K961488

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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2. Device name

Proprietary name: Elecsys® T-Uptake Assay

Common name: Electrochemiluminescence assay for the thyroxine-binding capacity (T-Uptake).

Classification name: Thyroxine-binding globulin test system

3. Predicate device

We claim substantial equivalence to the Enzymun-Test® TBK (T4 Uptake)

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), exogenous T4, and biotinylated T4-polyhapten (75 µL).
•2nd incubation (9 minutes): After addition of a specific anti-T4 antibody labeled with a ruthenium complex (75 µL), the polyhapten and the antibody derivative react to form a complex, the concentration of which is inversely proportional to the concentration of the excess, exogenous T4. This immunological complex is bound to the added streptavidin-coated microparticles (35 µL) via the interaction of biotin and streptavidin.

Continued on next page

510(k) Summary, Continued

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 thyroxine-binding capacity in human serum and plasma.

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6. Comparison to predicate device

The Boehringer Mannheim Elecsys® T-Uptake 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-Test® TBK (T4 Uptake).

The following table compares the Elecsys® T-Uptake with the predicate device, Enzymun-Test® TBK (T4 Uptake). 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:

- Detection of Thyroxine-Binding Capacity (T-Uptake)
- Sample type: Serum and plasma
- Reportable range of 0.2 - 1.9 TBI
- Standardized according to Enzymun-Test® TBK Assay
- Polyclonal Antibody: Sheep polyclonal anti-T-Uptake
- Solid phase binding principle: Streptavidin/Biotin

Differences:

Feature	Elecsys® T Uptake	Enzymun-Test® TBK
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.	Calibration required every run

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6. Comparison to predicate device, (cont.)

Performance Characteristics:

Feature	Elecsys® T Uptake			Enzymun-Test® TBK		
Precision	Modified NCCLS (TBI):			Modified NCCLS (TBI):		
Level	Sample	Control 1	Control 2	Low	Mid	High
N	60	60	60	118	120	119
Within-Run	0.95	0.94	1.09	0.61	0.93	1.28
%CV	2.15	3.29	2.39	5.7	2.6	1.4
Total	0.95	0.94	1.09	0.61	0.93	1.28
%CV	3.25	3.68	2.66	7.2	3.4	2.0
Lower Detection Limit	0.2 TBI			0.2 TBI		
Linearity	0.2 TBI to the value of the highest standard			0.2 TBI to the value of the highest standard		
Method Comparison	Vs Enzymun-Test® TBK Least Squares y =0.99x - 0.03 r=0.908 SEE =0.04 N=319 Passing/Bablok y = 1.07x - 0.12 r=0.908 SEE =0.04 N=319			Vs Enzymun-Test® TBK Least Squares y = 1.02x + 0.084 r= 0.986 SEE = 0.054 N= 52		

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510(k) Summary, Continued

6. Comparison to predicate device, (cont.)

Performance Characteristics, cont.:

Feature	Elecsys® T Uptake	Enzymun-Test® TBK
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	1.5	3.5
D-T3	1.4	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