K043320

DEC 17 2004

510(k) Summary - Elecsys® Folate II CalCheck II

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 9115 Hague Rd Indianapolis IN 46250 (317) 521-3544 Contact person: Kay A. Taylor Date prepared: December 1, 2004
Device Name	Proprietary name: Roche Diagnostics Elecsys® Folate II CalCheck II Common name: Calibration Verification Material Classification name: Single (specified) Analyte Controls (Assayed and Unassayed)
Device description	The Elecsys Folate II CalCheck II is a set of calibration verification solutions comprised of three levels, each with defined folate levels.
Intended use	For use in the verification of the calibration established by the Elecsys Folate II reagent on the Elecsys 2010 and MODULAR ANALYTICS E170 immunoassay analyzers.
Predicate Device	We claim substantial equivalence to the currently marketed Elecsys Folate CalCheck. (K974384).
Device Comparison	The table below illustrates the similarities between the Elecsys Folate CalCheck (K974384) and the Elecsys Folate II CalCheck II (modified device).

510(k) Summary - Elecsys® Folate II CalCheck II, continued

Topic	Elecsys® Folate CalCheck (K974384)	Elecsys® Folate II CalCheck II (Modified Device)
Intended Use / Indications for Use	For use in the verification of the calibration established by the... • Elecsys Folate reagent on the Elecsys 2010 • Elecsys Folate II reagent on the MODULAR ANALYTICS E170.	For use in the verification of the calibration established by the Elecsys Folate II reagent on the Elecsys 2010 and MODULAR ANALYTICS E170 immunoassay analyzers.
Matrix	Buffer with human albumin	Human serum
Storage Form	Liquid	Lypholized
Levels	Low: 1.5 ng/ml Mid: 8.7 ng/ml High: 16.0 ng/ml	Low: 2.0 ng/ml Mid: 7.5 ng/ml High:15.3 ng/ml
Standardization	The Elecsys Folate II assay has been standardized against the Elecsys Folate assay. The Elecsys Folate assay was standardized against a commercially available radiobinding folate assay. Note: the previously used radiobinding folate assay is no longer available.	The Elecsys Folate II assay has been standardized against the Elecsys Folate assay.
Stability	Store at 2-8°C unopened up to the expiration date. Opened: 5 hours at 20-25°C	Same

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC 17 2004

Ms. Kay A. Taylor, MT (ASCP), RAC
Regulatory Principal
Roche Diagnostics Corp.
Centralized Diagnostics
9115 Hague Road
Indianapolis, IN 46250

Re: k043320
Trade/Device Name: Roche Elecsys Folate II CalCheckII
Regulation Number: 21 CFR 862.1660
Regulation Name: Control Material
Regulatory Class: Class I
Product Code: JJX
Dated: December 1, 2004
Received: December 2, 2004

Dear Ms. Taylor:

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,

Cornelia B. Rooks

Cornelia B. Rooks, MA
Acting Director
Division of Chemistry and Toxicology
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): **K043320**

Device Name: **Roche Elecsys Folate II CalCheck II**

Indications For Use:

For use in the verification of the calibration established by the Elecsys Folate II reagent on the Elecsys 2010 and MODULAR ANALYTICS E170 immunoassay analyzers.

Prescription Use **XXX** AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Carol C. Benson
Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K043320