K961490

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Diagnostics

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® T4 Assay

Common name: Electrochemiluminescence assay for the determination of total thyroxine (T4).

Classification name: Radioimmunoassay, Total Thyroxine

3. Predicate device

We claim substantial equivalence to the Enzymun T4 Assay(K901346).

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	•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 total thyroxine in human serum and plasma.
6. Comparison to predicate device	The Boehringer Mannheim Elecsys® T4 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 T4 Assay (K901346). The following table compares the Elecsys® T4 Assay with the predicate device, Enzymun T4 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 total thyroxine •Sample type: Serum and plasma •Antibody: Polyclonal Sheep anti-T4 antibodies •Solid phase binding principle: Streptavidin/Biotin •Assay standardization: GC/MS Gas Chromatography/Mass Spectrometry

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6. Comparison to predicate device cont.

Differences:

Feature	Elecsys® T4	Enzymun T4
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 kit is not consumed; 4 weeks with same reagent lot if reagent is consumed within 7 days.	A calibration is required every run

Performance Characteristics:

Feature	Elecsys® T4			Enzymun T4		
Precision	Modified NCCLS (nmol/L):			Modified NCCLS (µg/dL):		
Level	Sample	Control 1	Control 2	Low	Mid	High
N	60	60	60	120	120	118
Within-Run	33.39	113.10	180.55	4.55	6.79	15.49
%CV	4.7	2.3	2.0	2.3	2.4	2.0
Total	33.39	113.10	180.55	4.55	6.79	15.49
%CV	6.9	3.3	2.7	3.1	2.9	2.5
	Modified NCCLS (µg/dL):					
	Sample	Control 1	Control 2			
N	60	60	60			
Within-Run	2.60	8.82	14.08			
%CV	4.7	2.3	2.0			
Total	2.60	8.82	14.08			
%CV	6.9	3.3	2.7			

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6. Comparison to predicate device, (cont.)

Performance Characteristics:

Feature	Elecsys® T4	Enzymun T4
Lower Detection Limit	0.23 µg/dL (3 nmol/L)	0.6 µg/dL (7.7 nmol/L)
Linearity	0.23 - 24.86 µg/dL (3.0 - 320 nmol/L) (with a deviation from a linear line of ±10%)	0.6 - 25.0 µg/dL (with a deviation from a linear line of ±10%)
Method Comparison	Vs Enzymun-Test® T4 Least Squares y =1.02x + 0.85 r=0.947 SEE =5.39 N=196 Passing/Bablok y =0.93x + 4.55 r=0.947 SEE =5.39 N=196	Vs Enzymun-Test® T4 Least Squares y =0.90x - 0.45 r=0.996 SEE =0.648 N=78

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6. Comparison to predicate device, (cont.)

Performance Characteristics:

Feature	Elecsys® T4	Enzymun T4
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