510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY

A. 510(k) Number:
k061970

B. Purpose for Submission:
Modification to the manufacturer's existing device including changes to a strictly mono-biotinylated monoclonal antibody (the antibody itself remains unchanged), deletion of an application for the Elecsys 1010 analyzer and modifications to specifications for linearity, intra-assay and inter-assay precision.

C. Measurand:
Quantitative determination of IgE in human serum and plasma

D. Type of Test:
Immunoassay

E. Applicant:
Roche Diagnostics.

F. Proprietary and Established Names:
Elecsys IgE II immunoassay

G. Regulatory Information:
1. Regulation section:
   21 CFR 866.5510, Immunoglobulins A, G, M, D and E Immunological test system
2. Classification:
   Class II
3. Product code:
   JHR, Radioimmunoassay, Immunoglobulins (D, E)
4. Panel:
   Immunology (82)

H. Intended Use:
1. Intended use(s):
   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.
2. Indication(s) for use:
   Same as Intended Use
3. Special conditions for use statement(s):
   For Prescription use only
4. Special instrument requirements:

I. 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.

J. Substantial Equivalence Information:
1. Predicate device name(s):

Elecsys IgE immunoassay
2. <u>Predicate 510(k) number(s):</u>
(K984326, K961481/A003)
3. <u>Comparison with predicate:</u>

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	0.100 – 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

K. Standard/Guidance Document Referenced (if applicable):
L. Test Principle:
Same
M. Performance Characteristics (if/when applicable):
1. <u>Analytical performance:</u>
   a. Precision/Reproducibility:

Special 510(k): Device Modification - Elecsys IgE II Immunoassay, continued

Topic	Elecsys IgE (K984326, K961481/A003)	Elecsys IgE II (Modified Device)
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
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	*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

     b. *Linearity/assay reportable range:*
       Not applicable
     c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*
     d. *Detection limit:*
       Same
     e. *Analytical specificity:*
       Same
     f. *Assay cut-off:*
       Not applicable.
  2. Comparison studies:
     a. *Method comparison with predicate device:*
     b. *Matrix comparison:*
       Not applicable
  3. Clinical studies:
     a. *Clinical Sensitivity:*
       No change.
     b. *Clinical specificity:*
       No change.
     c. *Other clinical supportive data (when a. and b. are not applicable):*
       Not applicable.
  4. Clinical cut-off**:**
     Not applicable.
  5. Expected values/Reference range:
  N. Software:
O. Proposed Labeling:

P. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.