JUN 2 5 2003

510(k) Summary - Elecsys® Folate II Assay K031756

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
Submitter name, address, contact	Roche Diagnostics Corporation 9115 Hague Rd Indianapolis IN 46250 (317) 521-3831 Contact person: Sherri L. Coenen Date prepared: June 6, 2003
Device Name	Proprietary name: Elecsys® Folate II Assay Common name: Elecsys® Folate II Assay Classification name: Vitamin B12 Test System
Device description	The Elecsys® Folate II Assay employs a competitive test principle using natural folate binding protein (FBP) specific for folate. Folate in the sample competes with the added folate labeled with biotin for the binding sites on the ruthenium labeled FBP-complex.
Intended use	Binding assay for the in vitro quantitative determination of folate in human serum. The binding assay is intended for use on the Roche Elecsys 2010 and Modular Analytics E170 immunoassay analyzers.
Predicate Device	We claim substantial equivalence to the currently marketed Elecsys® Folate Assay. (K973674).

510(k) Summary - COBAS Integra Creatinine plus ver.2,
continued

Reagent Summary

The following table describes the similarities and differences between the Elecsys® Folate II Assay and the predicate device.

Topic	Elecsys® Folate (K973674)	Elecsys® Folate II (Modified Device)
Intended Use	Binding assay for the in vitro quantitative determination of folate in human serum. The binding assay is intended for use on the Roche Elecsys 2010 and Modular Analytics E170 (Elecsys Module) immunoassay analyzers.	Same
Method	competitive chemiluminescent immunoassay	Same
Sample type	Human Serum	Same
Measuring range	0.600 - 20.00 ng/ml or 1.36 - 45.4 nmol/L	Same
Expected values	4.2 - 19.9 ng/ml	3.1 - 17.5 ng/ml

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUN 2 5 2003

Ms. Sherri L. Coenen MT(ASCP)
Regulatory Affairs Consultant
Regulatory Submissions, Centralized Diagnostics
Roche Diagnostics Corporation
9115 Hague Road
P.O. Box 50457
Indianapolis, IN 46250-0457

Re: k031756
Trade/Device Name: Elecsys® Folate II Assay
Regulation Number: 21 CFR 862.1295
Regulation Name: Folic acid test system
Regulatory Class: Class II
Product Code: CGN
Dated: June 3, 2003
Received: June 6, 2003

Dear Ms. Coenen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 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 information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): N/A K031756

Device Name: Elecsys® Folate II Assay

Indications For Use:

Binding assay for the in vitro quantitative determination of folate in human serum.
Measurements obtained by this device are used in the diagnosis and treatment of anemias of gastrointestinal malabsorption.
The binding assay is intended for use on the Roche Elecsys 2010 and Modular Analytics E170 immunoassay analyzers.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

(Optional Format 1-2-96)

Division Sign-Off for Jean Cooper

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K031756