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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 EDTA K_2. The Greiner Vacuette® blood collection tube with EDTA K_2 is an evacuated blood collection device containing EDTA K_2 anticoagulant additive and intended for use in evaluations of whole blood specimens.

Greiner is claiming substantial equivalence to Becton Dickinson's Vacutainer® brand EDTA K_2 additive tube. Both blood collection tubes have the same intended use and contain the same stopper material and additive. The tube material for the Greiner product is clear plastic, and the material for the Becton Dickinson product is glass. The equivalency of assay results of the two tubes was evaluated by testing paired samples collected in Greiner Vacuette® tubes and Becton Dickinson Vacutainer® tubes. Test results from paired samples for 15 hematology parameters were evaluated and good correlation was observed.

Greiner's 510(k) has been submitted on April 1, 1997, by Ed Maier, Managing Director, Greiner America, Inc., P.O. Box 953279, Lake Mary, Florida 32795/3279 (407/3332800).