

K961501



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510(k) Summary

Introduction According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

1) Submitter name, address, contact Boehringer Mannheim Corporation
9115 Hague Rd.
Indianapolis, IN 46250
(317) 845-2000

Contact Person: LeeAnn Chambers

Date Prepared: April 12, 1996

2) Device name Proprietary name: Elecsys® CK-MB

Common name: creatine kinase test

3) Predicate device We claim substantial equivalence to the Abbott IMx CK-MB (K931172)

4) Device Description The Elecsys® CK-MB test principle is based on a two-step sandwich with Streptavidin microparticles and electrochemiluminescence detection.

Total duration of the assay: 9 minutes

- 1st incubation: 15 µl of sample, a biotinylated monoclonal CK-MB-specific antibody and a monoclonal CK-MB-specific antibody labeled with a ruthenium complex react to form a sandwich complex
 - 2nd incubation: after the addition of streptavidin-coated microparticles, the complex becomes bound to the solid phase via interaction of biotin and streptavidin.
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4) Device Description, (cont.)

- The reaction mixture is aspirated into the measuring cell where the microparticles are magnetically captured onto the surface of the electrode. Unbound substances are then removed with ProCell. Application of a voltage to the electrode then induces chemiluminescent emission which is measured by a photomultiplier.
 - Results are determined via a calibration curve which is instrument-specifically generated by 2-point calibration and a master curve provided via the reagent bar code.
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5) Intended use

Immunoassay for the *in vitro* quantitative determination of the MB isoenzyme of creatine kinase (CK-MB) in human serum and plasma.

A creatine phosphokinase / creatine kinase or isoenzymes test system is a device intended to measure the activity of the enzyme creatine phosphokinase or its isoenzymes (a group of enzymes with similar biological activity) in plasma and serum. Measurements of creatine kinase and its isoenzymes are used in the diagnosis and treatment of myocardial infarction and muscle diseases such as progressive, Duchenne-type muscular dystrophy

6) Comparison to predicate device

The Boehringer Mannheim Elecsys® CK-MB is substantially equivalent to other products in commercial distribution intended for similar use. Most notably it is substantially equivalent to the currently marketed Abbott IMx CK-MB.

The following table compares the Elecsys® CK-MB with the predicate device, Abbott IMx CK-MB. Specific data on the performance of the test have been incorporated into the draft labeling in section 5. Labeling for the predicate device is provided in section 6.

Similarities:

- Intended use: immunoassay for the *in vitro* quantitative determination of the MB isoenzyme of creatine kinase (CK-MB)
 - Sample type - human serum or plasma
 - Two step sandwich immunoassay
 - Mouse monoclonal antibody utilized to capture the CK-MB analyte
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510(k) Summary, Continued

6) Comparison
to predicate
device, (cont.)

Differences:

Feature	Elecsys® CK-MB	IMx CK-MB
Reaction test principle	streptavidin microparticles and electrochemiluminescence technology	antibody coated microparticles and enzyme immunoassay technology
Instrument required	Elecsys 2010 analyzer	Abbott IMx System
Sample volume	15µl	150 µl

Performance Characteristics:

Feature	Elecsys® CK-MB	IMx CK-MB
NCCLS (modif.)		
Precision	HS1 HS2 HS3 CCI CCII	1 2 3
Sample	60 60 60 60 60	48 48 48
N	5.40 26.8 107.7 4.72 65.5	5.0 20.1 116.5
Mean	3.0 3.5 3.7 3.9 3.5	4.5 4.2 3.0
wi/in run %CV	5.1 4.1 4.4 4.6 4.4	6.3 6.1 5.4
total run %CV		
Sensitivity	Lower Detection Limit: 0.150 ng CK-MB / ml	Lower Detection Limit: 0.7 ng CK-MB / ml
Assay Range (LDL to highest standard)	0.100 - 500.0 ng/ml	0.7 - 300 ng/ml
Method Comparison	vs. Abbott IMx CK-MB (Least Squares) N = 95 $y = 0.9735 + 1.0224x$ $r = 0.996$ (Passing/Bablok) N = 95 $y = 0.2095 + 0.9465x$ $r = 0.996$	vs. Hybritech Tandem®-E CK-MB N = 693 $y = -0.52 + 0.82x$ $r = 0.975$

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6) Comparison to predicate device, (cont.) Performance Characteristics (cont.):

Interfering substances: Hemoglobin Lipemia Bilirubin	No interference at: 1.0 g/dl 1,500 mg/dl 28 mg/dl	No interference at: 50 mg/dl 750 mg/dl 1,000 mg/dl
Specificity CK-BB CK-MM	% Cross-reactivity 0.0600 (1,000 ng/ml) 0.1600 (2,500 ng/ml) 0.0020 (5,000 ng/ml) 0.0000 (10,000 ng/ml) 0.0500 (1,000 ng/ml) 0.0000 (2,500 ng/ml) 0.0000 (5,000 ng/ml) 0.0030 (10,000 ng/ml)	% Cross-reactivity 0.0005 (10,000 ng/ml) 0.012 (5,000 ng/ml)