K961489

Diagnostics

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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

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Date Prepared: April 9, 1996

2. Device name

Proprietary name: Elecsys® FT4 Assay

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

Classification name: Radioimmunoassay, Free Thyroxine

3. Predicate device

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

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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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.

5. Intended use

Immunoassay for the in vitro quantitative determination of free thyroxine in human serum and plasma.

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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6. Comparison to predicate device cont.

Differences:

Feature	Elecsys® FT4	Enzymun-Test® FT4
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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6. Comparison to predicate device, (cont.)

Performance Characteristics:

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

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6. Comparison to predicate device, (cont.)

Performance Characteristics, cont.:

Feature	Elecsys® FT4	Enzymun-Test® FT4
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	200 ng/mL
Specificity	% Cross-reactivity	% Cross-reactivity
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