K093421

510(k) Summary

APR 2 8 2010

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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Date Prepared: October 23, 2009

Device Name

Proprietary name: Elecsys® Testosterone II Immunoassay
Common name: Testosterone II Assay
Classification name: Testosterone Test System

Device Description

The Elecsys Testosterone II immunoassay is based on a competitive test principle with streptavidin-coated microparticles and electrochemiluminescence detection. Results are determined using a calibration curve that is generated specifically on each instrument by a 2-point calibration and a master curve provided with the reagent bar code.
The Elecsys Testosterone II reagent kit consists of a Reagent Pack (R1, R2, and M[Streptavidin-coated microparticles]).

Substantial Equivalence

The Elecsys Testosterone II Test System is substantially equivalent to other devices legally marketed in the United States. We claim equivalency to the currently marketed Elecsys Testosterone Assay (K964889).

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Substantial Equivalence-Comparison

The following table compares the Elecsys Testosterone II Immunoassay with the predicate device.

Table 1. Testosterone Immunoassay Comparison

Feature	Elecsys Testosterone II Assay	Predicate Device Elecsys Testosterone Assay (K964889)
Intended Use	Immunoassay for the in vitro quantitative determination of testosterone in human serum and plasma. The electrochemiluminescence immunoassay "ECLIA" is intended for use on Elecsys and **cobas e** immunoassay analyzers.	Immunoassay for the in vitro quantitative determination of testosterone in human serum and plasma. The electrochemiluminescence immunoassay "ECLIA" is intended for use on the Boehringer Mannheim Elecsys 1010 and 2010 immunoassay analyzers.
Indications for Use	Measurements of testosterone are used in the diagnosis and treatment of disorders involving the male sex hormones (androgens), including primary and secondary hypogonadism, delayed or precocious puberty, impotence in males and, in females hirsutism (excessive hair) and virilization (masculinization) due to tumors, polycystic ovaries, and adrenogenital syndromes.	Same
Assay Protocol	Competition principle	Same
Detection Protocol	Electrochemiluminescence immunoassay (ECLIA)	Same
Traceability/ Standardization	ID-GC/MS (Isotope Dilution Gas Chromatography/Mass Spectrometry)	Same
Sample Type	Human serum and plasma	Same

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510(k) Summary, Continued

Substantial Equivalence-Comparison (continued)

The following table compares the Elecsys Testosterone II Immunoassay with the predicate device.

Table 1. Testosterone Immunoassay Comparison, continued

Feature	Elecsys Testosterone II Assay	Predicate Device Elecsys Testosterone Assay (K964889)
Instrument Platform	Elecsys 2010 (Request for CLIA categorization has been made to add the MODULAR ANALYTICS E170, **cobas e** 411, and **cobas e** 601 analyzers according to the Replacement Reagent and Instrument Policy).	Elecsys 2010 (Elecsys 1010, MODULAR ANALYTICS E170, **cobas e** 411, and **cobas e** 601 analyzers added subsequent to clearance)
Measuring Range	2.5 – 1500 ng/dL (0.087 – 52.0 nmol/L)	2.0 – 1500 ng/dL (0.069 – 52.0 nmol/L)
Calibrator	Testosterone II CalSet II Calibrators 1 and 2 The stability, value assignment and matrix is identical to Testosterone CalSet II (cleared on K003411).	Same
Calibration Interval	Once per reagent lot and • After 1 month (28 days) when using the same reagent lot • After 7 days (when using the same reagent kit on the analyzer) • As required: e.g. quality control findings outside the specified limits	Same
Controls	PreciControl Universal 1 and 2 (cleared on K090541)	Same
Reagent Stability	• Unopened at 2-8°C – up to the expiration date • After opening at 2-8°C – 12 weeks • Onboard the analyzer – 8 weeks	• Same • After opening at 2-8°C – 8 weeks • Same

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Substantial Equivalence-Comparison (continued)

The following table compares the performance of the Elecsys Testosterone II Immunoassay with the predicate device.

