DEC 0 5 2008

K072617

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.

Submitter name, address, contact

Roche Diagnostics
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Indianapolis, IN 46250
(317) 521 - 3723

Contact Person: Theresa A. Bush

Date Prepared: November 21, 2008

Device Name

Proprietary name: (1) Elecsys Rubella IgG Immunoassay
(2) Elecsys Rubella IgG PreciControl

Common name: (1) Rubella IgG Immunoassay
(2) Rubella IgG PreciControl

Classification name: (1) Rubella Virus serological reagents
(2) Single (specified) analyte controls (assayed and unassayed)

Device Description

(1) The Elecsys Rubella IgG Immunoassay is a two-step sandwich immunoassay with streptavidin microparticles and electrochemiluminescence detection. The Rubella IgG assay contains: a biotin labeled monoclonal antibody against human IgG, a ruthenium-labeled anti-Rubella antibody fragment , biotin- and ruthenium-labeled Rubella-antigens and a Rubella-like particle. A relationship exists between the concentration of the IgG antibody targets present in a patient sample and the level of signal count detected by the system. The IgG assay is quantitative and is standardized against WHO materials. 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. The test kit contains the human serum-based calibrators intended for use with the system.
(2) The Elecsys Precicontrol Rubella IgG contains two levels of human serum with Rubella IgG antibodies.

Intended use	(1) The Elecsys Rubella IgG immunoassay is for the in vitro quantitative determination of IgG antibodies to rubella virus in human serum and Li-heparin, K3-EDTA and sodium citrate plasma. This assay may be used as an aid in the assessment of immune status to rubella in individuals including women of childbearing age. The electrochemiluminescence immunoassay "ECLIA" is intended for use on Elecsys and **cobas e** immunoassay analyzers. (2) Elecsys PreciControl Rubella IgG is used for quality control of the Elecsys Rubella IgG immunoassay on the Elecsys and **cobas e** immunoassay analyzers.
Indications for Use	The Elecsys Rubella IgG assay may be used as an aid in the assessment of immune status to rubella in individuals including women of childbearing age.
Substantial equivalence	The Elecsys Rubella IgG Test System is substantially equivalent to other devices legally marketed in the United States. Elecsys Rubella IgG Immunoassay is equivalent to the Zeus Scientific Rubella IgG ELISA Test System cleared in K983805

510(k) Summary, *Continued*

Substantial equivalence – similarities

(1) Rubella IgG Immunoassay Comparison		
Feature	**Elecsys Rubella IgG Immunoassay**	**Predicate Device: Zeus Scientific Rubella IgG ELISA Test System (K984180)**
Intended Use	The Elecsys Rubella IgG immunoassay is for the in vitro quantitative determination of IgG antibodies to rubella virus in human serum and Li-heparin, K3-EDTA and sodium citrate plasma. This assay may be used as an aid in the assessment of immune status to rubella in individuals including women of childbearing age. The **electrochemiluminescence immunoassay** "ECLIA" is intended for use on Elecsys and **cobas e** immunoassay analyzers.	The Zeus Scientific, Inc. Laboratories Rubella IgG ELISA Test System is designed for the qualitative and/or quantitative detection of IgG antibodies to rubella virus in human serum. The test system is intended to be used to evaluate single sera for immune status or paired sera to demonstrate seroconversion, and is for in vitro diagnostic use.
Indication for Use	This assay may be used as an aid in the assessment of immune status to rubella in individuals including women of childbearing age.	The test system is intended to be used to evaluate single sera for immune status or paired sera to demonstrate seroconversion, and is for in vitro diagnostic use.
Assay Protocol	Electrochemiluminescent Immunoassay	ELISA
Sample Type	Human serum, lithium heparin plasma, potassium EDTA plasma and sodium citrate plasma	Serum
Instrument Platform	Roche Elecsys 2010/ **cobas e** 411 and MODULAR ANALYTICS E170 (Elecsys module)/ **cobas e** 601 analyzers.	No automated instrument platform. ELISA equipment/ microwell plate reader needed. No specific model required.
Calibrator	Included in kit	Included in kit
Calibrator levels	Two	One
Format	Human serum	Human serum

Calibrator Stability	After opening at 2-8C: 8 weeks On Elecsys 2010/ **cobas e** 411: up to 5 hours On E170/ **cobas e** 601: use only once	Store between 2-8 °C.
Calibration frequency	Once per reagent lot and • After 1 month when using same reagent lot • After 7 days when using same reagent kit • As required per QC findings or pertinent regulations	Each time the assay is run.
Controls	PreciControl Rubella IgG (sold separately)	Positive and negative control included in kit.
Traceability	1st International Standard for Anti-Rubella Immunoglobulin, human, NIBSC RUBI-1-94; formerly referred to as proposed 3rd WHO Reference Standard Preparation	Recovery of WHO Reference Standard is shown.
Reagent Stability	Unopened 2-8°C – up to expiration Opened 2-8°C – 12 weeks Onboard– 2 weeks or 12 weeks (stored alternately in refrigerator and on the analyzer- ambient temperature 20-25°C; up to 84 hours opened in total.)	Unopened kit: Store at 2-8°C. Coated microwell strips: 2-8°C should be immediately resealed with dessicant, stable 60 days provided indicator on dessicant pouch remains blue. Conjugate, Control, Calibrator, TMB, and Diluent: 2-8°C Wash buffer and Stop Solution: 2-25°C Diluted wash buffer: stable at room temperature 7 days or 30 days at 2-8°C
Measuring Range	0.21 – 500 IU/mL	0-20 IU/mL

