Attachment J

Summary of Safety and Effectiveness

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

I. General Information

This Summary of 510(k) Safety and Effectiveness information is being submitted in accordance with the requirements of the SMDA of 1990 and 21 CFR 807.92

Establishment:

- **Address:** Becton Dickinson VACUTAINER Systems
  1 Becton Drive
  Franklin Lakes, NJ 07417-1885
- **Registration Number:** 2243072
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- **Date of Summary:** March, 1998

Device Name:

- **Trade Name:** VACUTAINER® Brand PLUS Tube
  with EDTA Anticoagulant and
  VACUTAINER® Brand PLUS Serum Tube
- **Classification Name :** Blood Specimen Collection Device
- **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

Substantial Equivalence Declaration: The term "Substantial Equivalence" is used in this 510(k) Premarket Notification is limited to the definition of Substantial Equivalence as found in the Federal Food, Drug, and Cosmetic Act, as amended and as applied under 21 CFR § 807, Subpart E under which a device can be marketed without pre-market apporval or reclassification.

• Device Description

The VACUTAINER® Brand PLUS Tube with EDTA and the VACUTAINER PLUS Serum Tube are evacuated plastic blood collection tubes for collecting, transporting and processing blood in a closed plastic tube. The VACUTAINER® Brand PLUS Tube with EDTA consists of closure assembly, a plastic tube and EDTA coating (dipotassium). The VACUTAINER PLUS Serum Tube consists of closure assembly, a plastic tube and silica clot activator.

The standard closure assembly is a basic rubber stopper. The tubes are also available with the VACUTAINER® Hemogard Closure Assembly, which consists of a rubber stopper and protective plastic shield to reduce user exposure to blood. The Hemogard closure assembly, intended to reduce user exposure to blood, was described in 510(k) Premarket Notification K945952 that received FDA clearance on January 18, 1995. All stopper/closures are color coded to reflect additive type (see the chart **VACUTAINER® Tube Stopper/Closure Color Code Cross Reference** located in the Product Insert, Attachment D)

• Intended Use

The VACUTAINER® Brand PLUS Tube with EDTA anticoagulant and the VACUTAINER Brand PLUS Serum Tube are evacuated blood collection tubes which provides a means collecting, transporting and processing blood in a closed plastic tube. Blood collected in a tube containing EDTA anticoagulant, VACUTAINER® Brand PLUS Tube with EDTA anticoagulant, is used primarily for clinical laboratory hematology studies. The VACUTAINER® Brand PLUS Serum Tube containing Silica activator is used primarily in clinical laboratory testing for chemistry assays.

In addition, the blood collected and processed in the VACUTAINER® Brand PLUS with EDTA anticoagulant and the VACUTAINER® Brand PLUS Serum Tube can be used immunohematology testing including ABO grouping, Rh typing and antibody screening which requires red cells and plasma or serum.

• Synopsis of Test Methods and Results

Clinical testing to evaluate the effectiveness of the tube for the additional Indications for Use described in premarket notification was performed. The results of the clinical evaluation demonstrate that the VACUTAINER® Brand PLUS (plastic) EDTA and PLUS Serum tubes provide equivalent results compared to the VACUTAINER® Brand (glass) Serum and EDTA tubes for immunohematology testing including ABO Grouping, Rh typing and antibody screening which requires red cells and plasma or serum.

• Substantial Equivalence

Becton Dickinson VACUTAINER Systems believes that the VACUTAINER® Brand PLUS Tube with EDTA and VACUTAINER® Brand PLUS Serum Tube with the expanded Indications for Use is substantially equivalent to a commercially available blood collection tube. Clinical testing, as described in this premarket notification, demonstrates equivalent performance and effectiveness and supports the determination of substantial equivalence. The predicate devices, manufacturer, K number and clearance date are identified below:

Manufacturer	Predicate Device	K-Number	Clearance Date
VACUTAINER Systems	VACUTAINER® Brand Serum Tube	Not Applicable	Pre-Amendment Device and, therefore, exempt from premarket notification requirements according to the MDA of 1976.
VACUTAINER Systems	VACUTAINER® Brand Tube with EDTA Anticoagulant	Not Applicable	Pre-Amendment Device and, therefore, exempt from premarket notification requirements according to the MDA of 1976.

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Regulatory Affairs Department

March 16, 1998
Date