K962126

JUN 21 [redacted]

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 CKMB II Immunoassay
Common Name:	CK-MB Immunoassay
Classification Name:	Class II, Creatine phosphokinase/creatine kinase or Isoenzymes test system, 21 CFR 862.1215

3. Predicate Device Information

Name:	Baxter Stratus CK-MB Fluorometric Enzyme Immunoassay
Manufacturer:	Baxter
510(k) Number:	Not Known

4. Device Description

The Ciba Corning ACS CKMB II assay is a two-site chemilumometric (sandwhich) assay. which uses constant amounts of two antibodies. The first antibody or Lite Reagent is a monoclonal mouse anti-CK-MB antibody labeled with acridinium ester. The second antibody or solid phase is a monoclonal mouse anti-CK-BB antibody covalently coupled to paramagnetic particles. A direct relationship exists between the CK-MB in a sample and the relative light units (RLUs) detected by the ACS:180 systems. The assay is unaffected by increased levels of other CK isoenzymes.

5. Statement of Intended Use

The intended use of ACS CKMB II is for the quantitative determination of CK-MB (CK-2) in serum or plasma using the Ciba Corning Automated Chemiluminescence Systems.

6. Summary of Technological Characteristics

The Ciba Corning CKMB II assay is a non-competitive chemiluminescence assay.

7. Performance Data

Sensitivity

The ACS CKMB II assay measures CK-MB concentrations up to 300.0 ng/mL with a minimum detectable concentration of 0.18 ng/mL.

Accuracy

For 1744 samples in the range of 0.0 to 280.0 ng/mL, the correlation between the ACS CKMB II assay and the FEIA reference method assay is described by the equation:

ACS CKMB II = 1.01 (FEIA reference method) + 0.24

Correlation coefficient (r) = 0.96

Precision

Total precision (Total % CV) ranged form 3.0 to 3.5.