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SUMMARY OF SAFETY AND EFFECTIVENESS

Name of Device: DSL 3100 ACTIVE™ T3 RIA Kit
Classification Name: Radioimmunoassay, Triiodothyronine
Analyte Code and Name: Total Triiodothyronine
Regulatory Class: II

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The DSL ACTIVE™ T3 RIA kit was developed for the quantitative measurement of Total T3 in human serum. The RIA format is a competitive binding protein assay. Radio-labeled T3 competes with un-labeled T3 in the serum sample for binding sites to the antibody. Separation of free from bound T3 is achieved by decanting the coated tubes after incubation. The resultant is analyzed in a gamma counter for bounds counts per minute. The amount of radio-labeled T3 bound to the antibody is inversely proportional to the concentration of the T3 present in the sample.

The DSL ACTIVE™ T3 RIA assay is intended for the quantitative determination of Total T3 in human serum. The measurement of T3 is used in the diagnosis and treatment of thyroid diseases such as hyperthyroidism.

The DSL ACTIVE™ T3 RIA is substantially equivalent to the DPC COAT-A-COUNT TOTAL T3 RIA.

To demonstrate substantial equivalence between the two assays, patient samples (n=30) were collected and assayed using both methods. Samples were chosen based on expected T3 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 $Y=1.09(X) + -8.8$ with a correlation coefficient of $(r) = 0.90$.

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