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DADE INTERNATIONAL

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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Name of Product: aca® ***plus*** Free Thyroxine (FT4) Method

FDA Classification Name: Free Thyroxine Test System

Predicate Device: Abbott Laboratories IMX® Free T4

Device Description: The FT4 assay is a one-step competitive enzyme immunoassay. Patient sample is added by the aca® ***plus*** to a reaction vessel containing chromium dioxide particles coated with monoclonal antibodies specific for FT4 and T3-alkaline phosphatase conjugate reagent. A particle/ FT4/ conjugate sandwich forms during an incubation period. The sandwich is washed to remove any unbound conjugate. The mixture is resuspended and the sandwich is transferred by the aca® ***plus*** to an FT4 test pack. The FT4 test pack is then placed into an aca® discrete clinical analyzer.

The bound alkaline phosphatase triggers an amplification cascade, resulting in the formation of a colored product. The color change measured at 510nm is directly proportional to the concentration of free thyroxine present in the patient sample.

Intended Use: The FT4 Method is used in the aca® ***plus*** immunoassay system to quantitatively measure free thyroxine (FT4) in human serum and heparinized plasma.

Comparison to Predicate Device:

Item	aca® ***plus*** FT4	IMx® Free T4
Technology	Competitive format monoclonal antibody immunoassay	Competitive format polyclonal antibody immunoassay
Detection	Colorimetric endpoint measurement at 510nm and 600nm	Fluorometric endpoint measurement

Comments on Substantial Equivalence: Split sample comparison between the aca® ***plus*** FT4 Method and the Imx® Free T4 assay gave a correlation coefficient of 0.9076, slope of 0.94, and an intercept of 0.16 when tested with 146 clinical patient samples.

Conclusion: The aca® ***plus*** FT4 Method is substantially equivalent in principle and performance to the IMx® Free T4 Assay based on the split sample comparison discussed above.

Cathy P. Craft
Regulatory Affairs and
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Date: