DADE

K970387

MAR 10 1997

Chemistry Systems
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Summary of Safety and Effectiveness Information

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

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Date of Preparation: 1/31/97

Name of Product: Human Chorionic Gonadotropin Method

FDA Classification Name: HCG Test System

Predicate Device: Abbott IMx® hCG

Device Description: The HCG method for the Dimension® RxL system with the heterogeneous immunoassay module is a two-step enzyme immunoassay based on the "sandwich" principle. Sample is incubated with chromium dioxide particles coated with monoclonal antibodies specific for the hCG alpha subunit to form a particle/hCG complex. Particles are separated magnetically and the supernatant removed. The particle/hCG complex is incubated with conjugate reagent (β-galactosidase labeled monoclonal antibodies specific for the hCG beta subunit) to form a particle/hCG/conjugate sandwich. Unbound conjugate and analyte are removed by magnetic separation and washing. The sandwich bound β-galactosidase is combined with the chromogenic substrate chlorophenol red-β-d-galactopyranoside (CPRG) and catalyzes the hydrolysis of CPRG to the chromophore chlorophenol red (CPR). The concentration of hCG in the patient sample is directly proportional to the rate of color change measured at 577nm due to formation of CPR.

Intended Use: The HCG method for the Dimension® RxL clinical chemistry system with the heterogeneous immunoassay module is used to quantitatively measure intact hCG in serum and plasma, for the early detection of pregnancy.

Comparison to Predicate Device:

Item	Dimension® RxL HCG Method	Abbott IMx® hCG
Technology	Sandwich format monoclonal antibody immunoassay	Sandwich format monoclonal/polyclonal antibody immunoassay
Detection	Colorimetric rate measurement at 577nm and 700nm	Fluorometric endpoint measurement

Comments on Substantial Equivalence: Split sample comparison between the HCG method for the Dimension® RxL system and the Abbott IMx® hCG assay gave a correlation coefficient of 0.986, slope of 1.270, and an intercept of 2.87 mIU/mL when tested with 134 clinical patient samples ranging from 0 - 984 mIU/mL.

Conclusion: The HCG Method for the Dimension® RxL system with the heterogeneous immunoassay module is substantially equivalent in principle and performance to the Abbott IMx® hCG Assay based on the split sample comparison summarized above.

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Date: 1/31/97