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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 sodium citrate. The Greiner Vacuette® blood collection tube with sodium citrate is an evacuated blood collection device containing sodium citrate anticoagulant additive and intended for use in evaluations of coagulation analyses.

Greiner is claiming substantial equivalence to Becton Dickinson's Vacutainer® sodium citrate 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 2 coagulation 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 (407/333-2800).