510(k) Summary

JAN 2 0 2011
K102814

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.

Submitter Name, Address, Contact

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Date Prepared: September 23, 2010

Device Name

Proprietary names: Elecsys® SHBG Immunoassay System

Common name: SHBG test

Classification name: Radioimmunoassay, Testosterones and Dihydrotestosterone

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510(k) Summary, continued

Device Description	A device for the measurement of human SHBG in serum or plasma.
Substantial Equivalence	The Elecsys SHBG Test System is substantially equivalent to other devices legally marketed in the United States. We claim equivalency to the currently marketed Elecsys SHBG Test System (K031717).

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510(k) Summary, continued

Premarket Notification, Traditional 510(k) for Elecsys SHBG Assay		
Immunoassay Comparison		
Feature	**Predicate Device: Elecsys SHBG Assay (K031717)**	**Elecsys SHBG Assay**
General Assay Features		
Intended Use/ Indications for Use	Immunoassay for the *in vitro* quantitative determination of sex hormone-binding globulin in human serum and plasma. The electrochemiluminescence immunoassay "ECLIA" is intended for use on Elecsys and **cobas e** immunoassay analyzers.	Same
Assay Protocol	Sandwich assay	Same
Detection Protocol	Electrochemiluminescent Immunoassay	Same
Application	18 Minute	Same
Instrument Platform	Roche Elecsys 1010, 2010/**cobas e** 411 and MODULAR ANALYTICS E170/**cobas e** 601	Same with the exception of the removal of the Elecsys 1010 analyzer
Sample Volume	10 µL	Same
Sample Type	Human serum and plasma treated with lithium heparin.	Same
Traceability	The Elecsys SHBG assay has been standardized against the 1st International Standard for SHBG, NIBSC code 95/560.	Same
Calibrator	Elecsys SHBG CalSet	Same

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510(k) Summary, continued

Immunoassay Comparison		
Feature	**Predicate Device: Elecsys SHGB Assay (K031717)**	**Elecsys SHBG Assay**
General Assay Features		
Calibration Interval	Calibration must be performed once per reagent lot using fresh reagent (i.e. not more than 24 hours since the reagent kit was registered on the analyzer). Renewed calibration is recommended as follows: MODULAR ANALYTICS E170, Elecsys 2010 and **cobas e** analyzers: • After 1 month (28 days) when using the same reagent lot • After 7 days (when using the same reagent kit on the analyzer) Elecsys 1010 analyzer: • With every reagent kit • After 7 days (ambient temperature 20-25 °C) • After 3 days (ambient temperature 25-32 °C)	Same with the exception of the removal of the Elecsys 1010 analyzer.
Controls	Elecsys PreciControl Universal 1 and 2	Same

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Immunoassay Comparison		
Feature	**Predicate Device: Elecsys SHBG Assay (K031717)**	**Elecsys SHBG Assay**
General assay features		
Reagent Stability/ Storage	Store at 2-8 °C. Store the Elecsys SHBG reagent kit upright in order to ensure complete availability of the microparticles during automatic mixing prior to use. Stability: Unopened at 2-8 °C—up to the stated expiration date After opening at 2-8 °C—12 weeks On MODULAR ANALYTICS E170 and **cobas e** 601—7 weeks On Elecsys2010 and **cobas e** 411—7 weeks On Elecsys 1010- 4 weeks (stored alternately in the refrigerator and on the analyzer – ambient temperature 20-25 °C; up to 20 hours opened in total)	Same with the exception of the removal of the Elecsys 1010 analyzer.

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<table>
<tr><th colspan="3">Immunoassay Comparison</th></tr>
<tr><th>Feature</th><th>Predicate Device: Elecsys SHBG Assay (K031717)</th><th>Elecsys SHBG Assay</th></tr>
<tr><th colspan="3">Labeled Performance Characteristics</th></tr>
<tr><td>Measuring Range</td><td>0.350-200 nmol/L</td><td>0.800 -200 nmol/L</td></tr>
<tr><td>Expected Values</td><td>Males: 10-80 nmol/L
Females, non-pregnant: 20-130 nmol/L</td><td>Reference ranges for the SHBG (nmol/L)
<table>
<tr><th></th><th>N</th><th>Median</th><th>5th Perc</th><th>95th perc</th></tr>
<tr><td>Males 20-49 years</td><td>136</td><td>33.5</td><td>16.5</td><td>55.9</td></tr>
<tr><td>Males ≥ 50 years</td><td>78</td><td>40.8</td><td>19.3</td><td>76.4</td></tr>
<tr><td>Females 21-49 years</td><td>89</td><td>64.3</td><td>24.6</td><td>122</td></tr>
<tr><td>Females ≥ 50 years</td><td>71</td><td>57.4</td><td>17.3</td><td>125</td></tr>
</table></td></tr>
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<table>
<tr><th colspan="3">Immunoassay Comparison</th></tr>
<tr><th>Feature</th><th>Predicate Device: Elecsys SHBG Assay (K031717) (18 Minute)</th><th>Elecsys SHBG Assay</th></tr>
<tr><th colspan="3">Labeled Performance Characteristics</th></tr>
<tr><td>Expected Values cont.</td><td></td><td>
Reference ranges for Testosterone II (nmol/L)
<table>
<tr><th></th><th>N</th><th>Median</th><th>5th Perc</th><th>95th perc</th></tr>
<tr><td>Males 20-49 years</td><td>136</td><td>18.6</td><td>8.64</td><td>29.0</td></tr>
<tr><td>Males ≥ 50 years</td><td>78</td><td>16.5</td><td>6.68</td><td>25.7</td></tr>
<tr><td>Females 21-49 years</td><td>89</td><td>0.941</td><td>0.290</td><td>1.67</td></tr>
<tr><td>Females ≥ 50 years</td><td>71</td><td>0.563</td><td>0.101</td><td>1.42</td></tr>
</table>
Calculation for obtaining FTI (or FAI):
%FTI = (Testosterone (nmol/L) ÷ SHBG (nmol/L)) x 100

