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K964694

BOEHRINGER MANNHEIM CORPORATION

510(k) Summary

[redacted]

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.

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1. Submitter name, address, contact

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2. Device name

Proprietary name: Elecsys® LH Assay

Common name: Electrochemiluminescence assay for the determination of human luteinizing hormone (LH).

Classification name: System, Test, Human Luteinizing Hormone

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3. Predicate device

We claim substantial equivalence to the Enzymun® LH Assay (K900799).

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4. Device Description

Sandwich principle. Total duration of assay: 18 minutes.
•1st incubation (9min.): 20 µL of sample, a biotinylated monoclonal LH-specific antibody (75 µL) and a monoclonal LH-specific antibody labeled with a ruthenium complex (75 µL)** react to form a sandwich complex.
•2nd incubation (9min.): after addition of streptavidin-coated microparticles (30 µL), the complex becomes bound to the solid phase via interaction of biotin and streptavidin.
**Tris(2,2'-bipytidyl)ruthenium(II) complex ($Ru(bpy)^{2+}_3$)

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510(k) Summary, Continued

4. Device Description

•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. Application of a voltage to the electrode then induces chemiluminescent emission which is measured by a photomultiplier (0.4 second read frame).
•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.

5. Intended use

Immunoassay for the in vitro quantitative determination of human luteinizing hormone in human serum and plasma.

6. Comparison to predicate device

The Boehringer Mannheim Elecsys® LH Assay is substantially equivalent to other products in commercial distribution intended for similar use. Most notably it is substantially equivalent to the currently marketed Enzymun® LH Assay (K900779).

The following table compares the Elecsys® LH Assay with the predicate device, Enzymun® LH Assay. Specific data on the performance of the test have been incorporated into the draft labeling in attachment 5. Labeling for the predicate device in provided in attachment 6.

Similarities:

•Intended Use: Immunoassay for the in vitro quantitative determination of human luteinizing hormone (LH)

•Sample type: Serum and plasma

•Antibody: Same pair of monoclonal mouse anti-LH antibodies

•Solid phase binding principle: Streptavidin/Biotin

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6. Comparison to predicate device cont.

Differences:

Feature	Elecsys® LH	Enzymun-Test® LH
Assay Standardization	Enzmun® LH	WHO # 80/552
Detection method	Electrochemiluminescence	ELISA/1-step sandwich assay using streptavidin technology
Instrument required	Elecsys® 2010	ES 300
Calibration Stability	A calibration is recommended every 7 days if kits is not consumed; 4 weeks with same reagent lot if reagent is consumed within 7 days.	Full calibration required every 2 weeks. One-point calibration required every run.

Performance Characteristics:

Feature	Elecsys® LH			Enzymun-Test® LH		
Precision	Modified NCCLS (mIU/mL):			Modified NCCLS (mIU/mL):		
Level	Low	Mid	High	Low	Mid	High
N	60	60	60	120	120	120
Within-Run Mean	0.54	9.38	50.72	3.6	13.5	59.5
%CV	1.82	1.13	0.81	2.9	3.8	1.5
Total Mean	0.54	9.38	50.72	3.6	13.5	59.5
%CV	5.17	1.97	1.99	4.4	4.7	3.9
Lower Detection Limit	0.10 mIU/mL			0.50 mIU/mL		

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6. Comparison to predicate device, (cont.)

Performance Characteristics:

Feature	Elecsys® LH	Enzymun-Test® LH
Linearity	0.1 - 200 mIU/mL (with a deviation from a linear line of ±10%)	0.5 - 150 mIU/mL (with a deviation from a linear line of ±10%)
Method Comparison	Vs Enzymun-Test® LH Least Squares y = 1.00x - 0.199 r = 0.993 SEE = 1.141 N = 166 Passing/Bablok y = 0.964x + 0.040 r = 0.993 SEE = 0.456 N = 166	Vs Enzymun-Test® LH Least Squares y = 0.93x + 0.42 r = 0.953 SEE = 5.079 N = 62
Interfering substances	No interference at:	No interference at:
Bilirubin	25.0 mg/dL	64.5 mg/dL
Hemoglobin	1 g/dL	1 g/dL
Lipemia	1500 mg/dL	1250 mg/dL
Biotin	30 ng/mL	40 ng/mL
Rheumatoid Factor	1500 U/mL	no interference
Specificity	Level tested % Cross-reactivity	Level tested % Cross-reactivity
FSH	300 mIU/mL < 0.1	200 mU/mL 0.00
HCG	600 IU/mL < 0.1	200 U/mL 0.00
TSH	300 µIU/mL < 0.1	100 µU/mL 0.00
HGH	600 µIU/mL < 0.1	200 ng/mL 0.00
HPL	13.80 pmol/mL < 0.1	--- ---