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I. 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

Greiner America, Inc. ("Greiner") is submitting a 510(k) premarket notification for: (1) its Greiner Vacuette® blood collection tube with EDTA and sodium fluoride; and (2) its Greiner Vacuette® blood collection tube with potassium oxalate and sodium fluoride. Both Greiner Vacuette® blood collection tubes are evacuated blood collection devices intended for use in testing glucose and lactate levels in blood.

For the above two tubes, Greiner is claiming substantial equivalence to, respectively: (1) Becton Dickinson's Vacutainer® tube with sodium EDTA/sodium fluoride; and (2) Becton Dickinson's Vacutainer® tube with sodium fluoride and potassium oxalate. Both the Greiner and Becton Dickinson blood collection tubes have the same intended use and contain the same stopper material and additives. 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® EDTA/sodium fluoride tubes and Becton Dickinson Vacutainer® sodium EDTA and sodium fluoride tubes, and paired samples collected in Greiner Vacuette® potassium oxalate and sodium fluoride tubes and Becton Dickinson potassium oxalate and sodium fluoride tubes. Glucose assay results from paired samples for each tube type 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).