DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUL 25 1997

Boehringer Mannheim Corporation
Laboratory Diagnostics Division
c/o Ms. Mary Koning, Regulatory Affairs Specialist
2400 Bisso Lane
P.O. Box 4117
Concord, California 94524

Re: K964351/S1
Trade Name: Elecsys® PSA Assay
Regulatory Class: II
Product Code: LTJ
Dated: May 12, 1997
Received: May 13, 1997

Dear Ms. Koning:

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 requirement, 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.

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 at (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html"

Sincerely yours,

Steven Gutman

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

JUL 25 1997

K964351

BOEHRINGER MANNHEIM CORPORATION

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
2400 Bisso Lane
P.O. Box 4117
Concord, CA 94524-4117
(510) 674 - 0690, extension 8415

Contact Person: Mary Koning

Date Prepared: October 31, 1996

2. Device name

Proprietary name: Elecsys® PSA Assay

Common name: Electrochemiluminescence assay for the determination of Prostate-Specific Antigen (PSA).

Classification name: System, Test , Prostate-Specific antigen

3. Predicate device

We claim substantial equivalence to the TOSOH AIA-PACK PA.

4. Device Description

The Elecsys® test principle is based on sandwich principle. Total duration of assay: 18 minutes (37° C).

- 1st incubation (9 minutes): Sample (40 µL), a biotinylated monoclonal PSA-specific antibody (60 µL), and a monoclonal PSA-specific antibody labeled with a ruthenium complex (60 µL) react to form a sandwich complex.
- 2nd incubation (9 minutes): After addition of streptavidin-coated microparticles (40 µL), the entire complex is bound to the solid phase via interaction of biotin and streptavidin.

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K964351

4. Device Description

•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 which is instrument-specifically generated by 2-point calibration and a master curve provided via the reagent bar code.

5. Intended use

Immunoassay for the in vitro quantitative determination of Prostate-Specific Antigen in human serum and plasma to aid in the management of prostate cancer patients.

6. Comparison to predicate device

The Boehringer Mannheim Elecsys® PSA Assay is substantially equivalent to other products in commercial distribution intended for similar use. Most notably it is substantially equivalent to the currently marketed TOSOH AIA-PACK PA.
The following table compares the Elecsys® PSA Assay with the predicate device, TOSOH AIA-PACK PA. 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 prostate-specific antigen. The assay is further indicated for serial measurement of PSA to aid in the management of cancer patients.

•Assay range: 0-100 ng/ml

•Assay methodology: Sandwich immunoassay

•Cross-Reactivity: 0% to PAP

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510(k) Summary, Continued

6. Comparison to predicate device cont.

Differences:

Feature	Elecsys® PSA	AIA-PACK PA
Reaction test principle	Electrochemiluminescence	Two-site immuno-enzymometric assay
Sample	Serum and Plasma	Serum
Instrument required	Elecsys® 2010	AIA-1200/AIA 600
Assay Standardization	Stanford Reference Standard (90% PSA-ACT + 10% free PSA)	Different Material - Stanford Reference Standard was unavailable at time of assay development
Calibration Stability	A calibration is recommended every 7 days if kit is not consumed; 8 weeks with same reagent lot if reagent is consumed within 7 days.	A calibration is required every 30 days.

Performance Characteristics:

Feature	Elecsys® PSA			AIA-PACK PA		
Precision Level	Modified NCCLS (ng/mL): Control 1	Control 2	Pool 1	Precision (ng/mL): A	B	C
N	60	60	60	20	20	20
Within-Run	1.88	14.00	0.29	6.61	51.68	95.10
%CV	1.1	1.2	1.5	2.9	3.9	3.0
Total	1.88	14.00	0.29	6.52	52.26	98.33
%CV	2.1	2.2	2.9	2.1	3.9	2.8
	Modified NCCLS (ng/mL): Pool 2	Pool 3				
N	60	60				
Within-Run	3.95	48.48				
%CV	1.8	1.6				
Total	3.95	48.48				
%CV	2.3	2.3				

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6. Comparison to predicate device, (cont.)

Performance Characteristics:

Feature	Elecsys® PSA	AIA-PACK PA
Lower Detection Limit	0.01 ng/mL Functional: 0.07 ng/mL	0.1 ng/mL
Linearity	0.01 - 100 ng/mL (with a deviation from a linear line of ±10%)	0.1 - 100 ng/mL
Method Comparison	Vs TOSOH AIA-PACK PA Least Squares y =0.86x + 0.01 r=0.995 SEE = 0.251 N=365 Passing/Bablok y =0.90x - 0.28 r=0.995 SEE = 0.892 N=365	Not shown
Interfering substances Bilirubin Hemoglobin Lipemia Biotin	No interference at: 25 mg/dL 1.0 g/dL 1000 mg/dL 30 ng/mL	No interference at: 17 mg/dL 0.47 g/dL 1600 mg/dL
Specificity PAP ACT PSA PSA-ACT	% Cross-reactivity none none 100% 100%	% Cross-reactivity 0.0 not available not available not available
Hook Effect	No Hook Effect up to 13,900 ng/ml PSA	Not available

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510(k) Number (if known): K964351
Device Name: Elecsys® PSA Assay
Indications for Use:

Immunoassay for the in vitro quantitative determination of Prostate-Specific Antigen in human serum and plasma. The Elecsys PSA assay is further indicated for serial measurement of PSA to aid in the management of prostate cancer.

The electrochemiluminescence immunoassay "ECLIA" is intended for use on the Boehringer Mannheim Elecsys 2010 immunoassay analyzers.

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K964351

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The Counter-Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)