

510(k) SUMMARY

CONTACT:

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NAME OF DEVICE:

Trade Name: **VACUETTE®** EDTA K2 Tube; **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™ No Additive, Non-Coated
Tube (glass) (pre-amendment)

DEVICE DESCRIPTION:

INTENDED USE: The **VACUETTE®** EDTA K2 and EDTA K3 Evacuated Blood Collection Tubes provide a means for collection, processing and transport of undiluted plasma specimens in a closed evacuated system. The tubes contains spray-dried EDTA K2 or EDTA K3, 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 K2 and EDTA K3 Tubes are used for plasma preparation and are made of plastic for the collection of venous blood which upon centrifugation separates undiluted plasma for use in viral marker testing in screening and diagnostic populations or in other procedures where an undiluted plasma specimen is required as determined by the laboratory.

SUBSTANTIAL EQUIVALENCE:

The Greiner tubes are substantially equivalent to the Becton Dickinson Vacutainer® glass No Additive, Non-Coated tube in intended use and design. Studies were conducted to demonstrate substantial equivalence of the Greiner **VACUETTE®** EDTA K2 and EDTA K3 tubes to the Becton Dickinson (BD) Vacutainer™ No Additive, Non-Coated Tube (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 antigen and confirmatory;
- Hepatitis antibodies: anti-HCV (and confirmatory) and total anti-HBc;
- HIV 1/2 antibodies and confirmatory;
- HTLV I/II antibodies;
- anti-CMV;
- Syphilis;
- ALT.

The conclusions from the study are:

- The Greiner **VACUETTE®** EDTA K2 and EDTA K3 tubes demonstrated substantial equivalence to the BD Vacutainer™ glass No Additive, Non-Coated tube in terms of agreement for the viral marker testing results in blood donors and antibody positive individuals.
- The Greiner **VACUETTE®** EDTA K2 and EDTA K3 tubes demonstrated similar results when testing was delayed 7 days (as compared to fresh sample testing) and when testing was performed on partially filled tubes (as compared to fully drawn tubes).