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SUMMARY OF SAFETY AND EFFECTIVENESS

Name of Device: DSL 4700 FSH IRMA Kit
Classification Name: Immunoradiometric Assay, FSH
Analyte Code and Name: Follicle Stimulating Hormone
Regulatory Class: I

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The DSL FSH IRMA kit was developed for the quantitative measurement of FSH 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 by decanting and washing the tubes. The resultant is analyzed in a gamma counter for bound counts per minute. The amount of bound FSH is directly proportional to the concentration of the FSH present in the sample.

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

The DSL FSH IRMA is substantially equivalent to the DPC FSH IMMULITE.

To demonstrate substantial equivalence between the two assays, patient samples (n=81) were collected and assayed using both methods. Samples were chosen based on expected FSH 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 $Y=0.66(X) + 1.26$ with a correlation coefficient of $(r) = 0.98$.