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SUMMARY OF SAFETY AND EFFECTIVENESS

Name of Device: DSL 10-8300 I-hCG ELISA Kit
Classification Name: Enzymeimmunoassay, Human Chorionic Gonadotropin
Analyte Code and Name: Human Chorionic Gonadotropin
Regulatory Class: II

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The DSL I-hCG ELISA kit was developed for the quantitative measurement of I-hCG in human serum. The ELISA format is a non-competitive assay in which the analyte to be measured is "sandwiched" between two antibodies. The first antibody is immobilized to the inside wall of the microtitration well, the other antibody is conjugated to the enzyme horseradish peroxidase for detection. The analyte present is bound by both the antibodies to form a "sandwiched" complex. Unbound materials are removed by washing the wells. The resultant is analyzed in a spectrophotometer for absorbance. The amount of bound hCG is directly proportional to the concentration of the hCG present in the sample.

The DSL I-hCG ELISA assay is intended for the quantitative determination of I-hCG in human serum. It is intended for in vitro diagnostic use by professional laboratory personnel as an aid in the detection of pregnancy.

The DSL I-hCG ELISA is substantially equivalent to the DSL I-hCG IRMA.

To demonstrate substantial equivalence between the two assays, patient samples (n=54) were collected and assayed using both methods. Samples were chosen based on expected hCG levels so that samples with low, intermediate and high levels would be evaluated. Linear regression analysis of the results obtained for the comparison gave the equation $Y=0.92(X) + 16.5$ with a correlation coefficient of (r) = 0.98.