
K. Summary of Safety and Effectiveness

K.1 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 Information :

- Address: BD Diagnostics, Preanalytical Systems
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- Registration Number: 2243072
- Contact Person: Stephen Anderson
Telephone No.: (201) 847-4727
Fax No.: (201) 847-4858
- Date of Summary: April 6, 2004
- Trade Name: BD Vacutainer® Plus Plastic Serum Tubes
- Classification Name: Blood Collection Tubes, Vials, Systems, Serum Separators,
- Classification: Class II
- Performance Standards: None Established under 514 of the Food, Drug and Cosmetic Act

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

- **Device Description:** The BD Vacutainer® Plus Plastic Serum Tube is a sterile, plastic, evacuated blood collection tube. The BD Vacutainer® Plus Plastic Serum Tube consists of (1) a closure assembly, (2) a silica clot activator, and (3) a plastic tube. The specimens are used for clinical laboratory assays involving the use of patient serum.
- **Intended Use:** An evacuated tube which provides a means of collecting, transporting, separating, and processing venous blood in a closed system. Blood collected in these tubes is primarily used for clinical laboratory chemistry assays using patient serum but may be used for other serum specimens as determined by the laboratory. In addition, the BD Vacutainer® Plus Plastic Serum Tube can be used for immunohematology testing including but not limited to ABO grouping, Rh typing, antibody screening, red cell phenotyping and DAT testing, which requires red blood cells or serum.
- **Synopsis of Test Methods and Results:** Extensive studies were performed to demonstrate that BD Vacutainer® Plus Plastic Serum Tubes can be used safely and effectively for immunohematology testing.
- **Substantial Equivalence:** Based on a comparison of the device features, materials, and intended use, the BD Vacutainer® Plus Plastic Serum Tubes are substantially equivalent to the commercially available predicate devices identified below:

BD Vacutainer® Plus Plastic Serum Tube

Manufacturer: BD Diagnostics, Preanalytical Systems

510(k) Number: K960250

Clearance Date: 3/29/96

BD Vacutainer® Brand Glass Serum Tube

Manufacturer: BD Diagnostics, Preanalytical Systems

510(k) Number: Preamendment

Clearance Date: N/A

Stephen B Anderson



April 6, 2004