Table 2. Testosterone Immunoassay Performance Comparison

Feature	Elecsys Testosterone II Assay	Predicate Device Elecsys Testosterone Assay (K964889)
Precision	**Elecsys 2010:** **Intermediate Precision (Total)** 18.5% CV @ 4.5 ng/dL 8.4% CV @ 9.5 ng/dL 3.2% CV @ 69.1 ng/dL 2.8% CV @ 216 ng/dL 2.8% CV @ 867 ng/dL 3.4% CV @ 1300 ng/dL 2.4% CV @ 1450 ng/dL **Repeatability (Within-Run)** 10.2% CV @ 4.5 ng/dL 4.7% CV @ 9.5 ng/dL 2.1% CV @ 69.1 ng/dL 1.9% CV @ 216 ng/dL 2.6% CV @ 867 ng/dL 1.2% CV @ 1300 ng/dL 1.5% CV @ 1450 ng/dL	**Elecsys 2010:** **Intermediate Precision (Total)** 7.4% CV @ 24 ng/dL 2.6% CV @ 195 ng/dL 2.2% CV @ 275 ng/dL 1.6% CV @ 620 ng/dL 1.7% CV @ 701 ng/dL **Repeatability (Within-Run)** 4.6% CV @ 24 ng/dL 1.7% CV @ 195 ng/dL 1.4% CV @ 275 ng/dL 0.9% CV @ 620 ng/dL 1.1% CV @ 701 ng/dL
LoQ (Functional Sensitivity)	12.0 ng/dL	Same
LoB (Limit of Blank)	1.2 ng/dL	N/A
LoD (Limit of Detection)	2.5 ng/dL	2.0 ng/dL (Lower Detection Limit, LDL)
Limitations	The assay is unaffected by: • Bilirubin: < 30 mg/dL • Hemoglobin: < 600 mg/dL • Intralipid: < 1000 mg/dL • Biotin: < 30 ng/mL	The assay is unaffected by: • Bilirubin: < 25 mg/dL • Hemoglobin: < 1 g/dL (1000 mg/dL) • Intralipid: < 1500 mg/dL • Biotin: < 30 ng/mL

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510(k) Summary, Continued

Substantial Equivalence-Comparison (continued)

The following table compares the performance of the Elecsys Testosterone II Immunoassay with the predicate device.

Table 2. Testosterone Immunoassay Performance Comparison, continued

Feature	Elecsys Testosterone II Assay	Predicate Device Elecsys Testosterone Assay (K964889)
Limitations, continued	• In patients receiving therapy with high biotin doses (i.e. > 5 mg/day), no sample should be taken until at least 8 hours after the last biotin administration. • No interference was observed from rheumatoid factors up to a concentration of 1000 IU/mL. • In vitro tests were performed with 18 commonly used pharmaceuticals. No interference with the assay was found. • Three additional drugs were tested: heparin clexane, dexamethasone, and Nandrolone. A strong interaction with Nandrolone was found. Do not use samples from patients under Nandrolone treatment. • In isolated cases, elevated testosterone levels can be seen in samples from female patients with end stage renal disease (ESRD).	• In patients receiving therapy with high biotin doses (i.e. > 5 mg/day), no sample should be taken until at least 8 hours after the last biotin administration. • In vitro tests were performed with 16 commonly used pharmaceuticals. No interference with the assay was found.

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510(k) Summary, Continued

Substantial Equivalence-Comparison (continued)

The following table compares the performance of the Elecsys Testosterone II Immunoassay with the predicate device.

Table 2. Testosterone Immunoassay Performance Comparison, continued

Feature	Elecsys Testosterone II Assay	Predicate Device Elecsys Testosterone Assay (K964889)
Limitations, continued	• In rare cases, interference due to extremely high titers of antibodies to analyte-specific antibodies, streptavidin or ruthenium can occur. These effects are minimized by suitable test design.	• In rare cases interference due to extremely high titers of antibodies to streptavidin can occur.
		• The risk of interference from potential immunological interactions between test components and rare sera have been minimized by the inclusion of suitable additives.
	• For diagnostic purposes, the results should always be assessed in conjunction with the patient's medical history, clinical examination and other findings.	• For diagnostic purposes, the results should always be assessed in conjunction with the patient's medical history, clinical examination and other findings.
	• Implausible elevated values in female samples should be verified by an extraction method or validated LC-MS/MS tandem method.	

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Substantial Equivalence-Comparison (continued)

The following table compares the performance of the Elecsys Testosterone II Immunoassay with the predicate device.

