

DEC 17 1997

**510(k) Summary**

K974421

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**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.

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**1.  
Submitter  
name, address,  
contact**

Boehringer Mannheim Corporation  
4300 Hacienda Drive  
Pleasanton, CA 94588-2722  
(510) 730 - 8415  
Contact Person: Jody J. Savage

Date Prepared: November 21, 1997

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**2.  
Device name**

Proprietary name: Elecsys CK-MB STAT Assay

Common name: Creatine Kinase Test

Classification name: Colorimetric method, CPK or Isoenzymes

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**3.  
Predicate device**

The Boehringer Mannheim Elecsys CK-MB STAT is substantially equivalent to other products in commercial distribution intended for similar use. Most notably it is substantially equivalent to the currently marketed first generation Boehringer Mannheim Elecsys CK-MB STAT (K961501).

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## 510(k) Summary, Continued

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**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

- 1<sup>st</sup> incubation: 15 µl of sample, a biotinylated monoclonal CK-MB-specific antibody and a monoclonal CK-MB-specific antibody labeled with a ruthenium complex
- 2<sup>nd</sup> incubation: after the addition of streptavidin-coated microparticles, the complex becomes bound to the solid phase via interaction of biotin and streptavidin.
- 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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## 510(k) Summary, Continued

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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.

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6. **Comparison to predicate device** The Boehringer Mannheim Elecsys CK-MB STAT as described in this submission is substantially equivalent to other products in commercial distribution intended for similar use. Most notably it is substantially equivalent to the currently marketed first generation Boehringer Mannheim Elecsys CK-MB STAT assay (K961501).

The first generation Boehringer Mannheim Elecsys CK-MB assay (K961501) was cleared for use on June 11, 1996, and is in commercial distribution. Subsequent to clearance, the Elecsys CK-MB was renamed the Elecsys CK-MB STAT, to emphasize the rapid (9 minute) assay time. This current submission reflects the addition of an anti-BB antibody to Reagent 1 of the Elecsys CK-MB STAT assay. This modification does not affect the intended use of the device or the basic fundamental scientific technology of the device.



Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

Jody J. Savage  
Consultant, Regulatory Affairs  
Boehringer Mannheim Corporation  
4300 Hacienda Drive  
P.O. Box 9002  
Pleasanton, California 94588-2722

DEC 17 1997

Re: K974421  
Elecsys® CK-MB STAT Assay  
Regulatory Class: II  
Product Code: JHY  
Dated: November 21, 1997  
Received: November 24, 1997

Dear Ms. Savage:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

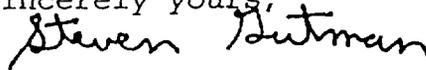
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your pre-market notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



Steven I. Gutman, M.D., M.B.A.  
Director  
Division of Clinical  
Laboratory Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

510(k) Number (if known): N/A

Device Name: Elecsys CK-MB STAT Assay

Indications For 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.

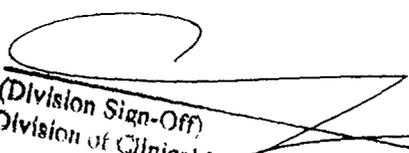
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use    
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)

  
(Division Sign-Off)  
Division of Clinical Laboratory Devices

510(k) Number 12979421