MAR 25 1998

510(k) Summary

Elecsys® CA 125II on Elecsys 1010

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
P.O. Box 9002
Pleasanton, CA 94566-0900
(510) 730-8415

Contact Person: Jody J. Savage
Date Prepared: January 22, 1998

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2. Device name

Proprietary name: Elecsys® CA 125II™
Common name: Epithelial Ovarian Tumor Associated Antigen
Classification name: Tumor Associated Antigen Immunological Test System

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3. Predicate device

We claim substantial equivalence to the Elecsys® CA 125II™ Assay on Elecsys 2010.

510(k) Summary, Continued

4. Device Description

The Elecsys® CA 125 II™ employs a sandwich test principle with monoclonal antibodies directed against CA 125 II and with streptavidin microparticles and electrochemiluminescence detection.

Total duration of assay: 18 minutes.

- 1st Incubation: 40 µl of sample, a biotinylated monoclonal CA 125 II-specific antibody and a monoclonal CA 125 II-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.

•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 determination of OC 125 reactive determinants. These determinants are associated with a high molecular weight glycoprotein in serum and plasma of women with primary epithelial invasive ovarian cancer, excluding those with cancer of low malignant potential. The Elecsys® CA 125II is indicated for use as an aid in the detection of residual or recurrent ovarian carcinoma in patients who have undergone first-line therapy and would be considered for diagnostic second-look procedures. The Elecsys CA 125II assay is further indicated for serial measurement of CA 125II to aid in the management of cancer patients.

510(k) Summary, Continued

6. Comparison to predicate device

The Boehringer Mannheim Elecsys® CA 125II Assay is under review for use on the Elecsys 2010 immunoassay analyzer (K972162). The application of the Elecsys® CA 125II Assay on the Elecsys 1010 immunoassay analyzer is substantially equivalent to the same assay (Elecsys CA 125II Assay) on the Elecsys 2010.

The following table compares the Elecsys® CA 125II on the Elecsys 1010 with the predicate device, Elecsys® CA 125II on the Elecsys 2010. Specific data on the performance of this test for both the Elecsys 1010 and 2010 have been incorporated into the draft labeling in Section 5. Labeling for the predicate device provided in Section 6 will be replaced upon the approval of this premarket approval submission with the combined Elecsys 2010 and 1010 insert (Section 5).

Similarities:

•Intended Use: Immunoassay for the in vitro determination of OC 125 reactive determinants. These determinants are associated with a high molecular weight glycoprotein in serum and plasma of women with primary epithelial invasive ovarian cancer, excluding those with cancer of low malignant potential. The Elecsys® CA 125II is indicated for use as an aid in the detection of residual or recurrent ovarian carcinoma in patients who have undergone first-line therapy and would be considered for diagnostic second-look procedures. An assay value of greater than or equal to 35 U/ml is predictive of residual disease. The Elecsys CA 125II assay is further indicated for serial measurement of CA 125II to aid in the management of cancer patients.

•Assay range: 0.6 - 5000 U/mL

•Assay methodology: Sandwich immunoassay

•Kit (cat. no. 1776223) intended for use on the Elecsys 2010 (K972162)

•Sample and reagent volumes

•Incubation temperature and reaction times

•Package insert

•Performance specifications

•Reagents

Continued on next page

510(k) Summary, Continued

6. Comparison to predicate device cont.

Differences:

Feature	Elecsys 1010	Elecsys 2010
Instrument required	Elecsys 1010	Elecsys 2010
Instrument System	Batch	Random access
Reagent Storage Temp (C)	Ambient Temperature	20° C

Performance Characteristics:

Feature	Elecsys 1010			Elecsys 2010		
Precision	Modified NCCLS (U/mL):			Modified NCCLS (U/mL):		
Sample	Control 1	Control 2	Pool 1	TM1	TM 2	HS low
N	60	60	60	60	60	60
Within-Run	41.8	129.2	44.1	39.03	121.45	7.83
%CV	0.98	1.15	1.15	1.91	1.41	3.29
Total	41.8	129.2	44.1	39.03	121.45	7.83
%CV	2.26	2.65	3.13	2.53	2.70	4.19
	Modified NCCLS (ng/mL):			Modified NCCLS (U/mL):		
	Pool 2	Pool 3		HS med	HS high	
N	60	60		60	60	
Within-Run	142.9	591.4		38.28	70.82	
%CV	0.84	0.76		2.14	2.06	
Total	142.9	591.4		38.28	70.82	
%CV	2.82	2.13		3.05	2.48	

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510(k) Summary, Continued

6. Comparison to predicate device, cont.

Performance Characteristics:

Feature	Elecsys 1010	Elecsys 2010
Lower Detection Limit	0.222 U/mL	0.5 U/ml
Linearity	0.6 – 5,000 U/ml	0.6 – 5,000 U/ml
Method Comparison	Vs Elecsys 2010 <u>Least Squares</u> y=0.9614x - 2.15 r=0.997 SEE=47.22 N=93 <u>Passing Bablock</u> y=0.9745x + 3.15 r=0.997 SEE=16.76 N=93	vs. CENTOCOR CA 125 II RIA <u>Least Squares</u>: N = 139 y = 0.93x + 5.57 r = 0.98 <u>Passing/Bablock</u> N = 139 y = 0.98x + 5.08 r = 0.98
Hook Effect	No Hook Effect up to 24,000 U/ml CA 125	No Hook Effect up to 30,000 U/mL CA 125

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ms. Patricia M. Klimley
Manager, Regulatory Affairs
Boehringer Mannheim Corporation
Laboratory Diagnostics
4300 Hacienda Drive
P.O. Box 9002
Pleasanton, California 94566-0900

MAR 25 1998

Re: K980240
Trade Name: Elecsys® CA 125 II™
Regulatory Class: II
Product Code: LTK
Dated: January 22, 1998
Received: January 23, 1998

Dear Ms. Klimley:

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

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

Device Name: Elecsys® CA 125Assay

Indications For Use:

Immunoassay for the in vitro determination of OC 125 reactive determinants. These determinants are associated with a high molecular weight glycoprotein in serum and plasma of women with primary epithelial invasive ovarian cancer, excluding those with cancer of low malignant potential. The Elecsys® CA 125II is indicated for use as an aid in the detection of residual or recurrent ovarian carcinoma in patients who have undergone first-line therapy and would be considered for diagnostic second-look procedures. The Elecsys CA 125II is further indicated for serial measurement of CA 125II to aid in the management of cancer patients.

Deborah M. Moore
for Dr Peter Major
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K980240

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)