K961109

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SUMMARY OF SAFETY AND EFFECTIVENESS

Name of Device: DSL 4600 LH IRMA Kit
Classification Name: Immunoradiometric Assay, LH
Analyte Code and Name: Luteinizing Hormone
Regulatory Class: I

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The DSL LH IRMA kit was developed for the quantitative measurement of LH in human serum. The IRMA 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 test tube, the other antibody is radiolabelled for detection. The analyte present is bound by both the antibodies to form a "sandwiched" complex. Unbound materials are removed be decanting and washing the tubes. The resultant is analyzed in a gamma counter for bounds counts per minute. The amount of bound LH is directly proportional to the concentration of the LH present in the sample.

The DSL LH IRMA assay is intended for the quantitative determination of LH in human serum. The measurement of LH is used as a diagnostic aid in the diagnosis and treatment of gonadal dysfunction.

The DSL LH IRMA is substantially equivalent to the DPC LH IRMA.

To demonstrate substantial equivalence between the two assays, patient samples (n=41) were collected and assayed using both methods. Samples were chosen based on expected LH 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 $Y=1.71(X) + 3.81$ with a correlation coefficient of $(r) = 0.95$.