

JUN 17 2005

510(k) Summary – Elecsys RBC Folate Hemolyzing Reagent

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: May 17, 2005

Device Name Proprietary name: Elecsys RBC Folate Hemolyzing Reagent

Common name: Folate Assay

Classification name: Acid, Folic, Radioimmunoassay

Device description The Elecsys RBC Folate Hemolyzing Reagent is an ascorbic acid solution with which whole blood treated with anticoagulants (heparin or EDTA) is diluted. After incubation the erythrocytes are lysed and intracellular folate is liberated and stabilized. The hemolysate is then used as a prediluted sample for subsequent measurement in the Elecsys Folate II assay.

Intended use Elecsys RBC Folate Hemolyzing Reagent is used together with the Elecsys Folate II assay for the quantitative determination of folate in erythrocytes (RBC folate).

Predicate Device We claim substantial equivalence to the Elecsys Red Blood Cell Folate Lysing Reagent currently marketed on the Elecsys 2010 and MODULAR ANALYTICS E170. (K981931).

510(k) Summary – Elecsys RBC Folate Hemolyzing Reagent, continued

Device Comparison The table below illustrates the similarities between the Elecsys Red Blood Cell Folate Lysing Reagent (K981931) and the Elecsys RBC Folate Hemolyzing Reagent (modified device).

| Topic | Elecsys Red Blood Cell Folate Lysing Reagent (K981931) | Elecsys RBC Folate Hemolyzing Reagent (Modified Device) |
|-------------------------------|---|--|
| Intended Use | The Elecsys Red Blood Cell Folate Lysing Reagent to be used in combination with the Elecsys Folate Assay for the quantitation of folate in human red blood cells. | Elecsys RBC Folate Hemolyzing Reagent is used together with the Elecsys Folate II assay for the quantitative determination of folate in erythrocytes (RBC folate). |
| Test Principle | Competitive chemiluminescence | Same |
| Sample Type | Whole blood, heparinized or EDTA | Same |
| Sample / Lysing Reagent Ratio | 1:31 | Same |
| Measuring range | Not provided | Without considering the hematocrit value: up to 1407 nmol/L (620 ng/mL) |
| Pretreatment incubation | 90 minutes ± 15 | Same |
| Stability | | |
| Ascorbic Acid | 7 days | 14 days |
| Whole blood at - room temp | 4 hours | 2 hours |
| - 2-8° C | 1 day | Same |
| Hemolysate at - room temp | not recommended | 3.5 hours |
| Expected Values | N=111, 342 - 786 ng/ml | (US) N=105, 342 – 786 ng/ml (Europe) N=282, 176 – 589 ng/ml |
| Precision | Modified NCCLS (N=60) Whole blood 2010 analyzer 6.5% CV @ 469 ng/ml 4.8% CV @ 850 ng/ml | Modified NCCLS (N=63) Whole blood 2010 analyzer 6.8% CV @ 478 ng/ml 6.6% CV @ 573 ng/ml 5.5% CV @ 623 ng/ml E170 analyzer 9.5% CV @ 188 ng/ml 6.1% CV @ 312 ng/ml 3.6% CV @ 410 ng/ml |



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

JUN 17 2005

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

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

Re: k051292
Trade/Device Name: Roche Elecsys Folate II Immunoassay
Regulation Number: 21 CFR 862.1295
Regulation Name: Folic acid test system
Regulatory Class: Class II
Product Code: CGN
Dated: May 17, 2005
Received: May 18, 2005

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.

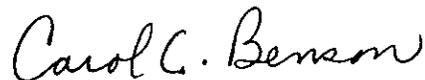
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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).

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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 (240) 276-0484. 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/industry/support/index.html>.

Sincerely yours,



Carol C. Benson, M.A.
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): 1051292

Device Name: Roche Elecsys Folate II Immunoassay

Indications For Use:

**Binding assay for the in vitro quantitative determination of folate in human serum.
Measurements obtained by this devices are used in the diagnosis and treatment of anemias.**

**The binding assay is intended for use on the Roche Elecsys 2010 and MODULAR
ANALYTICS E170 (Elecsys module) immunoassay analyzers.**

Prescription Use XX
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 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)


Division Sign-Off

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Office of In Vitro Diagnostic
Device Evaluation and Safety

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