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SUMMARY OF SAFETY AND EFFECTIVENESS

Name of Device: DSL 10-1700 ACTIVE CrossLaps™ ELISA Kit
Classification Name: Enzymeimmunoassay, Type I Collagen Telopeptide
Analyte Code and Name: Type I Collagen Telopeptide

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Date: March 15, 1996

The DSL ACTIVE CrossLaps™ ELISA kit was developed for the quantitative measurement of Type I Collagen Telopeptide (CrossLaps™) in human urine. The ELISA format is a competitive binding protein assay. CrossLaps™ in the urine sample competes with antigen coated to the microtitration wells for the enzyme labelled CrossLaps™ antibody. CrossLaps™ in the sample binds to the enzyme labelled antibody displacing it from binding to the antigen coated wells. Separation of free from bound CrossLaps™ is achieved by aspirating and washing the wells. The resultant is analyzed in a spectrophotometer for bound absorbance. The amount of enzyme-labeled CrossLaps™ bound to the microtiter well is inversely proportional to the concentration of the CrossLaps™ present in the sample.

The DSL ACTIVE CrossLaps™ ELISA assay is intended for the quantitative determination of CrossLaps™ in human urine. The measurement of CrossLaps™ is used as an indicator of human bone resorption.

The DSL 10-1700 ACTIVE CrossLaps™ ELISA is substantially equivalent to the OSTEX OSTEOMARK assay. Both kits are used *in vitro* as an indicator of human bone resorption.

To demonstrate substantial equivalence between the two assays, urine samples from sixty individuals were collected and assayed using both methods. Samples were chosen based on expected 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 $Y=3.18(X) + 16.69$ with a correlation coefficient of $(r) = 0.95$.