

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 Roche Diagnostics/Boehringer Mannheim Corporation
4300 Hacienda Drive
Pleasanton, CA 94566-0900
(925) 730-8215

Contact Person: Patricia M. Klimley

Date Prepared: June 1, 1998

2) Device name Proprietary name: Elecsys® Red Blood Cell Folate Lysing Reagent

Common name: Elecsys® Red Blood Cell Folate Lysing Reagent is to be used in combination with the Elecsys® Folate Assay for the quantitation of folate in human red blood cells.

Classification name: Folate Test System.

3) Predicate device We claim substantial equivalence to the Bio-Rad Quantaphase II® FOLATE Radiobinding assay (K935286).

4) Device Description

The Elecsys® test principle is based on the competitive principle. Total duration of assay: 90 +/- 15 minutes.

- Reconstitution Step: Add contents of the ascorbic acid packet to 100 mL distilled or deionized water.
 - Pretreatment Step: 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.
 - Proceed to conduct the Elecsys® Folate Assay (K973674) as per insert instructions.
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510(k) Summary, Continued

5) Intended use The Elecsys Red Blood Cell Folate Lysing Reagent is to be used in combination with the Elecsys Folate Assay for the quantitation of folate in human red blood cells.
The electrochemiluminescence assay “ECLIA” is intended for use on the Boehringer Mannheim Elecsys 2010 immunoassay analyzer.

6) Comparison to predicate device The Roche Diagnostics/Boehringer Mannheim Elecsys Red Blood Cell 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® Folate Radiobinding assay .

Elecsys studies performed include:

- evaluation of assay precision according to NCCLS recommendations
 - demonstration of linearity
 - correlation with the predicate device
 - sample type studies
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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

AUG 25 1998

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

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

Re: K981931
Elecsys® Red Blood Cell Folate Lysing Reagent
Regulatory Class: II
Product Code: CGN
Dated: June 1, 1998
Received: June 2, 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 requirements, 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.

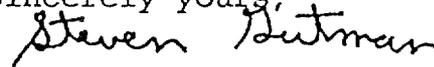
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Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

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 (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



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® Red Blood Cell Folate Lysing Reagent

Indications for Use:

The Elecsys® Red Blood Cell Folate Lysing Reagent is to be used in combination with the Elecsys® Folate Assay for the quantitation of folate in human red blood cells.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)



(Division Sign-Off)

Division of Clinical Laboratory Devices

510(k) Number 8981931