NOV 2 1 1997

510(k) Summary

K973351

BOEHRINGER MANNHEIM CORPORATION

[redacted]

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
Concord, CA 94524-4117
(317) 845-2000

Contact Person: Patricia M. Klimley

Date Prepared: September 2, 1997

2) Device name

Proprietary name: Elecsys® AFP

Common name: Alpha-Fetoprotein assay

Classification name: Alpha-Fetoprotein test kit for testicular cancer

3) Predicate device

We claim substantial equivalence to the Enzymun-Test® AFP (P860044).

4) Device Description

The Elecsys® test principle is based on the sandwich principle. Total duration of assay: 18 minutes.

- 1st incubation: 15 µl of sample, a biotinylated monoclonal AFP-specific antibody and a monoclonal AFP-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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[redacted]

4) Device Description, cont.

- The reaction mixture is aspirated into the measuring cell where the micro-particles 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.

5) Intended use

Immunoassay for the in vitro quantitative determination of α_1-fetoprotein in human serum and plasma to aid in the management of patients with non-seminomatous germ cell tumors.

6) Comparison to predicate device

The Boehringer Mannheim Elecsys AFP 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 AFP.

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, lipemia, 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 AFP and the predicate device were performed with samples from serially monitored patients diagnosed and treated for testicular cancer.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

NOV 21 1997

Ms. Patricia M. Klimley
Manager, Regulatory Affairs
Boehringer Mannheim Corporation
2400 Bisso Lane
Concord, California 94524-4117

Re: K973351
Trade Name: Elecsys® AFP
Regulatory Class: II
Product Code: LOJ
Dated: September 2, 1997
Received: September 5, 1997

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): K973351
Device Name: Elecsys® AFP
Indications for Use:

Immunoassay for the in vitro quantitative determination of α_1-fetoprotein in human serum and plasma to aid in the management of patients with non-seminomatous germ cell tumors.

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Peter E Maglini

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K973351

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

(Optional Format 1-2-96)