 K960195

14. SMDA Summary

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92. This new immunometric assay device is a single-use Class II medical device for professional use that is designed to indicate whether a serum sample contains TSH in a concentration > 5 µIU/ml. The intended use, technical characteristics, efficacy, and safety of this new device are substantially equivalent at detecting TSH > 5 µIU/ml to a number of other TSH immunoassays that have been commercially available both before and after 1978, and Franklin believes that demonstration of substantial equivalence to a legally marketed predicate device in accordance with section 510(k) has been demonstrated.

This document contains the results of a number of validation studies which compares the performance of ThyroChek at detecting TSH > > 5 µIU/ml to that of a predicate medical device, Immunolite Third Generation TSH Assay, 510(k) number K930007. The validating studies performed and the results obtained are as follows:

1. **Quantitative Recovery.** This demonstrated the ability of this assay to discriminate serum samples containing TSH at concentrations of 5.2, 5.7, and 6.5 µIU/ml, as determined by the predicated device, from samples containing TSH at a concentration of 4.1 and 4.5 µIU/ml.

2. **Serial Dilution.** This demonstrated the ability of this assay to distinguish serum samples containing TSH > 5 µIU/ml from those with a TSH concentration diluted below 5 µIU/ml.

3. **Coefficient of Variation.** 5 sets of 30 replicates showed uniform results, that is 30 identical results, using ThyroChek in 4 of 5 sets and 29 of 30 replicates agreed in 1 of 5 sets. Additionally 25 samples measured in duplicate showed 100% agreement between both replicates. This represents an intra-assay coefficient of variation of less than 3%.

4. **Parallelism.** 328 patient samples were assayed in parallel by the predicate device and by ThyroChek. 65 of 66 patients with TSH > 5 µIU/ml, as determined by the predicate device, were correctly identified using ThyroChek. 262 of 262 patients with TSH < 5 µIU/ml, as determined by the predicate device, were correctly identified by ThyroChek.

5. **Cross-Reactivity.** Because of the structural similarity between TSH and hCG, LH, and FSH, studies were performed to determine if maximal clinical concentrations of these hormones would interfere with ThyroChek performance. These studies showed that hCG, in concentrations as high as 150,000 mIU/ml, and LH / FSH > 40 mIU/ml, as encountered in 17 postmenopausal women, did not produce false negative or positive test results or affect ThyroChek's ability to determine whether a serum sample contained > 5 µIU/ml.

6. **Interference.** Elevated concentrations of glucose, uremic metabolites, lipids, or hemolyzed red blood cells as encountered in patient samples did not interfere with device performance.

This 510(k) Summary Statement was revised by J. Ehrenkranz, M.D. on 20 March, 1996.