K061970

AUG 31 2006

510(k) Summary - Elecsys IgE II Immunoassay

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: July 11, 2006

Device Name

Proprietary name: Elecsys IgE II immunoassay

Common name: IgE test

Classification name: radioimmunoassay, immunoglobulins (d, e)

Device description

The Elecsys IgE II immunoassay is a two step sandwich immunoassay with streptavidin microparticles and electrochemiluminescence detection. Results are determined using a calibration curve that is generated specifically on each instrument by a 2 point calibration and a master curve provided with the reagent bar code.

Intended Use / Indications for Use

Immunoassay for the in vitro quantitative determination of immunoglobulin E in human serum and plasma. Determination of total IgE is useful as an aid in the diagnosis of allergic diseases.

Substantial equivalence

The Elecsys IgE II immunoassay is substantially equivalent to another device legally marketed in the United States. Elecsys IgE II (modified) assay is equivalent to the Elecsys IgE immunoassay (K984326, K961481/A003). Both products are intended for use in the quantitative determination of IgE in serum and plasma.

Device Comparison

The table below compares the device features of the Elecsys IgE II immunoassay (modified) and original (K984326, K961481/A003).

510(k) Summary – Elecsys IgE II Immunoassay, continued

Topic	Elecsys IgE (K984326, K961481/A003)	Elecsys IgE II (Modified Device)
Intended use	Immunoassay for the in vitro quantitative determination of immunoglobulin E in human serum and plasma. Determination of total IgE is useful as an aid in the diagnosis of allergic diseases.	Same
Analyzers	Roche Elecsys 1010/2010 and MODULAR ANALYTICS E170 (Elecsys module) immunoassay analyzers.	Roche Elecsys 2010 and MODULAR ANALYTICS E170 (Elecsys module) immunoassay analyzers.
Traceability	Assay standardized against the 2nd IRP WHO Reference Standard 75/502	Same
Assay Protocol	Sandwich	Same
Sample Type	Serum and plasma	Same
Calibrator, Calibration Verification & Controls	IgE CalSet IgE CalCheck PreciControl Universal	Same
Measuring Range	0.10 – 2500 IU/ml	Same
Analytical Sensitivity	0.10 IU/ml	Same
Functional Sensitivity	0.50 IU/ml	Same
Composition	R1: 2.4 mg/L AB-Bi, buffer, preservative R2: 4.8 mg/L AB-Ru, buffer, preservative M: 0.72 mg/ml streptavidin-coated microparticles, preservative	R1: 2.5 mg/L (mono-Bi)AB-Bi, buffer, preservative R2: 5.5 mg/L AB-Ru, buffer, preservative M: 0.72 mg/ml streptavidin-coated microparticles, preservative
Dilution Recommendation	Concentration of diluted samples must be > 60 IU/mL	Concentration of diluted samples must be > 125 IU/mL
Interferences	No affect up to, bilirubin < 37 mg/dl hemoglobin < 1.1 g/dl triglycerides < 2200 mg/dl biotin < 100 ng/ml	No affect up to, Bilirubin - Same hemoglobin < 0.1 g/dl triglycerides - Same biotin – Same

Topic	Elecsys IgE (K984326, K961481/A003)	Elecsys IgE II (Modified Device)
Precision	*Elecsys 1010 / 2010:* Intra-assay HS1 3.6% CV @ 5.18 IU/mL HS2 3.2% CV @ 398 IU/mL HS3 2.4% CV @ 1010 IU/mL Total: HS1 4.2% CV @ 5.18 IU/mL HS2 3.9% CV @ 398 IU/mL HS3 3.1% CV @ 1010 IU/mL *E170:* Intra-assay HS1 2.3% CV @ 3.36 IU/mL HS2 2.2% CV @ 457 IU/mL HS3 2.6% CV @ 1128 IU/mL Total: HS1 4.3% CV @ 3.31 IU/mL HS2 3.8% CV @ 443 IU/mL HS3 6.5% CV @ 1215 IU/mL	*Elecsys 2010:* Intra-assay: HS1 4.1% CV @ 32.7 IU/mL HS2 2.4% CV @ 265 IU/mL HS3 2.6% CV @ 1295 IU/mL Total: HS1 5.1% CV @ 32.7 IU/mL HS2 3.8% CV @ 265 IU/mL HS3 3.9% CV @ 1295 IU/mL *E170:* Intra-assay: HS1 1.4% CV @ 4.4 IU/mL HS2 0.7% CV @ 261 IU/mL HS3 1.0% CV @ 1018 IU/mL Total: HS1 2.7% CV @ 30.2 IU/mL HS2 2.8% CV @ 245 IU/mL HS3 3.4% CV @ 1207 IU/mL

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ms. Kay A. Taylor, MT (ASCP), RAC
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US Regulatory Affairs
Roche Diagnostics, Inc.
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P.O. Box 50416
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AUG 3 1 2006

Re: k061970
Trade/Device Name: Elecsys IgE II Immunoassay
Regulation Number: 21 CFR § 866.5510
Regulation Name: Immunoglobulins A, G, M, D and E Immunological Test System
Regulatory Class: II
Product Code: JHR
Dated: August 22, 2006
Received: August 23, 2006

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 (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,

Robert L. Becker, Jr., MD, Ph.D
Director
Division of Immunology and Hematology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K061970

Device Name: Elecsys IgE II Immunoassay

Indications For Use:

Immunoassay for the in vitro quantitative determination of immunoglobulin E in human serum and plasma.

Determination of total IgE is useful as an aid in the diagnosis of allergic diseases.

The electrochemiluminescence immunoassay "ECLIA" is intended for use on the Roche Elecsys 2010 and MODULAR ANALYTICS E170
(Elecsys module) immunoassay analyzers.

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K061970

Prescription Use **XXXX** 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)