K964368

JUN 16 1997

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® CEA Assay

Common name: Electrochemiluminescence assay for the determination of Carcinoembryonic antigen (CEA).

Classification name: Kit, Test , Carcinoembryonic antigen

3. Predicate device

The Boehringer Mannheim Elecsys® CEA is substantially equivalent to other products in commercial distribution intended for similar use. Most notably it is substantially equivalent to the currently marketed Enzymun-Test CEA (P860058).

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 (30 µL), biotinylated monoclonal CEA-specific antibody (60 µL), and a monoclonal CEA-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 (50 µL), the complex is 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 (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 carcinoembryonic antigen (CEA) in human serum and plasma.

Measurements of CEA aid in the management of cancer patients by monitoring CEA concentrations.

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

6. Comparison to predicate device

The Boehringer Mannheim Elecsys® CEA Assay is substantially equivalent to other products in commercial distribution intended for similar use. Most notably it is substantially equivalent to the currently marketed Enzymun-Test CEA Assay (P860058).

The following table compares the Elecsys® CEA Assay with the predicate device, Enzymun-Test CEA Assay (P860058):

Similarities:

- Intended Use: Immunoassay for the in vitro quantitative determination of Carcinoembryonic Antigen (CEA). The assay is further indicated for serial measurement of CEA to aid in the management of cancer patients.
- Solid phase binding principle: Streptavidin/Biotin
- Calibrators: Same formulation
- Assay standardization: 1st WHO Reference Standard 73/601

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6. Comparison to predicate device, cont.

Differences:

Feature	Elecsys® CEA	Enzymun CEA
Reaction test principle	Electrochemiluminescence	ELISA/1-step sandwich assay using streptavidin technology
Instrument required	Elecsys® 2010	ES 300
Antibodies	Mouse/chimeric	Mouse/mouse
Sample Material	Serum and Plasma	Serum
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 run

Performance Characteristics:

Feature	Elecsys® CEA			Enzymun-Test CEA		
Precision Level	Modified NCCLS (ng/mL): Control 1	Control 2	Pool 1	Low	Mid	High
N	60	60	60	120	120	120
Within-Run	5.10	35.51	3.99	2.3	12.4	26.4
%CV	1.8	1.4	1.7	5.6	3.7	3.3
Total	5.10	35.51	3.99	2.3	12.4	26.4
%CV	3.5	2.8	3.2	6.3	4.1	3.7
	Modified NCCLS (ng/mL): Pool 2	Pool 3				
N	60	60				
Within-Run	17.16	546.00				
%CV	1.7	1.4				
Total	17.16	546.00				
%CV	3.2	3.4				

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510(k) Summary, Continued

6. Comparison to predicate device, cont.

Performance Characteristics:

Feature	Elecsys® CEA	Enzymun-Test CEA
Lower Detection Limit	0.2 ng/mL	0.5 ng/mL
Linearity	0.2 - 1000 ng/mL (with a deviation from a linear line of ±10%)	0.5 - 55 ng/mL (with a deviation from a linear line of ±10%)
Method Comparison	Vs Enzymun-Test® CEA 0 - 50 ng/mL Least Squares y =1.25x - 0.86 r=0.976 SEE = 1.421 N=397 Passing/Bablok y =1.22x - 0.69 r=0.976 SEE = 0.471 N=397 0 - 600 ng/mL Least Squares y =1.05x + 0.46 r=0.991 SEE = 6.093 N=446 Passing/Bablok y =1.13x - 0.53 r=0.991 SEE = 0.714 N=446	Vs Enzymun-Test® CEA Least Squares y =0.97x - 0.064 r=0.989 SEE =1.649 N=69

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6. Comparison to predicate device, cont.

Performance Characteristics:

Feature	Elecsys® CEA	Enzymun-Test CEA
Interfering substances	No interference at:	No interference at:
Bilirubin	25 mg/dL	64.5 mg/dL
Hemoglobin	1000 mg/dL	50 mg/dL
Lipemia	1000 mg/dL	1250 mg/dL
Biotin	30 ng/mL	40 ng/mL
Specificity	% Cross-reactivity	% Cross-reactivity
Non-specific cross reacting antigen		
NCA 1	< 0.7%	< 0.7%
NCA 2	70%	70%
α_1 -acid glycoprotein	none	none
Hook Effect	No Hook Effect up to 49,100 ng/ml CEA	No Hook Effect up to 5,800 ng/ml CEA

6. Comparison to predicate device, cont.

Clinical specimens

Serial samples from 50 patients with colorectal cancer were tested on the Elecsys CEA. Chi square analysis of the samples showed a statistically significant association between clinical outcome and CEA test result.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUN 16 1997

Ms. Mary Koning
Regulatory Affairs Specialist
Boehringer Mannheim Corporation
2400 Bisso Lane
Concord, California 94524-4117

Re: K964368/S1
Trade Name: Elecsys® CEA Assay and Elecsys® CEA CalSet Calibrators
Regulatory Class: II
Product Code: DHX
Dated: April 30, 1997
Received: May 1, 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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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