K. Premarket Notification [510(k)] Summary

K.1 General Information:

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: BK050036

Establishment Information:

- **Address:** BD Diagnostics, Preanalytical Systems
  1 Becton Drive, MC 300
  Franklin Lakes, NJ 07417-1885
- **Registration Number:** 1024879
- **Contact Person:** Stephen Anderson
  Telephone No.: (201) 847-4727
  Fax No.: (201) 847-4858
- **Date of Summary:** March 20, 2006
- **Common Name:** Blood Collection Tubes
- **Trade Name(s):** BD Vacutainer® Plus Serum Tubes
  BD Vacutainer® Plus K_2EDTA Tubes
  BD Vacutainer® SST™ Plus Tubes
  BD Vacutainer® SST™ Glass Tubes
  BD Vacutainer® SST™ II *Advance* Tubes
- **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

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K.2 Safety and Effectiveness Information Supporting the Substantial Equivalence Determination:

- **Device Description:** The BD Vacutainer® Tubes are sterile, plastic, evacuated blood collection tubes. These tubes generally consist of a closure assembly and a plastic tube. Some tubes contain a barrier forming gel and/or one or more additives. The specimens are used for clinical laboratory assays involving the use of patient blood.

- **Intended Use:** BD Vacutainer® Plus Serum Tubes, BD Vacutainer® SST™ Plus Tubes, BD Vacutainer® SST™ Glass Tubes, and BD Vacutainer® SST™ II *Advance* Tubes may be used for routine blood donor screening and diagnostic testing of serum for infectious disease. The performance characteristics of these tubes have not been established for infectious disease testing in general; therefore, users must validate the use of these tubes for their specific assay-instrument/reagent system combinations and specimen storage conditions.

  BD Vacutainer® Plus Serum and BD Vacutainer® Plus K_2EDTA Tubes may be used for routine immunohematology testing and blood donor screening. The performance characteristics of these tubes have not been established for immunohematology testing in general; therefore, users must validate the use of these tubes for their specific assay-instrument/reagent system combinations and specimen storage conditions.

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- **Synopsis of Test Methods and Results:**

The principal devices:
BD Vacutainer® Plus Serum Tubes,
BD Vacutainer® SST™ Plus Tubes,
BD Vacutainer® SST™ Glass Tubes, and
BD Vacutainer® SST™ II *Advance* Tubes
were compared with predicate BD Vacutainer® Glass Serum Tubes for collecting blood for infectious disease marker immunoassays.

In addition, the principal BD Vacutainer® Plus K_2EDTA Tubes were compared with predicate BD Vacutainer® Glass K_3EDTA Tubes for collecting blood for infectious disease marker immunoassays.

Assays were performed on blood collected in both principal and predicate tubes for a battery of infectious disease marker immunoassays. The sensitivity and specificity of the principal tubes for each of the immunoassays were then compared with the rates from the immunoassay kits. Results demonstrated that the sensitivity and specificity of the principal blood collection tubes (calculated using the discrepancies versus the predicate tubes) were within the ranges established by the manufacturers of the immunoassay kits. Based on these performance evaluations, it is clear that the principal devices described are suitable for use in conjunction with immunoassays for infectious disease markers.

In addition, principal BD Vacutainer® Plus K_2EDTA Tubes were compared with predicate BD Vacutainer® Glass K_3EDTA Tubes for collecting samples for DAT. These results, when combined with previous evaluations, indicate that BD Vacutainer® Plus K_2EDTA Tubes are suitable for immunohematology testing, including but not limited to, immunohematology testing performed by blood banks.

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- **Substantial Equivalence:**

Based on a comparison of the device features, materials, and intended use, the aforementioned principal devices are substantially equivalent to the respective predicate legally marketable devices identified below:

Name:	BD Vacutainer® Glass Serum Tubes
Manufacturer:	Becton, Dickinson and Company
510(k) No.:	Preamendment
Name:	BD Vacutainer® Plus Serum Tubes
Manufacturer:	Becton, Dickinson and Company
510(k) No.:	BK040030
Name:	BD Vacutainer® Glass K_3EDTA Tubes
Manufacturer:	Becton, Dickinson and Company
510(k) No.:	Preamendment
Name:	BD Vacutainer® Plus K_2EDTA Tubes
Manufacturer:	Becton, Dickinson and Company
510(k) No.:	BK980011
Name:	BD Vacutainer® SST™ Plus Tubes
Manufacturer:	Becton, Dickinson and Company
510(k) No.:	K023075
Name:	BD Vacutainer® SST™ Glass Tubes
Manufacturer:	Becton, Dickinson and Company
510(k) No.:	K921806
Name:	BD Vacutainer® SST™ II *Advance* Tubes
Manufacturer:	Becton, Dickinson and Company
510(k) No.:	K023331

Stephen B Anderson

March 20, 2006