

K972162

MAR 18 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 Rd.
Indianapolis, IN 46250
(317) 845-2000

Contact Person: LeeAnn Chambers, RAC

Date Prepared: June 5, 1997

2) Device name Proprietary name: Elecsys® CA 125 II™

Common name: Epithelial Ovarian Tumor Associated Antigen

Classification name: Tumor Associated Antigen Immunological Test System

3) Predicate device We claim substantial equivalence to CENTOCOR® CA 125 II™ RIA.

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.
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510(k) Summary, Continued

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.
 - 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.

6) Comparison to predicate device

The Boehringer Mannheim Elecsys CA 125 II is substantially equivalent to other products in commercial distribution intended for similar use. Most notably it is substantially equivalent to the currently marketed CENTOCOR CA 125 II RIA.

Studies performed include:

- evaluation of assay precision according to NCCLS recommendations,
- determination of the lower detection limit,
- demonstration of linearity,
- correlation with the predicate device,
- evaluation of the effect of various endogenous substances (hemoglobin, biotin, triglyceride, bilirubin, and rheumatoid factor), and commonly used pharmaceutical compounds, and serum / plasma sample comparisons,
- determination of hook effect, and
- stability studies.

In addition, comparisons of the Elecsys CA 125 II and the predicate device were performed with samples from serially monitored patients diagnosed and treated for ovarian cancer.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

MAR 18 1998

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

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

Re: K972162
Trade Name: Elecsys® CA 125 II™
Regulatory Class: II
Product Codes: LTK
Dated: December 17, 1997
Received: December 18, 1997

Dear Ms. Klimely:

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.

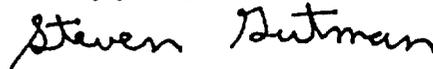
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (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,

A handwritten signature in black ink that reads "Steven Gutman". The signature is written in a cursive style with a large initial 'S' and 'G'.

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):
Device Name: Elecsys CA 125 II
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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Deborah M. Moore
for Dr. Peter Mepine

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K972162

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)