



K961172

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SUMMARY OF SAFETY AND EFFECTIVENESS

Name of Device: DSL 2800 IGF-I IRMA Kit
Classification Name: Immunoradiometric, IGF-I
Analyte Name: Insulin-like Growth Factor-I
Regulatory Class:

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The DSL Active IGF-I IRMA kit was developed for the quantitative measurement of Insulin-like Growth Factor-I in human serum and plasma. This IRMA format is a capture assay. Mouse monoclonal antibody to IGF-I is immobilized to the inner surface of the coated test tubes. IGF-I in the standards or samples is "sandwiched" between this monoclonal and the goat-anti-IGF-I polyclonal antibody labelled with Iodine-125.

The DSL IGF-I IRMA assay is intended for the quantitative determination of IGF-I in human serum or EDTA plasma. The measurement of serum/plasma IGF-I is used as a diagnostic aid in the evaluation of growth status disorders.

The DSL IGF-I IRMA is substantially equivalent to the DSL 5600 IGF-I IRMA. These kits have the same intended use.

To demonstrate substantial equivalence between the two assays, patient samples (n=146) were collected and assayed simultaneously by both methods. Samples were chosen based on expected IGF-I levels so that samples with low, intermediate and high levels of IGF-I would be evaluated. Linear regression analysis of the results obtained for the comparison with the IGF-1 assay gave the equation $Y = 1.19(X) - 22.07$ with a correlation coefficient of $(r) = 0.98$.