Reference ranges for Free Testosterone Index (FTI) / Free Androgen Index (FAI) (nmol/L)
<table>
<tr><th></th><th>N</th><th>Median</th><th>5th Perc</th><th>95th perc</th></tr>
<tr><td>Males 20-49 years</td><td>136</td><td>57.2</td><td>35.0</td><td>92.6</td></tr>
<tr><td>Males ≥ 50 years</td><td>78</td><td>38.2</td><td>24.3</td><td>72.1</td></tr>
<tr><td>Females 21-49 years</td><td>89</td><td>1.53</td><td>0.297</td><td>5.62</td></tr>
<tr><td>Females ≥ 50 years</td><td>71</td><td>1.15</td><td>0.187</td><td>3.63</td></tr>
</table>
</td></tr>
</table>

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510(k) Summary, continued

Immunoassay Comparison		
Feature	**Predicate Device: Elecsys SHBG Assay (K031717) (18 Minute)**	**Elecsys SHBG Assay**
Labeled Performance Characteristics		
Precision	E1010/ 2010/ 411 • Within Run 2.1 – 2.7 % CV from 14.1 -204 nmol/L • Total 2.6 -5.6% CV from 14.1 -204 nmol/L E170/ e601 • Within run 1.1 – 1.7% CV from 14.9 – 219 nmol/L • Total 1.8 – 4.0% CV from 14.9 -219 nmol/L	Same with the exception of the removal of the Elecsys 1010 analyzer.
Analytical Sensitivity	Limit Detection Level (LDL): 0.35 nmoL/L	Limit of Blank (LoB): 0.500 nmol/L Limit of Detection (LoD): 0.800 nmol/L Limit of Quantitation (LoQ): 2.00 nmol/L
Hook Effect	There is no high-dose hook effect at SHBG concentrations up to 1000 nmol/L.	Same

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510(k) Summary, continued

Immunoassay Comparison		
Feature	**Predicate Device: Elecsys SHBG Assay (K031717) (18 Minute)**	**Elecsys SHBG Assay**
Labeled Performance Characteristics		
Limitations	The assay is unaffected by: • Hemoglobin < 2.9 mg/dL • Bilirubin < 60 g/dL • Intralipid < 2700 mg/dL • Biotin < 60 ng/mL • Rheumatoid factors up to 1160 IU/mL • In vitro tests were performed on 16 commonly used pharmaceuticals. No interference with the assay was found. • As with all tests containing monoclonal mouse antibodies, erroneous findings may be obtained from samples taken from patients who have been treated with monoclonal mouse antibodies or have received them for diagnostic purposes. • In rare cases, interference due to extremely high titers of antibodies to streptavidin and ruthenium can occur. These effects are minimized by suitable test design. • For diagnostic purposes, the results should always be assessed in conjunction with the patient's medical history, clinical examination and other findings.	Same

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510(k) Summary, continued

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<tr><th>Feature</th><th>Predicate Device: Elecsys SHBG Assay (K031717) (18 Minute)</th><th>Elecsys SHBG Assay</th></tr>
<tr><td colspan="3">Labeled Performance Characteristics</td></tr>
<tr><td>Method Comparison</td><td colspan="2">A comparison of the Elecsys SHBG assay (y) with a commercially available SHBG assay (x) using clinical samples gave the following correlation:
<table>
<tr><td>n = 109
Min =11.2 nmol/L
Max = 155 nmol/L</td><td>Passing/Bablok</td><td>Linear Regression</td></tr>
<tr><td>Slope</td><td>1.17</td><td>1.15</td></tr>
<tr><td>Intercept</td><td>-3.26</td><td>-1.82</td></tr>
<tr><td>Tau / r</td><td>0.909</td><td>0.981</td></tr>
</table></td></tr>
</table>

Confidentiality

Roche Diagnostics Corporation requests that the FDA not disclose the nature or existence of the premarket notification until the substantial equivalence decision has been reached.

Closing

We trust that the information provided in this Premarket Notification will support a determination of substantial equivalence for the Elecsys SHBG Immunoassay.

If you should have questions or require further information, please do not hesitate to contact me.

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- FAX: (317) 521-2324

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Sincerely,

Kelly French, RN, BSN, RAC
Regulatory Affairs Consultant
US Regulatory Submissions
Roche Diagnostics Corporation

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Regulatory Affairs Consultant
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Indianapolis, IN 46250-0416

JAN 20 2011

Re: k102814
Trade Name: Elecsys SHBG
Regulation Number: 21 CFR §862.1680
Regulation Name: Radioimmunoassay, testosterone and dihydrotestosterone
Regulatory Class: Class I, reserved
Product Codes: CDZ
Dated: December 15, 2010
Received: December 16, 2010

Dear Ms. French:

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 Parts 801 and 809), 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 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) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Courtney 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): K102814

Device Name: Elecsys SHBG

Indication For Use:

Immunoassay for the in vitro quantitative determination of sex hormone-binding globulin in human serum and plasma. The Elecsys SHBG Immunoassay is intended for use as an aid in the diagnosis of androgen disorders. The electrochemiluminescence immunoassay "ECLIA" is intended for use on Elecsys and **cobas e** immunoassay analyzers.

Prescription Use __X____ And/Or Over the Counter Use ____.
(21 CFR Part 801 Subpart D) (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)

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

510(k) K102814