Table 2. Testosterone Immunoassay Performance Comparison, continued

Feature	Elecsys Testosterone II Assay	Predicate Device Elecsys Testosterone Assay (K964889)
Method Comparison	Four method comparison studies were performed to demonstrate the accuracy of the Elecsys Testosterone II assay. (1) Isotope dilution/liquid chromatographic-tandem mass spectrometry (ID/LC-MS/MS) was validated against the reference method, isotope-dilution/gas chromatography-mass spectrometry (ID-GC/MS). A total of 52 serum samples with testosterone values ranging from 8 to 1383 ng/dL were measured. The following table summarizes the results. **Deming Regression** n: 52 Range: 8–1383 ng/dL Slope: 1.024 y-int: -0.060 Correlation Coefficient: r = 0.996	The Elecsys Testosterone assay was compared to the Coat-A-Count® Total Testosterone Assay. A total of 71 clinical samples with testosterone values ranging from 20 – 1269 ng/dL were tested in singlicate. The following table summarizes the results. **Passing/Bablok** / **Least Squares** n: 71 / 71 Range: 20–1269 ng/dL / 20–1269 ng/dL Slope: 1.02 / 0.956 y-int: -0.108 / 0.049 tau/r: 0.963 / 0.963

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Substantial Equivalence-Comparison (continued)

The following table compares the performance of the Elecsys Testosterone II Immunoassay with the predicate device.

Table 2. Testosterone Immunoassay Performance Comparison, continued

Feature	Elecsys Testosterone II Assay	Predicate Device Elecsys Testosterone Assay (K964889)
Method Comparison continued	(2) The Elecsys Testosterone II assay was compared to the ID-GC/MS reference method. A total of 55 serum samples with testosterone values ranging from 7.6 to 1383 ng/dL were measured. The following table summarizes the results. **Deming Regression** n: 55 Range: 7.6–1383 ng/dL Slope: 1.032 y-int: -0.055 Correlation Coefficient: r = 0.999 (3) The Elecsys Testosterone II assay was compared to the validated ID/LC-MS/MS method. A total of 142 female serum samples with testosterone values ranging from 3 – 517 ng/dL were measured. The following table summarizes the results. **Deming Regression** n: 142 Range: 3–517 ng/dL Slope: 0.928 y-int: 0.047 Correlation Coefficient: r = 0.959	

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Substantial Equivalence-Comparison (continued)

The following table compares the performance of the Elecsys Testosterone II Immunoassay with the predicate device.

Table 2. Testosterone Immunoassay Performance Comparison, continued

Feature	Elecsys Testosterone II Assay	Predicate Device Elecsys Testosterone Assay (K964889)
Method Comparison continued	(4) The Elecsys Testosterone II assay was compared to the predicate device, the Elecsys Testosterone assay (K964889). A total of 239 male and 148 female serum samples with testosterone values ranging from 6.3 – 1400 ng/dL and 2.5 – 926 ng/dL, respectively, were measured in singlicate. The following tables summarize the results. **Male samples** Deming Regression: n = 239; Range = 6.3–1400 ng/dL; Slope = 0.971; y-int = 0.085; Correlation Coefficient r = 0.985 **Female samples** Deming Regression: n = 148; Range = 2.5–926 ng/dL; Slope = 0.984; y-int = -7.34; Correlation Coefficient r = 0.972 **Male and Female Samples Combined** Deming Regression: n = 387; Range = 2.5–1400 ng/dL; Slope = 0.989; y-int = -2.87; Correlation Coefficient r = 0.992	

DEPARTMENT OF HEALTH & HUMAN SERVICES

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APR 23 2010

Re: k093421
Trade Name: Elecsys® Testosterone II Assay
Regulation Number: 21 CFR §862.1680
Regulation Name: Testosterone test system
Regulatory Class: Class I, reserved
Product Codes: CDZ
Dated: April 19, 2010
Received: April 20, 2010

Dear Ms. Baumann:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney C. Harper, Ph.D.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): k093421

Device Name: Elecsys® Testosterone II Assay

Indication For Use:

Immunoassay for the in vitro quantitative determination of testosterone in human serum and plasma. The electrochemiluminescence immunoassay "ECLIA" is intended for use on Elecsys and **cobas e** immunoassay analyzers.

Measurements of testosterone are used in the diagnosis and treatment of disorders involving the male sex hormones (androgens), including primary and secondary hypogonadism, delayed or precocious puberty, impotence in males and, in females hirsutism (excessive hair) and virilization (masculinization) due to tumors, polycystic ovaries, and androgenital syndromes.

Prescription Use ___X___ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use _____ (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Carol C. Benson

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K093421