510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY

A. 510(k) Number:
k051890

B. Purpose for Submission:
Modifications to the manufacturer's existing device.

C. Measurand:
Thyroid peroxidase anti-body (anti-TPO)

D. Type of Test:
Quantitative Electro-chemiluminescence immunoassay.

E. Applicant:
Roche Diagnostics Corp.

F. Proprietary and Established Names:
Roche Diagnostics COBAS Elecsys® Anti-TPO

G. Regulatory Information:

1. Regulation section:
   21 CFR 866.5870 Thyroid autoantibody immunological test system
2. Classification:
   Class II
3. Product code:
   JZO System, Test, Thyroid autoantibody
4. Panel:
   Immunology 82

H. Intended Use:

1. Intended use(s):
   The Elecsys Anti-TPO immunoassay is for the *in vitro* quantitative determination of antibodies to thyroid peroxidase in human serum and plasma. The anti-TPO determination is used as an aid in the diagnosis of autoimmune thyroid diseases. The electrochemiluminescence immunoassay "ECLIA" is intended for use on the Roche Elecsys 1010/2010 and MODULAR ANALYTICS E170 (Elecsys module) immunoassay analyzers.
2. Indication(s) for use:
   For *in vitro* diagnostic use.
   The immunoassay is for the *in vitro* quantitative determination of antibodies to thyroid peroxidase in human serum and plasma. The anti-TPO determination is used as an aid in the diagnosis of autoimmune thyroid diseases.
3. Special conditions for use statement(s):
   For prescription use only.
4. Special instrument requirements:
   For use on the Roche Elecsys® 1010/2010 and MODULAR ANALYTICS E170 (Elecsys® module) immunoassay analyzers previously cleared under k961481 and k961481/A003.

I. Device Description:
The COBAS Elecsys® Anti-Thyroid Peroxidase Antibody test system includes:

streptavidin-coated microparticles, polyclonal anti-TPO antibody coated with ruthenium complex (Anti-TPO-Ab-Ru(bpy)2+/3), biotinylated TPO, two polyclonal anti-TPO (A-TPO) antibody (sheep) calibrators (1 & 2) and two anti-TPO (PreciControl A-TPO 1 & 2) (human) antibody controls.

J. Substantial Equivalence Information:

1. Predicate device name(s):
   ELECSYS® Anti-Thyroid Peroxidase Antibody Test System
2. Predicate 510(k) number(s):
   k000155
3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Intended Use/Indications for use	Immunoassay for the *in vitro* quantitative determination of antibodies to thyroid peroxidase in human serum and plasma. The anti-TPO determination is used as an aid in the diagnosis of autoimmune thyroid diseases. The electro-chemiluminescence immunoassay "ECLIA" is intended for use on the Roche Elecsys 1010/2010 and MODULAR ANALYTICS E170 (Elecsys® module) immunoassay analyzers.	Same
Capture and detection reagents	Streptavidin-coated microparticles, polyclonal anti-TPO-Ab-Ru(bpy)2+/3 and biotinylated TPO	Same
Sample Type	Human serum and plasma	Same
Traceability/ Standardization	WHO 66/387	Same
Test Principle	Competitive chemiluminescence	Same
Measuring range	5-600 IU/ml	Same
Reagent Stability	Unopened: - at 2-8 ^{o}C up to the expiration date. Opened: - at 2-8 ^{o}C up to six weeks. - on E170/2010: two weeks. - on 1010: one weeks storage, alternately in refrigerator and on analyzer – at ambient temperature 20-25 ^{o}C; up to 20 hours total	Same
Limitations	No interference from: Bilirubin up to 66 mg/dl Hemolysis up to 1.5 g/dl Lipemia up to 2100 mg/dl Rheumatoid factors up to 1500 U/ml	Same

Differences		
Item	Device	Predicate
R2 Composition	20 ng/mL Biotin	0 ng/mL Biotin
PreciControl Anti-TPO	anti-TPO antibodies at approx 35 IU/mL	Level 1 = approx 20 IU/mL anti-TPO antibodies

K. Standard/Guidance Document Referenced (if applicable):

Not referenced.

L. Test Principle:

This is an *in vitro,* prescription device to measure the amount of thyroid peroxidase antibodies in human serum. It is an electrochemiluminescence competitive assay. Patient samples and controls are incubated with anti-TPO antibodies labeled with a ruthenium complex. After addition of biotinylated TPO and streptavidin-coated microparticles, the anti-TPO antibodies in the sample compete with the ruthenium conjugated anti-TPO-Ab for the biotinylated TPO antigen. The immunocomplexes produced become bound to the solid phase via biotin-streptavidin interaction. The reaction mixture is aspirated into the measuring cell where the microparticles are magnetically captured onto the surface of the electrode. Unbound substances are then removed with ProCell buffer. Application of a voltage to the electrode then induces chemiluminescent emission which is measured by a photomultiplier. The results are determined via a calibration curve which is instrument specifically generated by 2-point calibration and a master curve provided via the reagent bar code.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

   Analytical performance of the modified device was supported by the following studies:

Performance characteristic	Acceptance Criteria
Precision	Intra-assay precision: ≤ 10% at 15-40 IU/ml ≤ 7% at > 40 IU/ml; Inter-assay precision: ≤ 18% at 15-40 IU/ml, ≤ 12% at > 40 IU/ml
Analytical Sensitivity	5.0 IU/ml
Reportable Range	5-600 IU/ml
Linearity	Within 15% of expected value
Specificity	Within 10% of control value
Calibration Curve Stability	Within 15% of control values

   a. *Precision/Reproducibility:*
      No change.
   b. *Linearity/assay reportable range:*
      No change.
   c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*
      No change.
   d. *Detection limit:*
      No change.

e. Analytical specificity:
No change.

f. Assay cut-off:
No change.

2. Comparison studies:

a. Method comparison with predicate device:
The modified device and the original device were compared by testing 50 clinical samples (naturally occurring and spiked samples) covering the reportable range. Results were within specified acceptance criteria for a slope of 0.97 to 1.03.

Risk analysis studies to determine the impact for the changes to the original device and steps, if any, to minimize any potential hazard were provided.

b. Matrix comparison:
No change

3. Clinical studies:

a. Clinical Sensitivity:
Not applicable.

b. Clinical specificity:
Not applicable.

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:
No change.

N. Proposed Labeling:
The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

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