

K964155

NOV 25 1996

510(k) Notification
Genzyme Diagnostics
Contrast[®] / *Rapid*[™] hCG
October 15, 1996

**510(k) Summary of Safety and Effectiveness
Information Upon Which An Equivalence Determination Could Be Made**

Trade or Proprietary Name: *Contrast*[®] hCG Urine/Serum Test
Rapid hCG[™] hCG Urine/Serum Test

Common or Usual Name: Human Chorionic Gonadotropin Test System

Product Classification Number: 21 CFR § 862.1155, Class II

Manufacturer: Genzyme Diagnostics
1531 Industrial Road
San Carlos, CA 94070

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Equivalence Device: *Rapid* hCG[™] Urine/Serum Test
510(k) Number: **K952319**
Cleared June 20, 1995

Device Description: Rapid membrane based immunoassay for the qualitative detection of hCG using mouse monoclonal anti-hCG and sheep anti-alpha hCG polyclonal antibodies.

Intended Use: The qualitative detection of human chorionic gonadotropin (hCG) in urine or serum for the early determination of pregnancy for use in the physician's office and clinical laboratories.

A multicenter sensitivity and reproducibility study was performed in three physician's offices/clinics (POL). The legally marketed Genzyme Diagnostics *Rapid* hCG[™] Urine/Serum Test was provided to the sites. Coded serum specimens, spiked with hCG at different levels, were provided to all sites. Tests were performed in triplicate on each of three different days. Results indicated the Genzyme Diagnostics *Rapid* hCG[™] Urine/Serum Test can detect 10 mIU/mL hCG in serum at 7 minutes.