JAN 23 2007

SHBG

510(k) Summary (Summary of Safety and Effectiveness)

This summary of the 510(k) safety and effectiveness information is being submitted in accordance with the requirements of CFR.

The Assigned 510(k) Number is: K060818

Preparation date: February 21st, 2006

Applicant Name:
Mr. Joan Guixer
Director of Quality Assurance and Regulatory Affairs
Biokit S.A.
Llica d'Amunt
Barcelona, Spain 08186

Device Name:
Reagent
Classification Name: Radioimmunoassay, testosterones and dihydrotestosterone
Trade Name: ARCHITECT® SHBG
Device Classification: 21 CFR 862.1680
Device Class: Class I
Classification Panel: Clinical Chemistry
Product Code: CDZ

Calibrators
Classification Name: Calibrator, Secondary
Trade Name: ARCHITECT® SHBG Calibrators
Device Classification: 862.1150
Device Class: Class II
Classification Panel: Clinical Chemistry
Product Code: JIT

Controls
Classification Name: Single (Specified) Analyte Controls (assayed and unassayed)
Trade Name: ARCHITECT® SHBG Controls
Device Classification: 862.1660
Device Class: Class I
Classification Panel: Clinical Chemistry
Product Code: JJX

Identification of Predicate Device:
Elecsys® SHBG Immunoassay System (Roche, k#031717)

Intended Use of Device:

The ARCHITECT® SHBG assay is a chemiluminescent microparticle immunoassay (CMIA) for the quantitative determination of sex hormone binding globulin (SHBG) in human serum and plasma on the ARCHITECT *i* System.

The ARCHITECT® SHBG Calibrators are for the calibration of the ARCHITECT *i* System when used for the quantitative determination of SHBG in human serum and plasma.

The ARCHITECT® SHBG Controls are for the verification of the accuracy and precision of the ARCHITECT *i* System when used for the quantitative determination of SHBG in human serum and plasma.

Description of Device:

The ARCHITECT SHBG assay is a two-step immunoassay to determine the presence of SHBG in human serum and plasma using CMIA technology with flexible assay protocols, referred to as Chemiflex®. In the first step, sample, assay diluent, and anti-SHBG coated paramagnetic microparticles are combined. SHBG present in the sample binds to anti-SHBG coated microparticles. After washing, the SHBG binds to the anti-SHBG acridinium-labeled conjugate that is added in the second step. Following another wash cycle, pretrigger and trigger solutions are added to the reaction mixture. The resulting chemiluminescent reaction is measured as relative light units (RLUs). A direct relationship exists between the amount of SHBG in the sample and the RLUs detected by the ARCHITECT *i* System optics. The concentration of SHBG in the sample is determined by comparing the chemiluminescent signal in the reaction to the ARCHITECT SHBG calibration.

Comparison of Technological Characteristics:

The ARCHITECT® SHBG assay is a chemiluminiscent microparticle immunoassay (CMIA) method for the quantitative determination of the SHBG in human serum or plasma.

Summary of Non-Clinical Performance:

The ARCHITECT® SHBG assay is substantially equivalent to the Elecsys® SHBG assay in terms of precision, linearity and interferences as demonstrated in non-clinical performance data in this 510(k) submission.

Summary of Clinical Performance:

The ARCHITECT® SHBG assay demonstrated substantially equivalent performance to the Elecsys® SHBG indicated by a method comparison with a correlation coefficient of 0.98.

Reagents:

Similarities:

