

K961510

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Summary of Safety and Effectiveness

As required by 21 CFR 807.92, the following 510(k) Summary is provided:

1. Submitter Information

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2. Device Information

Proprietary Name: ACS FrT4 Immunoassay
Common Name: FrT4 Immunoassay
Classification Name: Class II, Free Thyroxine Test
Kit, 21 CFR 862.1695

JM
10/11/96
ACS
FrT4

3. Predicate Device Information

Name: Amerlex-MAB FT4
Manufacturer: Amerlex
510(k) Number: Not Known

4. Device Description

The Ciba Corning ASC FrT4 Immunoassay is a competitive immunoassay. FT4 in the sample competes with the acridinium ester (AE-labeled T4 (Lite Reagent) for a limited amount of polyclonal rabbit anti-T4 antibody, which is covalently coupled to paramagnetic particles (solid phase). An indirect relationship exists between the FT4 in a sample and the relative light units (RLUs) detected.

5. Statement of Intended Use

For the quantitative determination of free thyroxine (FT4) in serum using the Ciba Corning Automated Chemiluminescence Systems.

6. Summary of Technological Characteristics

The Ciba Corning ACS FrT4 procedure is a competitive chemiluminescence immunoassay.

7. Performance Data

Sensitivity

The ACS FrT4 immunoassay measures FT4 concentrations up to 11.0 ng/dl with a minimum detectable concentration of 0.1 ng/dl.

Accuracy

For 74 samples in the range of 0.62 to 4.26 ng/dl, the correlation between the ACS FrT4 immunoassay and the RIA reference method assay is described by the equation:

$$\text{ACS FrT4} = 1.06 (\text{RIA}) - 0.33$$

Correlation coefficient (r) = 0.97

Precision

Total precision (Total % CV) ranged from 2.81 to 4.65.