DUPLICATE K973674

510(k) Summary

NOV 1 2 1997

BOEHRINGER MANNHEIM CORPORATION

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
4300 Hacienda Drive
Pleasanton, CA 94588-2722
(510) 730-8215

Contact Person: Patricia M. Klimley

Date Prepared: September 24, 1997

2) Device name

Proprietary name: Elecsys® FOLATE

Common name: Electrochemiluminescent assay for the determination of FOLATE.

Classification name: Folate Test System.

3) Predicate device

We claim substantial equivalence to the Bio-Rad Quantaphase II® B12/FOLATE Radioassay (K935286).

4) Device Description

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

- 1st Incubation (9 min.): By incubating the sample (15 µl) with the folate pretreatment 1 (15 µl) and pretreatment 2 (10 µl), bound folate is liberated into the serum.
- 2nd Incubation (9 min.): By incubating the pretreated sample with the Ruthenylated folate binding protein (80 µl), an FBP-folate complex is formed, the amount of which is dependent upon the analyte concentration in the sample.
- 3rd incubation (9 min.): after the addition of streptavidin-coated microparticles (30 µl) and folate labeled with biotin (50 µl), the unbound sites of the Ruthenylated folate binding protein become occupied, with formation of a Ruthenylated folate binding protein-folate biotin complex. The entire complex becomes bound to the solid phase via interaction of biotin and streptavidin.

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 by washing 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-specific generated by 2-point calibration and a master curve provided via the reagent bar code.

5) Intended use

Assay for the in vitro quantitative determination of folate in human serum.

6) Comparison to predicate device

The Boehringer Mannheim Elecsys FOLATE is substantially equivalent to other products in commercial distribution intended for similar use. Most notably it is substantially equivalent to the currently marketed Bio-Rad Quantaphase II® B12/FOLATE Radioassay (K935286).

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 (biotin, triglyceride, lipemia, and rheumatoid factor), and commonly used pharmaceutical compounds and serum sample comparisons, and
- stability studies.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ms. Patricia M. Klimley
Head, Elecsys Regulatory Program
Boehringer Mannheim Corporation
4300 Hacienda Drive
Pleasanton, California 94588-2722

NOV 12 1997

Re: K973674
Trade Name: Elecsys® FOLATE
Regulatory Class: II
Product Code: CDD
Dated: September 24, 1997
Received: September 26, 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):
Device Name: Elecsys® FOLATE
Indications for Use:

Assay for the in vitro quantitative determination of folate in human serum.
The electrochemiluminescence assay "ECLIA" is intended for use on the Boehringer Mannheim Elecsys assay analyzers.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K973674

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

(Optional Format 1-2-96)