

DEC 16 1996

K964693

510(k) Summary

BOEHRINGER  
MANNHEIM  
CORPORATION

**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**  
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Contact Person: Betsy Soares-Maddox

Date Prepared: November 19, 1996

**2. Device name**  
Proprietary name: Elecsys® FSH Assay  
Common name: Electrochemiluminescence assay for the determination of human follicle stimulating hormone (FSH).

Classification name: System, Test, Human Follicle Stimulating Hormone

**3. Predicate device**  
We claim substantial equivalence to the Enzymun® FSH Assay (K900763).

**4. Device Description**  
Sandwich principle. Total duration of assay: 18 minutes.  
•1st incubation (9 min.): 40 µL of sample, a biotinylated monoclonal FSH-specific antibody (80 µL) and a monoclonal FSH-specific antibody labeled with a ruthenium complex (50 µL)\*\* react to form a sandwich complex.  
•2nd incubation (9 min.): 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'-bipyridyl)ruthenium(II) complex (Ru(bpy)<sup>2+</sup>)<sub>3</sub>

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## 510(k) Summary, Continued

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**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.

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**5.  
Intended use**

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

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**6.  
Comparison  
to predicate  
device**

The Boehringer Mannheim Elecsys® FSH Assay is substantially equivalent to other products in commercial distribution intended for similar use. Most notably it is substantially equivalent to the currently marketed Enzygum® FSH Assay (K900763).

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

**Similarities:**

- Intended Use: Immunoassay for the in vitro quantitative determination of human follicle stimulating hormone (FSH)
  - Sample type: Serum and plasma
  - Antibody: Same pair of monoclonal mouse anti-FSH antibodies
  - Solid phase binding principle: Streptavidin/Biotin
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## 510(k) Summary, Continued

**6. Comparison to predicate device cont.**

**Differences (continued):**

<b>Feature</b>	<b>Elecsys® FSH</b>	<b>Enzymun-Test® FSH</b>
Assay Standardization	Enzymun-Test® FSH	WHO 78/549
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 kit 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:**

<b>Feature</b>	<b>Elecsys® FSH</b>			<b>Enzymun-Test® FSH</b>		
Precision	Modified NCCLS (mIU/mL):			Modified NCCLS (mIU/mL):		
Level	<u>Low</u>	<u>Mid</u>	<u>High</u>	<u>Low</u>	<u>Mid</u>	<u>High</u>
N	60	60	60	120	119	120
Within-Run: Mean	1.20	11.1	103.0	8.7	13.8	30.7
%CV	1.75	1.95	1.80	2.1	1.8	1.2
Total: Mean	1.20	11.1	103.0	8.7	13.8	30.7
%CV	5.26	3.69	5.08	2.3	2.6	3.1
Lower Detection Limit	0.10 mIU/mL			0.50 mIU/mL		

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## 510(k) Summary, Continued

### 6. Comparison to predicate device, (cont.)

#### Performance Characteristics:

Feature	Elecsys® FSH	Enzymun-Test® FSH																																				
Linearity	0.10-200 mIU/mL (with a deviation from a linear line of $\pm 10\%$ )	0.50-150 mIU/mL (with a deviation from a linear line of $\pm 10\%$ )																																				
Method Comparison	Vs Enzymun-Test® FSH <u>Least Squares</u> $y = 1.10 + 0.11x$ $r = 0.998$ SEE = 1.552 N = 160  <u>Passing/Bablok</u> $y = 1.09x + 0.21$ $r = 0.998$ SEE = 0.504 N = 160	Vs Enzymun-Test® FSH <u>Least Squares</u> $y = 0.96x + 0.04$ $r = 0.993$ SEE = 3.37 N = 76																																				
Interfering substances	No interference at:	No interference at:																																				
Bilirubin	25 mg/dL	64.5 mg/dL																																				
Hemoglobin	1 g/dL	1 g/dL																																				
Lipemia	1500 mg/dL	1250 mg/dL																																				
Biotin	30 ng/mL	90 ng/mL																																				
Rheumatoid Factor	1500 IU/mL	no interference																																				
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