K961487

Diagnostics

JUN 12 1996

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.

1. Submitter name, address, contact

Boehringer Mannheim Corporation
2400 Bisso Lane
P.O. Box 4117
Concord, CA 94524-4117
(510) 674 - 0690 extension 8415

Contact Person: Mary Koning

Date Prepared: April 9, 1996

2. Device name

Proprietary name: Elecsys® HCG Assay

Common name: Electrochemiluminescence assay for the determination of human chorionic gonadotropin (HCG).

Classification name: System, Test, Human Chorionic Gonadotropin

3. Predicate device

We claim substantial equivalence to the Enzymun® HCG Assay(K896901).

4. Device Description

The Elecsys® test principle is based on competition principle. Total duration of assay: 18 minutes (37° C).

- 1st incubation (9 minutes): Sample (15 µL), a biotinylated HCG specific antibody (75 µL), and a specific anti-HCG antibody labeled with a ruthenium complex (75 µL).
- 2nd incubation (9 minutes): After addition of streptavidin-coated microparticles (35 µL), the still-free binding sites of the labeled antibody become occupied, with formation of an antibody-hapten complex. The entire complex is bound to the solid phase via interaction of biotin and streptavidin.

Continued on next page

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 chorionic gonadotropin in human serum and plasma.

6. Comparison to predicate device

The Boehringer Mannheim Elecsys® HCG 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® HCG Assay (K896901).

The following table compares the Elecsys® HCG Assay with the predicate device, Enzymun® HCG 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 chorionic gonadotropin (HCG)

•Sample type: Serum and plasma

•Antibody: Polyclonal Sheep anti-HCG antibodies

•Solid phase binding principle: Streptavidin/Biotin

•Assay standardization: World Health Organization Standard (WHO) 75/537 (1st IRP).

Continued on next page

510(k) Summary, Continued

6. Comparison to predicate device cont.

Differences:

Feature	Elecsys® HCG	Enzymun® HCG
Reaction test principle	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.	Calibration required every run

Performance Characteristics:

Feature	Elecsys® HCG			Enzymun® HCG		
Precision	Modified NCCLS (mIU/mL):			Modified NCCLS (µg/dL):		
Level	Serum	Control 1	Control 2	Low	Mid	High
N	60	60	60	58	58	53
Within-Run	24.80	35.39	854.30	19.9	181.5	593.8
%CV	4.5	3.3	2.7	4.6	2.9	3.1
Total	24.80	35.39	854.30	19.9	181.5	593.8
%CV	5.8	3.9	4.5	5.7	4.6	4.1
Lower Detection Limit	0.5 mIU/mL			1.5 mIU/mL		

Continued on next page

510(k) Summary, Continued

6. Comparison to predicate device, (cont.)

Performance Characteristics:

Feature	Elecsys® HCG	Enzymun® HCG
Linearity	0.5 - 1,000 mIU/mL (with a deviation from a linear line of ±10%)	1.5 - 600 mIU/mL (with a deviation from a linear line of ±10%)
Method Comparison	Vs Enzymun-Test® HCG Least Squares y =1.35x - 9.21 r=0.989 SEE =17.50 N=64 Passing/Bablok y =1.29x - 4.05 r=0.989 SEE =17.50 N=64	Vs Enzymun-Test® HCG Least Squares y =1.047x - 4.92 r=0.996 SEE =13.056 N=49
Interfering substances	No interference at:	No interference at:
Bilirubin	25 mg/dL	51.7 mg/dL
Hemoglobin	1 g/dL	1 g/dL
Lipemia	1500 mg/dL	1250 mg/dL
Biotin	30 ng/mL	200 ng/mL
Specificity	Level tested (mIU/mL) / % Cross-reactivity	Level tested (mIU/mL) / % Cross-reactivity
LH	1000 / 0.07	400 / 0.15
FSH	1000 / 0.09	400 / 0.28
TSH	2500 / 0.000	2000 / 5.0