K960858 AUG 30 1996

I. 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

Greiner America, Inc. ("Greiner") is submitting a 510(k) premarket notification for its Greiner Vacuette™ blood collection tube with clot activator and gel separator. The Greiner Vacuette™ blood collection tube with clot activator and gel separator is an evacuated blood collection device containing a clot activator (silicondioxide) and an inert polymeric barrier material. The product is intended for use in holding and separating blood serum from the cellular components of blood.

Greiner is claiming substantial equivalence to Becton Dickinson's Vacutainer® SST tubes (K921806). Both blood collection tubes have the same intended use and contain the same stopper material, clot activator and separator. The tube material for the Greiner product is clear plastic, whereas the material for the Becton Dickinson product is glass. The equivalency of assay results for both tubes was evaluated by testing paired samples collected in Greiner Vacuette™ tubes and Becton Dickinson Vacutainer® tubes. Test results from paired samples for 41 analytes were evaluated demonstrating good correlation (correlation coefficients ranging from .864 to 1.000).

Greiner's 510(k) has been submitted on February 27, 1996, by Ed Maier, Managing Director, Greiner America, Inc., 7 Henry Court, Wilmington, Delaware, 19808 (302/998-8046).