecting blood in Vacutainer™ PLUS SST™ tubes for TDM. This will ensure specimen integrity is maintained.

➢ Substantial Equivalence:

Based on a comparison of the device features, materials, and intended use, the Vacutainer™ PLUS SST™ Tubes are substantially equivalent to the commercially available predicate device. The only difference between the predicate and the Vacutainer™ PLUS SST™ Tubes is the performance claim for therapeutic drug monitoring (TDM). The predicate device, K number, and clearance date are identified below:

Manufacturer	Predicate Device	K-Number	Clearance Date
BD Vacutainer Systems, Preanalytical Solutions	Vacutainer™ PLUS SST™ Serum Separator Tube	K960250	March 29, 1996



Jing Zhang
Manager Regulatory Affairs

11/21/02
Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

NOV 25 2002

Mr. Jing Zhang
Manager, Regulatory Affairs
BD Vacutainer Systems, Preanalytical Solutions
1 Becton Drive, MCC 300
Franklin Lakes, NJ 07417

Re: k023075
Trade/Device Name: BD Vacutainer™ PLUS SST™ Tube
Regulation Number: 21 CFR 862.1675
Regulation Name: Blood specimen collection device
Regulatory Class: Class II
Product Code: JKA
Dated: August 29, 2002
Received: September 16, 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 Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 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 information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 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
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

B. INDICATIONS FOR USE

510(k) Number (if known): K023075

Device Name: BD Vacutainer™ PLUS SST™ Tube

Indications for Use:

The Vacutainer™ PLUS SST™ Tube is a plastic evacuated blood collection tube with silica clot activator and gel that provides a means of collecting, transporting, separating, and processing blood in a closed tube. Blood collected in a Vacutainer™ PLUS SST™ Tube is primarily used for clinical laboratory testing in chemistry using patient serum, but may be used for other assays requiring serum specimens as determined by the laboratory. In addition, the Vacutainer™ PLUS SST™ Tube is compatible with many commonly used therapeutic drugs therefore suitable for therapeutic drug monitoring (TDM). Blood can be collected, processed and stored in a Vacutainer™ PLUS SST™ tube for at least 24 hours for therapeutic drug monitoring without large losses in recovery.

(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 K023075