Characteristics	Device	Predicate
Product Type	Immunoassay	Immunoassay
Methodology	Chemiluminescent Microparticle Immunoassay (CMIA)	Chemiluminescence a solid phase enzyme immunoassay
Intended Use	The ARCHITECT® SHBG assay is a chemiluminescent microparticle immunoassay (CMIA) for the quantitative determination of sex hormone binding globulin (SHBG) in human serum and plasma on the ARCHITECT *i* System.	Immunoassay for the in vitro quantitative determination of sex hormone-binding globulin in human serum and plasma. The ECLIA is intended for use on the Roche Elecsys® 1010/2010 and MODULAR ANALYTICS E170 (Elecsys module) immunoassay analyzers.
Where Used	Clinical Laboratories	Clinical Laboratories
Assay Protocol	Two-step direct sandwich immunoassay	Sandwich principle
Specimen Type	Human serum or plasma (Lithium Heparin, Sodium Heparin, Ammonium Heparin, Potassium EDTA)	Human Serum and Lithium Heparin Plasma
Interpretation of Results	Standard Curve	Standard Curve
Interferences	Non significant interferences with: Hemoglobin, bilirubin, triglycerides, protein	Non significant interferences with: Bilirubin, hemolysis, lipemia, biotin
Measuring Range	0.1 – 250 nmol / L	0.350 – 200 nmol / L
Analytical Sensitivity	0.1 nmol / L	0.35 nmol / L
Analytical Specificity	Non detectable cross-reactivities were found for: AFP, cortisol, 11-Deoxycortisol, Estradiol, testosterone, 5-dihydrotestosterone, TG, TBG and transferrin.	Non detectable cross-reactivities were found for: AFP, CBG, DHT, estradiol, fibrinogen, human IgA, human IgG, plasminogen, TBG, testosterone, TG, transferrin and TSH.
Method Comparison	ARCHITECT SHBG was compared to the predicate device. 626 specimens ranging 6.5 nmol/L to 1072.0 nmol/L were evaluated and the correlation coefficient obtained was 0.98.	

Differences:

Characteristics	Device	Predicate
Platform	ARCHITECT *i* System	ROCHE Elecsys® 1010/1020 Analyzer and MODULAR ANALYTICS E170
Components	**Microparticles** 1or 4 Bottle(s) (6.6 mL each) Anti-SHBG(mouse monoclonal) coated microparticles in TRIS buffer. Preservative: sodium azide. **Conjugate** 1or 4 Bottle(s) (5.9 mL each) Anti-SHBG(mouse,monoclonal) acridinium-labeled conjugate in phosphate buffer with protein (mouse, bovine) stabilizer. Preservative: sodium azide. **Assay Diluent** 1or 4 Bottle(s) (8.0 mL each) SHBG Assay Diluent containing phosphate buffer with protein (mouse,bovine) stabilizer. Preservative: sodium azide.	**Microparticles** 1 bottle of 6.5mL. Streptavidin-coated microparticles, 0.72 mg/mL; binding capacity: 470 ng biotin/mg microparticles. Preservative. **R1 – Anti-SHBG-Ab~biotin** - 1 bottle (10.0 mL) Biotinylated monoclonal anti-SHBG antibody (mouse) 1.25 mg/L; phosphate buffer 100 mmol/L, pH 7.2. Preservative. **R2 – Anti-SHBG-Ab~Ru** 1 bottle, 10 mL Monoclonal anti-SHBG antibody (mouse) labeled with ruthenium complex 1.25 mg/L; phosphate buffer 100mmol/L, pH 7.2. Preservative

Calibrators:

Similarities:

Characteristics	Device	Predicate
Intended Use	The ARCHITECT® SHBG Calibrators are for the calibration of the ARCHITECT *i* System when used for the quantitative determination of SHBG in human serum and plasma.	Elecsys® SHBG CalSet is used for calibrating the quantitative Elecsys SHBG assay on the Elecsys immunoassay systems.
Standardization/Traceability	Traceable to the WHO Standard Material NIBSC CODE: 95/560.	Against the first International Standard for SHBG from the National Institute for Biological Standards and Control (NIBSC) code 95/560.

Differences:

Characteristics	Device	Predicate
Calibrator Components	6 Bottles (2.0 mL each) of ARCHITECT SHBG Calibrators. Calibrator A contains phosphate buffered saline with protein (goat) stabilizer. Calibrators B to F contain SHBG in phosphate buffered saline with protein (goat) stabilizer. Preservatives: sodium azide and ProClin® 300.	SHBG Cal1 and Cal2 (1.0 mL each) The concentration of SHBG Cal1 is approximately 0.0 nmol/L; SHBG Cal2 contains approximately 40 nmol/L human SHBG in a human serum matrix.
Calibrator Concentrations	CAL A – 0.0 nmol/L CAL B – 2.0 nmol/L CAL C – 6.0 nmol/L CAL D – 25.0 nmol/L CAL E – 125.0 nmol/L CAL F – 250.0 nmol/L	0.0 and 40 nmol/L
Matrix	Purified Human SHBG in a phosphate buffered saline	Lyophilized equine serum (cal1) and human serum (cal2). Both containing SHBG.

