

SEP 24 1998

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 Road
Indianapolis, IN 46250
(317) 845 - 3723

Contact Person: Priscilla A. Hamill

Date Prepared: September 08, 1998

**2.
Device name**

Proprietary name: Elecsys® Myoglobin STAT Assay

Common name: Electrochemiluminescence assay for the determination of Myoglobin.

Classification name: Myoglobin immunological test system

**3.
Predicate
device**

The Boehringer Mannheim Elecsys Myoglobin is substantially equivalent to other products in commercial distribution intended for similar use. Most notably it is substantially equivalent to the currently marketed Boehringer Mannheim Tina-quant Myoglobin Assay.

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4. Device Description

The Elecsys ® Myoglobin test principle is based on the sandwich principal. Total duration of assay: 9 minutes, 37 °C.

- 1st incubation (4.5 minutes): By incubating the sample (15 µL) with a biotinylated monoclonal myoglobin-specific antibody (75 µl) and a monoclonal myoglobin -specific antibody labeled with a ruthenium-complex** (75 µL), a sandwich immunocomplex is formed, the amount of which is dependent upon the analyte concentration in the sample.

- 2nd incubation (4.5 minutes): After addition of streptavidin-coated microparticles (35 µL) 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 (0.4 second read frame).

- Results are determined via a calibration curve that is instrument-specifically generated by 2-point calibration and a master curve provided via the reagent bar code.

**Tris(2,2'-bipyridyl)ruthenium(II) complex (Ru(bpy)₂²⁺)₃

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- 5. Intended use** Immunoassay for the in vitro quantitative determination of myoglobin in human serum and plasma.
The electrochemiluminescence immunoassay “ECLIA” is intended for use on the Boehringer Mannheim Elecsys 1010 and 2010 immunoassay analyzers.
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- 6. Comparison to predicate device** The Boehringer Mannheim Elecsys® Myoglobin is substantially equivalent to other products in commercial distribution intended for similar use. Most notably it is substantially equivalent to the currently marketed Tina-quant® Myoglobin Assay (K972513).
- The following table compares the Elecsys® Myoglobin with the predicate device, Tina-quant® Myoglobin Assay. Specific data on the performance of the test have been incorporated into the draft labeling in attachment 5. Labeling for the predicate device is provided in attachment 6.
- Similarities:**
- Intended Use: Immunoassay for the in vitro quantitative determination of Myoglobin
 - Sample type: Serum and plasma

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6. Comparison to predicate device cont.

Differences:

Feature	Elecsys® Myoglobin STAT	Tina-quant® Myoglobin
Reaction test principle	Electrochemiluminescence	Immunoturbidity
Instrument required	Elecsys analyzer	Hitachi analyzer

Performance Characteristics:

Feature	Elecsys® Myoglobin STAT			Tina-quant® Myoglobin		
Precision Level	Modified NCCLS (ng/mL)			HS1	HS2	Control
	HS1	HS4	HS5			
N	60	60	60	21	21	21
Intra-assay	43.0	1147	3056	73.3	536.7	53.1
SD	0.89	39.5	161	0.9	1.6	1.1
%CV	2.1	3.4	5.3	1.2	0.3	2.1
Total	43.0	1147	3056	70.8	528.2	51.8
SD	1.11	46.3	204	1.6	7.7	1.9
%CV	2.6	4.0	6.7	2.3	1.5	3.7
Precision Level	Modified NCCLS (ng/mL)					
	PCC1	PCC2				
N	60	60				
Intra-assay	82.5	672				
SD	1.03	12.5				
%CV	1.3	1.9				
Total	82.5	672				
SD	1.31	15.6				
%CV	1.6	2.3				
Lower Detection Limit	15 ng/mL			3 ng/mL		

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510(k) Summary, Continued

6.
Comparison to
predicate
device, (cont.)

Performance Characteristics:

Feature	Elecsys® Myoglobin STAT	Tina-quant® Myoglobin
Lower Detection Limit	15 ng/mL	3.0 ng/mL
Linearity	15 - 3,000 ng/mL	3.0 - 560 ng/mL
Method Comparison	Vs Tina-quant Myoglobin <u>Passing/Bablok</u> $y = 1.01x - 0.13$ $r = 1.0$ $SEE = 4.54$ $N = 398$ <u>Least Squares</u> $y = 1.0x + 1.28$ $r = 1.0$ $SEE = 7.58$ $N = 398$	
Interfering substances	No interference at:	No interference at:
Bilirubin	65 mg/dL	60 mg/dL
Hemoglobin	1.4 g/dL	0.5 g/dL
Lipemia	2200 mg/dL	1500 mg/dL
Biotin	50 ng/mL	



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

SEP 24 1998

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Priscilla A. Hamill
Regulatory Affairs Consultant
Boehringer Mannheim Corporation
9115 Hague Road
P.O. Box 50457
Indianapolis, Indiana 46250-0457

Re: K983176
Elecsys® Myoglobin STAT
Regulatory Class: II
Product Code: DDR
Dated: September 8, 1998
Received: September 10, 1998

Dear Ms. Hamill:

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 (Premarket 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 premarket 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.

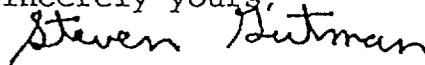
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Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

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 K983176

Device Name: Elecsys® Myoglobin STAT Assay

Indications For Use:

For the in vitro quantitative determination of myoglobin in human serum and plasma. The electrochemiluminescence immunoassay "ECLIA" is intended for use on the Boehringer Mannheim immunoassay analyzers.

A myoglobin immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the myoglobin (an oxygen storage protein found in muscle) in serum and other body fluids. Measurement of myoglobin aids in the rapid diagnosis of heart and renal disease.

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IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K983176

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)