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DADE INTERNATIONAL

Chemistry Systems
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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: 1/31/97

Name of Product: Thyroid Stimulating Hormone (TSH) Method

FDA Classification Name: Thyroid Stimulating Hormone Test System

Predicate Device: Abbott AxSYM® Ultrasensitive hTSH

Device Description: The TSH method is a one-step enzyme immunoassay. Sample is incubated with chromium dioxide particles (CrO_2) coated with monoclonal antibodies specific for the intact TSH molecule and conjugate reagent [alkaline phosphatase (ALP) labeled monoclonal antibodies specific for the TSH beta subunit] to form a particle/TSH/conjugate sandwich. Unbound conjugate and analyte are removed by magnetic separation and washing. The sandwich bound ALP initiates an amplification cascade. ALP dephosphorylates synthetic flavin adenine dinucleotide phosphate (FADP) to give FAD. FAD binds to APO d-amino acid oxidase and converts it to active holo d-amino acid oxidase. Each molecule of holo d-amino acid oxidase then produces multiple molecules of hydrogen peroxide (H_2O_2), which in the presence of horseradish peroxidase (HRP), converts 3,5-dichloro-2-hydroxybenzenesulfonic acid (DCHBS) and 4-aminoantipyrine (4-AAP) to a colored product that absorbs at 510nm. The color measured is directly proportional to the concentration of TSH present in the patient sample.

Intended Use: The TSH method is used on the Dimension® RxL clinical chemistry system with the heterogeneous immunoassay module to quantitatively measure TSH in human serum and plasma. Measurements of TSH aid in the diagnosis of thyroid or pituitary disorders.

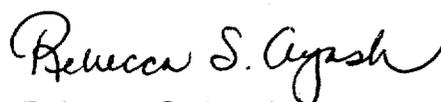
Comparison to Predicate Device:

Item	Dimension® RxL TSH Method	Abbott AxSYM® Ultrasensitive hTSH
Technology	Sandwich format monoclonal antibody immunoassay	Sandwich format polyclonal/monoclonal antibody immunoassay
Detection	Colorimetric rate measurement at 577nm and 700nm	Fluorometric endpoint measurement

Comments on Substantial

Equivalence: Split sample comparison between the TSH method on the Dimension® RxL clinical chemistry system and the Abbott AxSYM® Ultrasensitive hTSH assay gave a correlation coefficient of 0.99, slope of 1.06 and an intercept of -0.03 µIU/mL when tested with 86 clinical patient samples ranging from ~~0.04~~ to 49.21 µIU/mL.

Conclusion: The TSH method for the Dimension® RxL system with the heterogeneous immunoassay module is substantially equivalent in principle and performance to the Abbott AxSYM® Ultrasensitive hTSH Assay based on the split sample comparison summarized above.



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Date: 2/21/97