Controls:

Similarities:

Characteristics	Device	Predicate
Intended Use	The ARCHITECT® SHBG Controls are for the verification of the accuracy and precision of the ARCHITECT *i* System when used for the quantitative determination of SHBG in human serum and plasma.	Elecsys® PreciControl Universal is used for quality control of Elecsys immunoassay on the Elecsys immunoassay systems.
Methodology	Chemiluminescent Microparticle Immunoassay (CMIA)	Chemiluminescence a solid phase enzyme immunoassay
Matrix	Purified Human SHBG in buffer	SHBG human serum in buffer

Differences:

Characteristics	Device	Predicate
Control Components	3 Bottles (4.0 mL each) of ARCHITECT SHBG Controls contain SHBG (human, purified) in phosphate buffered saline with protein (goat) stabilizer. Preservatives: sodium azide and ProClin® 300.	SHBG Controls (LSHC1, LSHC2) Two vials of lyophilized SHBG in a nonhuman protein/buffer matrix.
Control Concentrations	Low – 9.0 nmol/L Medium – 25.0 nmol/L High – 150.0 nmol/L	Target values and concentration range are indicated in a value sheet.

Conclusion:

As summarized above the ARCHITECT® SHBG Reagents, Calibrators (A-F) and Controls (Low, Medium and High) are substantially equivalent to the ROCHE Elecsys® SHBG Reagents, Calibrators and Controls. Substantial equivalence for the reagents and calibrators has been demonstrated as recommended by the FDA guidance for Industry "Format for Traditional and Abbreviated 510(k)s" (Issued on: August 12, 2005) and for controls as recommended by the FDA Guidance for Industry "Points to Consider Document on Assayed and Unassayed Quality Control Material" (Draft Guidance released for comment on February 3, 1999).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Mr. Joan Guixer
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JAN 23 2007

Re: k060818
Trade/Device Name: ARCHITECT® SHBG Reagents, Calibrators (A-F) and ARCHITECT® SHBG Controls (Low, Medium, High)
Regulation Number: 21 CFR§ 862.1680
Regulation Name: Testosterone test system
Regulatory Class: Class I, reserved
Product Code: CDZ, JIT, JJX
Dated: December 20, 2006
Received: December 26, 2006

Dear Mr. Guixer:

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 (240) 276-0490. 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 (240) 276-3150 or at its Internet address at http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Jean M. Cooper, M.S., D.V.M.

Jean M. Cooper, M.S., D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
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Enclosure

Indications for Use Statement

510(k) Number (if known): K060818

Device Name: ARCHITECT® SHBG REAGENTS, CALIBRATORS (A-F) and ARCHITECT® SHBG CONTROLS (LOW, MEDIUM, HIGH)

Indications for Use:

Reagents

The ARCHITECT® SHBG assay is a chemiluminescent microparticle immunoassay (CMIA) for the quantitative determination of sex hormone binding globulin (SHBG) in human serum and plasma on the ARCHITECT *i* System.

The ARCHITECT SHBG assay is intended for use as an aid in the diagnosis of androgen disorders.

Calibrators

The ARCHITECT® SHBG Calibrators are for the calibration of the ARCHITECT *i* System when used for the quantitative determination of SHBG in human serum and plasma.

Controls

ARCHITECT® SHBG Controls are for the verification of the accuracy and precision of the ARCHITECT *i* System when used for the quantitative determination of SHBG in human serum and plasma.

For *in vitro* diagnostic use.

Prescription Use X (Part 21 CFR 801 Subpart D)	**OR**	Over-The-Counter Use _____ (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K060818