

K900489



Diagnostics

JUN 11 1996

## 510(k) Summary

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**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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Contact Person: Betsy Soares-Maddox

Date Prepared: April 9, 1996

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**2. Device name**

Proprietary name: Elecsys® FT4 Assay

Common name: Electrochemiluminescence assay for the determination of free thyroxine (FT4).

Classification name: Radioimmunoassay, Free Thyroxine

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**3. Predicate device**

We claim substantial equivalence to the Enzymun-Test® FT4 (K900883)

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**4. Device Description**

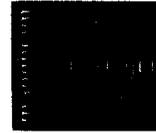
The Elecsys® test principle is based on competition principle. Total duration of assay: 18 minutes (37° C).

•1st incubation (9 minutes): Sample (15 µL) and a specific anti-T4 antibody labeled with a ruthenium complex (75 µL).

•2nd incubation (9 minutes): After addition of biotinylated T4 (75 µL) and 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.

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## 510(k) Summary, Continued

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**4. Device Description, cont.**

- 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 free thyroxine in human serum and plasma.

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**6. Comparison to predicate device**

The Boehringer Mannheim Elecsys® FT4 is substantially equivalent to other products in commercial distribution intended for similar use. Most notably it is substantially equivalent to the currently marketed Enzymun-Test® FT4 (K900883).

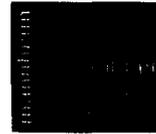
The following table compares the Elecsys® FT4 with the predicate device, Enzymun-Test® FT4. Specific data on the performance of the test have been incorporated into the draft labeling in attachment 5. Labeling for the predicate device is provided in attachment 6.

**Similarities:**

- Intended Use: Immunoassay for the in vitro quantitative determination of free thyroxine
- Sample type: Serum and plasma
- Antibody: Polyclonal Sheep anti-FT4 antibodies
- Solid phase binding principle: Streptavidin/Biotin
- Assay standardization: Equilibrium dialysis

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### 510(k) Summary, Continued

6. Comparison to predicate device cont.

**Differences:**

<b>Feature</b>	<b>Elecsys® FT4</b>	<b>Enzymun-Test® FT4</b>
Reaction test principle	Electrochemiluminescence	ELISA/1-step sandwich assay using streptavidin technology
Instrument required	Elecsys® 2010	ES 300
Assay Range	Reportable Range: 0.023 ng/dL - 7.77 ng/dL (0.3 - 100.0 pmol/L)	Reportable Range: 0.1 ng/dL - 6.5 ng/dL (1.29 - 83.69 pmol/L)
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.	A calibration is required every 2 weeks.

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**510(k) Summary, Continued**

6.  
Comparison  
to predicate  
device, (cont.)

**Performance Characteristics:**

<b>Feature</b>	<b>Elecsys® FT4</b>			<b>Enzymun-Test® FT4</b>		
<b>Precision</b>	<b>Modified NCCLS (pmol/L):</b>			<b>Modified NCCLS (ng/dL):</b>		
<b>Level</b>	<b>Sample</b>	<b>Control 1</b>	<b>Control 2</b>	<b>Low</b>	<b>Mid</b>	<b>High</b>
N	60	60	60	117	120	120
Within-Run %CV	8.77	17.53	50.84	0.49	1.17	4.43
Total %CV	1.58	1.43	2.85	3.9	2.4	1.2
	8.77	17.53	50.84	0.49	1.17	4.43
	3.54	2.72	6.59	5.1	2.9	2.0
	<b>Modified NCCLS (ng/dL):</b>					
	<b>Sample</b>	<b>Control 1</b>	<b>Control 2</b>			
N	60	60	60			
Within-Run %CV	0.684	1.367	3.97			
Total %CV	1.58	1.43	2.85			
	0.684	1.367	3.97			
	3.54	2.72	2.85			
<b>Sensitivity</b>	<b>Lower Detection Limit:</b> 0.023 ng/dL (0.3 pmol/L)			<b>Lower Detection Limit:</b> 0.1 ng/dL (1.29 pmol/L)		
<b>Method Comparison</b>	<b>Vs Enzymun-Test® FT4</b> <u>Least Squares</u> $y = 0.954x + 0.18$ $r = 0.981$ SEE = 1.11 N = 315  <u>Passing/Bablok</u> $y = 1.02x + 0.36$ $r = 0.981$ SEE = 1.11 N = 315			<b>Vs Enzymun-Test® FT4</b> <u>Least Squares</u> $y = 0.88x + 0.15$ $r = 0.984$ SEE = 0.199 N = 77		

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**510(k) Summary, Continued**

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

**Performance Characteristics, cont.:**

<b>Feature</b>	<b>Elecsys® FT4</b>	<b>Enzymun-Test® FT4</b>
<b>Interfering substances</b>	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	200 ng/mL
<b>Specificity</b>	<b>% Cross-reactivity</b>	<b>% Cross-reactivity</b>
L-T4	100	100
D-T4	100	100
L-T3	1.53	3.5
D-T3	1.38	2.9
3-iodo-L-tyrosine	0.002	<0.1
3,5-diiodo-L-tyrosine	0.01	<0.1
Tetraiodo-thyroacetic acid	38.5	20