Precision	Intrassay: (range of values) Low Control: SD 0.075-0.176 IU/mL High Control: CV 1.20-6.79 % Plasma Samples < 5 IU/mL: SD 0.059 – 0.3.99 IU/mL Plasma Samples > 5 IU/mL: CV 1.64 – 8.21% Inter-assay: Low Control: SD 0.118-0.319 IU/mL High Control: CV 3.35 – 7.69% Plasma Samples < 5 IU/mL: SD 0.076 – 0.428 IU/mL Plasma Samples > 5 IU/mL: CV 2.08 – 9.54%	Intraassay: Low: 5.1-6.2% Medium: 6.8-13.2% High: 4.4-8.96% Inter-assay: Low:6.3 % Medium:5.8% High:8.7%
Limit of Blank	< 0.17 IU/mL	Not stated.
Limit of Detection	< 0.21 IU/mL	Not stated.
Analytical Specificity	96.6 % agreement with predicate for 60 specimens representing a variety of disease states.	Not stated.
Interferences	The assay is unaffected by icterus (bilirubin < 513 µmol/L or < 30 mg/dL), hemolysis (Hb < 3.47 mmol/L or < 5.6 g/dL), lipemia (Intralipid < 1500 mg/dL), Immunoglobulin A up to 1440 mg/dL, and biotin < 123 nmol/L or < 30 ng/mL. Criterion: Recovery of positive samples within ± 20% of initial value. No interference was observed from rheumatoid factors up to a concentration of 6210 IU/mL. Rubella-specific Immunoglobulin M may cause interference. Elevated levels of Immunoglobulin G may cause interference. There is no high dose hook effect within the assay measuring range.	No anticoagulants or preservatives should be added; avoid using hemolyzed, lipemic, or bacterially contaminated samples.

Expected Values	Studies indicate that 80-90% of the adult population have detectable antibodies to rubella. According to the literature, in general, 90% of the U.S. population has either been vaccinated or exposed to rubella, with rubella IgG values greater than or equal to 10 IU/mL. In a study of 500 subjects from a United States reference laboratory, the prevalence of IgG antibodies to Rubella was shown to be 95%. Prevalence was 94.7% among women of childbearing age.	80-90% of adult population has detectable antibodies to rubella.
Method Comparison with 95% CI (Elecsys® vs Zeus Scientific Rubella IgM):	<u>US Routine Clinical Specimens and Acute/Recent Infection:</u> Negative Agreement: 64.0% (16/25) 42.5 - 82.0% Positive Agreement: 98.1% (466/475) 96.4-99.1% <u>Banked Samples</u>: Negative Agreement: 96.6% (140/145) 92.1-98.9% Positive Agreement: 84.0% (168/200) 78.2-88.8% <u>Samples Collected During a Rubella Outbreak:</u> Negative Agreement: 100% (10/10) 69.1-100.0% Positive Agreement: 82.0% (50/61) 70.02-90.6% <u>Pregnant Women</u> Serum samples were collected from 150 pregnant women in the US and tested on the Elecsys and the reference assay. The Elecsys Rubella IgG showed 100 % agreement (95% CI: 97.57- 100%), with 150/150 positive tests.. <u>Vaccinated Individuals:</u> Commercially available vaccination follow-up panels comprising 152 samples from 13 subjects were also tested. The final specimen from each panel yielded 100 % agreement (95% CI: 75.29%~100%) between the methods, with 13/13 positive test results. <u>Testing of Low Positive Samples</u> 84 serum samples that gave low positive (10-20 IU/mL) on the reference assay were tested with the Elecsys Rubella IgG assay. The positive agreement was 80/84 or 95.2%. (88.25 - 98.69%)	

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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DEC 0 5 2008

Re: k072617
Trade/Device Name: Elecsys Rubella IgG immunoassay
Elecsys Rubella IgG PreciControl
Regulation Number: 21 CFR 866.3510
Regulation Name: ELISA, Rubella
Regulatory Class: Class II
Product Code: LFX, JJX
Dated: November 13, 2008
Received: November 14, 2008

Dear Dr. Bush:

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

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 advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at 240-276-0450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Sally A. Hojvat, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of *In Vitro* Diagnostic Device
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Enclosure

Indications for Use

510(k) Number (if known): K072617

Device Name: Elecsys Rubella IgG Immunoassay

Indications For Use:

The Elecsys Rubella IgG immunoassay is for the in vitro quantitative determination of IgG antibodies to rubella virus in human serum and Li-heparin, K3-EDTA and sodium citrate plasma.
This assay may be used as an aid in the assessment of immune status to rubella in individuals including women of childbearing age.
The electrochemiluminescence immunoassay "ECLIA" is intended for use on Elecsys and **cobas e** immunoassay analyzers.

Prescription Use XXX (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____. (21 CFR Part 801 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K072617

Elecsys Rubella IgG and IgM Test Systems

Indications for Use

510(k) Number (if known): K072617

Device Name: Elecsys PreciControl Rubella IgG

Indications For Use:

Elecsys PreciControl Rubella IgG is used for quality control of the Elecsys Rubella IgG immunoassay on the Elecsys and cobas e immunoassay analyzers.

Prescription Use XXX (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____. (21 CFR Part 801 Subpart C)

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Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

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