SECTION III - 510k Summary

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.

Submitter name, address, contact

Roche Diagnostics Corporation
9115 Hague Road
Indianapolis, IN 46250
(317) 521 - 3723

Contact Person: Theresa M. Ambrose

Date Prepared: May 28, 2003

Device Name

Proprietary name: Elecsys® SHBG Immunoassay System

Common name: SHBG test

Classification name: Testosterone test system

Device Description

A device for the measurement of human SHBG in serum or plasma.

Intended use

For the in vitro quantitative determination of sex hormone binding globulin in human serum and plasma.

Indications for Use

An aid in the diagnosis of androgen disorders including hirsuitism, virilization, polycystic ovarian syndrome, adrenogenital syndrome, and hyperandrogenism; the correct interpretation of testosterone and estradiol concentrations; investigation of the androgen-estrogen balance in gonadal and sexual dysfunction; assessment of the peripheral effect of hormones which regulate SHBG concentrations

510(k) Summary, Continued

Substantial equivalence

The Elecsys SHBG Immunoassay is substantially equivalent to other devices legally marketed in the United States. We claim equivalence to the DPC Immulite SHBG cleared under K941797. Both products are intended for use in the quantitative determination of sex hormone binding globulin.

Substantial equivalence - comparison

The following table compares the Roche Elecsys SHBG Immunoassay with the predicate device.

Feature	Elecsys SHBG Immunoassay	DPC Immulite SHBG (predicate)
Intended Use	For the in-vitro quantitative determination of SHBG in serum and plasma.	For the quantitative measurement of SHBG, as an aid in the differential diagnosis of hirsuitism.
Indication for Use	An aid in the diagnosis of androgen disorders including hirsuitism, virilization, polycystic ovarian syndrome, adrenogenital syndrome, and hyperandrogenism; the correct interpretation of testosterone and estradiol concentrations; investigation of the androgen-estrogen balance in gonadal and sexual dysfunction; assessment of the peripheral effect of hormones which regulate SHBG concentrations	For the quantitative measurement of SHBG as an aid in the differential diagnosis of hirsuitism.
Assay Protocol	Electrochemiluminescent Immunoassay	Chemiluminescent Immunoassay
Traceability / Standardization	1st International Standard for SHBG, NIBSC code 95/560	DPC's IRMA-Count SHBG assay

Feature	Elecsys SHBG Immunoassay	DPC Immulite SHBG (predicate)
Calibration Interval	E170/E2010 • After 1 month when using the same reagent lot • After 7 days when using the same reagent kit E1010 • With every reagent kit • After 7 days (20-25°C) • After 3 days (25-32°C)	2 weeks
Sample Type	Human serum and Li-heparin plasma	Human serum
Reagent Stability	Unopened • Up to stated expiration date stored at 2-8°C Opened • 12 weeks at 2-8° • 7weeks on E170/ 2010 • 4 weeks on E1010 (20-25° ambient temp - up to 20 hours opened in total)	• 7 days at 2-8°C. • 2 months at -20°C
Calibrator	Elecsys SHBG CalSet	SHBG Adjustors
Controls	Elecsys PreciControl Universal 1 and 2	SHBG Controls
Expected Values	Males: 10-80 nmol/L Females: 20-130 nmol/L	Males: Central 95%13-71 nmol/L; Median 32 nmol/L Females: Central 95% 18-114 nmol/L; Median 51 nmol/L
Instrument	Elecsys family of analyzers (Elecsys 1010, Elecsys 2010 and Elecsys E170 MODULAR Analytics Immunoassay Analyzers)	IMMULITE Analyzers
Measuring Range	0.350- 200 nmol/L	0.2 –180 nmol/L

510(k) Summary, Continued

Substantial equivalence – performance characteristics

The performance characteristics of the Elecsys SHBG Immunoassay and the predicate device are compared in the table below.

Feature	Elecsys SHBG Immunoassay	DPC Immulite SHBG (predicate)
Precision	E170 • 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 E1010/2010 • 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	• Within-run 4.1-7.7 %CV from 4.5-121 nmoL/L • Total 5.8% - 13% CV from 6.0-105 nmol/L
Hook Effect	No high dose hook effect up to 1000 nmol/L	No high-dose hook effect up to 11,000 nmol/L
Analytical sensitivity (LDL)	0.35 nmoL/L	0.2 nmol/L

Feature	Elecsys SHBG Immunoassay	DPC Immulite SHBG (predicate)
Limitations/Warnings/Precautions	• No interference from bilirubin up to 60 mg/dL • No interference from hemoglobin up to 2.9 g/dL • No interference from Intralipid up to 2700 mg/dL • No interference with biotin up to 60 ng/mL • No interference from rheumatoid factor up to 1160 IU/mL • No interference from 16 commonly used pharmaceuticals • In patients receiving high biotin doses > 5 mg/dL, sample should not be taken until 8 hours after administration. • Erroneous findings may be obtained in samples from patients who have been treated with monoclonal mouse antibodies • In rare cases interference due to extremely high titers of antibodies to ruthenium or streptavidin can occur	• Lipemia may interfere • Fibrin clots may cause erroneous results • Results from hemolyzed specimens should be interpreted with caution • No interference from packed red blood cells up to 30 uL/mL • No interference from bilirubin up to 200mg/L • No interference from hemoglobin up to 10000 mg/dL • Heterophilic antibodies in human serum can react with assay components to cause interference. • SHBG results should be interpreted in conjunction with measures of the hormones with which it binds, notably testosterone.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

AUG - 5 2003

Theresa M. Ambrose, Ph.D., FACB
Regulatory Affairs Principal
Roche Diagnostics Corporation
9115 Hague Road
Indianapolis, Indiana 46250

Re: k031717
Trade/Device Name: Elecsys® SHBG Immunoassay
Regulation Number: 21 CFR § 862.1150
Regulation Name: Calibrator
Regulatory Class: II
Product Code: JIS, CDZ, JJY
Dated: May 28, 2003
Received: June 3, 2003

Dear Dr. Ambrose:

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); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): N/A K031717

Device Name:

Elecsys® SHBG Immunoassay

Indications For Use:

Immunoassay for the in vitro quantitative determination 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 including hirsuitism, virilization, polycystic ovarian syndrome, adrenogenital syndrome, and hyperandrogenism; the correct interpretation of testosterone and estradiol concentrations; investigation of the androgen-estrogen balance in gonadal and sexual dysfunction; assessment of the peripheral effect of hormones which regulate SHBG concentrations. The electrochemiluminescence immunoassay "ECLIA" is intended for use on the Roche Elecsys family of analyzers.

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Division Sign-Off for: Jean Cooper

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K031717