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Interoffice Memorandum

## Summary of Safety and Effectiveness Information

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

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**Date of Preparation:** March 27, 1997

**Name of Product:** FT4 Method for the Dimension® RxL Clinical Chemistry System

**FDA Classification Name:** Free Thyroxine Test System

**Predicate Device:** Abbott Laboratories Imx® Free T4

**Device Description:** The FT4 assay is a two-step competitive enzyme immunoassay. Sample is incubated with chromium dioxide particles, coated with monoclonal antibodies specific for FT4 to form a particle/T4 complex. Particles are separated magnetically and the supernatant removed. The particle/T4 complex is incubated with conjugate reagent to react with unoccupied binding sites on the particles. Unbound conjugate is removed by washing. The bound alkaline phosphatase triggers an amplification cascade, resulting in the formation of a colored product. The color change measured at 510nm is inversely proportional to the concentration of free thyroxine present in the patient sample.

**Intended Use:** The FT4 Method for the Dimension® RxL clinical chemistry system with the heterogeneous immunoassay module is used to quantitatively measure free thyroxine (FT4) in human serum and heparinized plasma.

**Comparison to Predicate  
Device:**

<u>Item</u>	<u>Dimension® RxL FT4</u>	<u>Imx®Free T4</u>
Technology	Competitive format monoclonal antibody immunoassay	Competitive format polyclonal antibody immunoassay
Detection	Colorimetric endpoint measurement at 510nm and 700nm	Fluorometric endpoint measurement

**Comments on Substantial**

**Equivalence:** Split sample comparison between the The FT4 Method for the Dimension® RxL Clinical Chemistry System and the Abbott Imx® Free T4 assay gave a correlation coefficient of 0.988, slope of 0.963, and an intercept of 0.02 ng/dL when tested with 156 clinical patient samples.

**Conclusion:** The The FT4 Method for the Dimension® RxL clinical chemistry system is substantially equivalent in principle and performance to the Imx® Free T4 assay based on the split sample comparison discussed above.



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