

April 9, 2005

**510(k) SUMMARY**

**CONTACT:**

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**NAME OF DEVICE:**

Trade Name: **VACUETTE®** No Additive Tube; **VACUETTE®** Clot Activator Tube  
Common Names/Descriptions: Evacuated Blood Collection System  
Classification Name: Tubes, Vials, Systems, Serum Separators, Blood Collection

**PREDICATE DEVICE:**

Becton Dickinson Vacutainer® glass serum tube (pre-amendment)

**DEVICE DESCRIPTION:**

**INTENDED USE:** Greiner **VACUETTE®** No Additive Tubes and **VACUETTE®** Clot Activator Tubes are used to collect, transport and process blood for testing serum or clotted cells in the immunohematology laboratory, i.e. red cell grouping, Rh typing and antibody screens.

**PRODUCT DESCRIPTION:** The **VACUETTE®** No Additive Tubes and **VACUETTE®** Clot Activator Tubes are used for serum preparation and are made of plastic for the collection of venous blood which upon centrifugation separates serum from clotted cells. The **VACUETTE®** Clot Activator Tubes are coated with micronised silica particles which activate clotting when tubes are gently inverted.

**SUBSTANTIAL EQUIVALENCE:**

The Greiner **VACUETTE®** No Additive Tube and **VACUETTE®** Clot Activator Tube are substantially equivalent to the Becton Dickinson Vacutainer® glass serum tube (pre-amendment) in intended use and design. Studies were conducted to demonstrate substantial equivalence 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 (**VACUETTE®** Clot Activator Tube only).

The conclusions from the study were:

- The Greiner **VACUETTE®** No Additive Tube and **VACUETTE®** Clot Activator Tube demonstrated substantially equivalent results to the BD glass serum tube in terms of accuracy and reactivity for ABO, Rh, antigen and antibody testing in both donor and recipient populations.
- The Greiner **VACUETTE®** No Additive Tube and **VACUETTE®** Clot Activator Tube demonstrated similar results when testing was delayed 14 days (as compared to fresh sample testing) and when testing was performed on partially filled tubes (as compared to fully drawn tubes).