K960857 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 anticoagulant lithium heparin and gel separator. The Greiner Vacuette™ blood collection tube with lithium heparin and gel separator is an evacuated blood collection device containing lithium heparin, an anticoagulant additive, and an inert polymeric barrier material. The product is intended for use in holding and separating blood plasma from the cellular components of blood.

Greiner is claiming substantial equivalence to Becton Dickinson's Vacutainer® brand lithium heparin additive tube (K944566). Both blood collection tubes have the same intended use and contain the same stopper material, additive 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 was evaluated by testing paired samples collected in Greiner Vacuette™ tubes and Becton Dickinson Vacutainer® tubes. Test results from paired samples for 23 analytes and 3 hormones were evaluated. Good correlation was observed, with correlation coefficients ranging from 168 to 0.900.

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).