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SUMMARY OF SAFETY AND EFFECTIVENESS

Name of Device: DSL C2700 DHEA-S-7 RIA Kit
Classification Name: Radioimmunoassay, DHEA-S
Analyte Code and Name: DHEA-S-7
Regulatory Class: I

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The DSL C2700 DHEA-S-7 RIA kit was developed for the quantitative measurement of DHEA-S in human serum. The RIA format is a competitive binding protein assay. Radio-labeled DHEA-S competes with un-labeled DHEA-S in the serum sample for binding sites to the DHEA-S antiserum provided with the kit. Separation of free from bound DHEA-S is achieved by the centrifugation and decantation of the tubes. The resultant is analyzed in a gamma counter for bound counts per minute. The amount of radio-labeled DHEA-S bound to the antibody is inversely proportional to the concentration of the DHEA-S present in the sample.

The DSL C2700 DHEA-S-7 RIA assay is intended for the quantitative determination of DHEA-S in human serum. The measurement of DHEA-S is used for in vitro diagnostic use in the diagnosis and treatment of DHEA-secreting adrenal carcinomas.

The DSL C2700 DHEA-S-7 RIA is substantially equivalent to the DSL 2700 DHEA-S RIA. Both kits have the same intended use.

To demonstrate substantial equivalence between the two assays, patient samples (n=418) were collected and assayed using both methods. Samples were chosen based on expected DHEA-S 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 $Y=0.76(X) + 36.2$ with a correlation coefficient of $(r) = 0.98$.