

**JUN 21 1996**

## 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 LH2 Immunoassay  
Common Name: LH Immunoassay  
Classification Name: Class I, Luteinizing hormone test system, 21 CFR 862.1485

### 3. Predicate Device Information

Name: ACS LH Immunoassay  
Manufacturer: Ciba Corning Diagnostics Corp.  
510(k) Number: K910198

### 4. Device Description

The Ciba Corning ASC LH2 assay is a two-site chemilumometric (sandwich) assay which uses constant amounts of two antibodies that have specificity for the intact LH molecule. The first antibody or Lite Reagent is a monoclonal mouse anti-LH antibody labeled with acridinium ester. The second antibody or solid phase is a monoclonal mouse anti-LH antibody covalently coupled to paramagnetic particles. A direct relationship exists between the LH in a sample and the relative light units (RLUs) detected by the ACS:180 systems.

### 5. Statement of Intended Use

The intended use of ACS LH2 is for the quantitative determination of LH in serum using the Ciba Corning Automated Chemiluminescence Systems.

## 6. Summary of Technological Characteristics

The Ciba Corning LH2 assay is a non-competitive chemiluminescence assay

## 7. Performance Data

### Sensitivity

The ACS LH2 assay measures LH concentrations up to 200 mIU/mL with a minimum detectable concentration of 0.07 mIU/mL.

### Accuracy

For 689 samples in the range of 0.1 to 96.6 mIU/mL, the correlation between the ACS LH2 assay and the reference method assay is described by the equation:

$$\text{ACS LH2} = 0.93 (\text{reference method}) + 0.87$$

$$\text{Correlation coefficient (r)} = 0.97$$

### Precision

Total precision (Total % CV) ranged from 4.0 to 6.0.