K023331

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: Oct. 3, 2002

Device

- Trade Name: BD Vacutainer™ SST™ II PLUS 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 BD Vacutainer™ SST™ II PLUS Tubes are sterile, plastic, evacuated blood collection tubes. The BD Vacutainer™ SST™ II PLUS Tube consists of: (1) a closure assembly, (2) an acrylic gel barrier, (3) silica clot activator, (4) a silicone surfactant coating, and (5) a 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 and TDM involving the use of patient serum.

➢ Intended Use:

The BD Vacutainer™ SST™ II PLUS Tube is a plastic evacuated blood collection tube with silica clot activator and gel barrier material that provides a means of collecting, transporting, separating, and processing blood in a closed tube. Blood collected in a BD Vacutainer™ SST™ II PLUS Tube is primarily used for clinical laboratory testing – chemistry assays using patient serum but may be used for other assays requiring serum specimens as determined by the laboratory. In addition, the BD Vacutainer™ SST™ II PLUS Tube is compatible with many commonly used therapeutic drugs and is therefore suitable for therapeutic drug monitoring (TDM).

➢ Claims:

- SST II tubes demonstrate equivalent clinical performance to the predicate PLUS SST tubes and Glass Serum Tubes for clinical laboratory testing – chemistry assays using patient serum.
- SST II tubes demonstrate equivalent clinical performance to the predicate Glass Serum tubes for many commonly used therapeutic drugs and are therefore suitable for therapeutic drug monitoring (TDM).
- SST II tubes demonstrate better compatibility than the predicate PLUS SST tubes with many commonly used therapeutic drugs.

➢ Synopsis of Test Methods and Results

Clinical evaluations were performed to determine the efficacy of the BD Vacutainer™ SST™ II PLUS Tube. The results of the clinical evaluation demonstrated that blood can be collected, processed and stored in a BD Vacutainer™ SST™ II PLUS tube for chemistry assays and Therapeutic Drug Monitoring.

➢ Substantial Equivalence

Based on a comparison of the device features, materials, and intended use, the BD

Vacutainer™ SST™ II PLUS Tubes are substantially equivalent to the commercially available predicate devices identified below:

Manufacturer	Predicate Device	510(k) Number	Clearance Date
BD Vacutainer Systems	BD Vacutainer™ Brand Serum Tube	Preamendment	NA
BD Vacutainer Systems	BD Vacutainer™ PLUS SST Tube	K960250	3/29/96

Jing Zhang
Manager Regulatory Affairs

10/3/02
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: k023331
Trade/Device Name: BD Vacutainer™ SST™ II PLUS Tube
Regulation Number: 21 CFR 862.1675
Regulation Name: Blood specimen collection device
Regulatory Class: Class II
Product Code: JKA
Dated: October 3, 2002
Received: October 4, 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): K023331

Device Name: BD Vacutainer™ SST™ II PLUS Tube

Indications for Use:

The BD Vacutainer™ SST™ II PLUS Tube is a plastic evacuated blood collection tube with silica clot activator and gel barrier material that provides a means of collecting, transporting, separating, and processing blood in a closed tube. Blood collected in a BD Vacutainer™ SST™ II PLUS Tube is primarily used for clinical laboratory testing – chemistry assays using patient serum but may be used for other assays requiring serum specimens as determined by the laboratory. In addition, the BD Vacutainer™ SST™ II PLUS Tube is compatible with many commonly used therapeutic drugs and is therefore suitable for therapeutic drug monitoring (TDM).

(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 K023331