

## 510(k) SUMMARY

CONTACT:

Douglas L. Harris  
Greiner Bio-One Vacuette® North America, Inc.  
4238 Capital Drive  
Monroe, NC 28110

NAME OF DEVICE:

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

PREDICATE DEVICE:

Becton Dickinson Vacutainer™ Non-additive, Uncoated Tubes (glass) (pre-amendment)

DEVICE DESCRIPTION:

Intended Use: **VACUETTE®** Tubes, Holders and Needles are used together as a system for the collection of venous blood. **VACUETTE®** tubes are used to collect, transport and process blood for testing serum, plasma or whole blood in the clinical laboratory. **VACUETTE®** No Additive Tubes and **VACUETTE®** Serum Clot Activator Tubes may be used for viral marker testing in screening and clinical laboratories.

Product Description: The **VACUETTE®** No Additive and Serum Clot Activator tubes are plastic tubes used for the collection of venous blood which centrifugation separates serum from the blood clot. The **VACUETTE®** No Additive tube does not contain any additive; the **VACUETTE®** Serum Clot Activator tube contains micronized silica particles which activate clotting when tubes are gently inverted.

SUBSTANTIAL EQUIVALENCE:

The Greiner tubes are substantially equivalent to the Becton Dickinson Vacutainer® (BD) Non-additive, Uncoated Tubes (glass) in intended use, design and composition. Studies were conducted to demonstrate substantial equivalence of the Greiner **VACUETTE®** No Additive and Serum Clot Activator tubes to the BD Vacutainer™ Non-additive, Uncoated Tubes (glass) when samples from these tubes are used in viral marker screening assays. The substantial equivalence studies included the following viral marker tests performed on apparently healthy blood donors and known antibody positive individuals:

- Hepatitis B surface;
- Hepatitis antibodies – anti-HCV and total anti-HBc;
- HIV 1/2 antibodies;
- HTLV I/II antibodies;
- HCV and HIV nucleic acid testing;
- ALT;
- anti-CMV;
- RPR.

The conclusions from the study are:

- The Greiner **VACUETTE®** No Additive and Serum Clot Activator tubes demonstrated substantial equivalence to the BD Vacutainer™ Non-additive, Uncoated Tubes (glass) in terms of agreement for the viral marker testing results in blood donors and antibody positive individuals.
- The Greiner **VACUETTE®** No Additive and Serum Clot Activator tubes demonstrated similar results when testing was delayed 7 days (as compared to fresh sample testing), when testing was performed on partially filled tubes (as compared to fully drawn tubes), and for the No Additive tubes, when testing was performed on tubes that were subject to delayed mixing.