

**510(k) SUMMARY**

**CONTACT:**

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**NAME OF DEVICE:**

Trade Name: **VACUETTE®** EDTA K3 Tube  
Common Names/Descriptions: Evacuated Blood Collection System  
Classification Name: Tubes, Vials, Systems, Serum Separators, Blood Collection

**PREDICATE DEVICE:**

Becton Dickinson Vacutainer® EDTA K3 Tube (pre-amendment); Vacutainer® Plus EDTA K2 Tube (K981013)

**DEVICE DESCRIPTION:**

**INTENDED USE:** The **VACUETTE®** EDTA K3 tube provides a means for collection, processing and transportation of an undiluted plasma specimen in a closed evacuated system. The tube contains spray-dried K3 EDTA, yielding a ratio of 1.8mg/mL of blood when the evacuated tube is filled correctly to its fill volume.

**PRODUCT DESCRIPTION:** The **VACUETTE®** EDTA K3 Tube is used for plasma preparation and is made of plastic for the collection of venous blood which upon centrifugation separates undiluted plasma. The tube may be used for routine immunohematology testing i.e. red cell grouping, Rh typing and antibody screens.

**SUBSTANTIAL EQUIVALENCE:**

The purpose of this premarket submission is to add an immunohematology claim to the FDA-cleared Greiner **VACUETTE®** EDTA K3 tube. In this submission, the Greiner tube is substantially equivalent to the Becton Dickinson Vacutainer® EDTA K3 and K2 Tubes in intended use, design and composition. Studies were conducted to demonstrate substantial equivalence of the Greiner **VACUETTE®** EDTA K3 Tube to the Becton Dickinson (BD) Vacutainer® EDTA K3 and K2 Tubes when samples from these tubes are used in immunohematology assays. The substantial equivalence studies included the following immunohematology tests performed on apparently healthy blood donors, known antibody positive blood donors, and hospitalized patients:

- ABO and Rh grouping, antigen phenotyping;
- Antibody screening and identification;
- Direct Antibody Testing (DAT);
- Rare antibody identification;
- Delayed testing;
- Partial tube draw.

The conclusions from the study were:

- The Greiner **VACUETTE®** EDTA K3 Tube demonstrated substantially equivalent results to the BD EDTA K3 and K2 tubes in terms of accuracy and reactivity for ABO, Rh, antigen and antibody testing in both donor and recipient populations.
- The Greiner **VACUETTE®** EDTA K3 Tube demonstrated similar results when testing was delayed at least 14 days (as compared to fresh sample testing) and when testing was performed on partially filled tubes (as compared to fully drawn tubes).