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SUMMARY OF SAFETY AND EFFECTIVENESS

Name of Device: DSL 10-3700 ULTRA-SENSITIVE UNCONJUGATED ESTRIOL EIA Kit
Classification Name: Enzyme Immunoassay, UNCONJUGATED ESTRIOL
Analyte Code and Name: Unconjugated Estriol
Regulatory Class: I

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The DSL Ultra-Sensitive Unconjugated Estriol EIA kit was developed for the quantitative measurement of Unconjugated Estriol in human serum. The EIA format is a competitive binding protein assay. Horseradish peroxidase labelled unconjugated estriol competes with un-labeled Unconjugated Estriol in the serum sample for antibody binding sites. After incubation and washing the wells are incubated with the substrate tetramethylbenzidine (TMB). An acidic stopping solution is then added and the degree of enzymatic turnover of the substrate is determined by dual wavelength absorbance measurement.

The DSL ULTRA-SENSITIVE UNCONJUGATED ESTRIOL EIA assay is intended for the quantitative determination of Unconjugated Estriol in human serum. The measurement of Unconjugated Estriol is used as a diagnostic aid in the diagnosis and treatment of fetoplacental distress.

The DSL ULTRA-SENSITIVE UNCONJUGATED ESTRIOL EIA is substantially equivalent to the DSL ULTRA-SENSITIVE UNCONJUGATED ESTRIOL RIA.

To demonstrate substantial equivalence between the two assays, patient samples (n=106) were collected and assayed using both methods. Samples were chosen based on expected Unconjugated Estriol 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 $Y=0.85(X) -0.11$ with a correlation coefficient of $(r) = 0.93$.