DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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ANGELS ROMA, REGULATORY AFFAIRS AND MARKET SURVEILLANCE DIRECTOR
CAN MALE, S/N
08186 LLICA D'AMUNT 08186
BARCELONA, SPAIN

February 11, 2016

Re: K152185
Trade/Device Name: ARCHITECT SHBG
Regulation Number: 21 CFR 862.1680
Regulation Name: Testosterone test system
Regulatory Class: I, Reserved
Product Code: CDZ
Dated: December 10, 2015
Received: December 14, 2015

Dear Angels Roma:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Katherine Serrano -S

For: Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K152185

Device Name
ARCHITECT SHBG

Indications for Use *(Describe)*
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 used as an aid in the diagnosis of androgen disorders.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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I. 510(k) Summary

The summary of the 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Date: February 1, 2016

Applicant Name:

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Device Name:

Reagents

Classification Name: Radioimmunoassay, Testosterones, and Dihydrotestosterone
Trade Name: ARCHITECT SHBG
Governing Regulation: 21 CFR 862.1680
Device Classification: Class I Reserved
Classification Panel: Clinical Chemistry
Product Code: CDZ

Legally marketed device to which equivalency is claimed:

ARCHITECT SHBG assay (K060818)

Intended Use/Indications for 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.

The ARCHITECT SHBG assay is used as an aid in the diagnosis of androgen disorders.

Description of Device:

The ARCHITECT SHBG assay is a two-step immunoassay to determine the presence of SHBG in human serum and plasma using chemiluminescent microparticle immunoassay (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, pre-trigger 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:

Both the submission device (ARCHITECT SHBG) and the predicate device (ARCHITECT SHBG [K060818]) have the same technological characteristics. Both devices use a chemiluminescent microparticle immunoassay (CMIA) technology for the quantitative determination of sex hormone binding globulin in human serum and plasma. There are no technological differences between the submission and predicate devices.

Comparison of Assay Performance

The reagents, calibrators, and controls for the submission device and the predicate device are the same. The submission is to update the Free Testosterone Index (FTI) (also known as Free Androgen Index [FAI]) expected values section of the labeling. The risk assessment was performed and there is no change in the performance of the previously cleared assay. The performance data provided in K060818 still apply.

Summary of Supporting Data:

The FTI/FAI expected values that are currently in the ARCHITECT SHBG reagent insert were calculated using ARCHITECT Testosterone (List Number [LN] 6C28, cleared under K983212) and ARCHITECT SHBG (LN 8K26) assays. A new study was conducted in 2014 to calculate FTI or FAI using ARCHITECT 2nd Generation Testosterone (LN 2P13, cleared under K120009) and ARCHITECT SHBG (LN 8K26) assay results. The %FTI or %FAI calculated as [Total Testosterone] / [SHBG] provides an index of free testosterone status. The %FTI or %FAI correlates with the value of free testosterone.

FTI/FAI Expected Values

The new FTI/FAI expected values study was performed on a minimum of 120 samples from individuals in the following categories: normal males 21-49 years of age, normal males ≥ 50 years of age, premenopausal normal females 21-49 years of age, and postmenopausal normal females ≥ 50 years of age not on hormone replacement therapy.

The following inclusion/exclusion criteria apply to the study:

Samples that were within the expected values of the ARCHITECT 2nd Generation Testosterone (LN 2P13) reagent insert and the ARCHITECT SHBG (LN 8K26) reagent insert were included in the study.

The data from this study are summarized in the following tables.

SHBG nmol/L					Testosterone nmol/L [ng/dL]		
Category	**N**	**Median**	**2.5th Percentile**	**97.5th Percentile**	**Median**	**2.5th Percentile**	**97.5th Percentile**
Males (21-49 years of age)	163	31.1	16.2	68.5	15.33 [442.07]	8.76 [252.73]	27.85 [803.24]
Males (≥ 50 years of age)	144	35.3	13.7	69.9	14.42 [415.85]	8.58 [247.50]	23.37 [674.13]
Females (Premenopausal, 21-49 years of age)	174	48.6	14.7	122.5	1.05 [30.43]	0.52 [14.92]	1.72 [49.56]
Females (Postmenopausal, ≥ 50 years of age)	175	49.9	16.7	124.4	0.76 [21.83]	0.46 [13.34]	1.18 [33.90]

The % FTI or % FAI values for the different groups are summarized in the following table.

% FTI or % FAI				
Category	**N**	**Median (%)**	**2.5th Percentile (%)**	**97.5th Percentile (%)**
Males (21-49 years of age)	163	46.6	24.5	113.3
Males (≥ 50 years of age)	144	40.7	19.3	118.4
Females (Premenopausal, 21-49 years of age)	174	2.0	0.7	8.7
Females (Postmenopausal, ≥ 50 years of age)	175	1.5	0.5	4.7

Conclusion:

The submission is for a labeling change for the %FTI or %FAI Expected Values only. The risk assessment was performed and there is no change in the performance of the previously cleared assay. The performance data provided in K060818 still apply.

The submission device is substantially equivalent to the predicate device because the proposed labeling change does not alter the intended use, indications for use, or the fundamental scientific technology of the predicate device. Furthermore, the residual risk is broadly acceptable because the identified and verified control measures eliminate or reduce the potential effects of failure.

Both ARCHITECT 2nd Generation Testosterone (K152155) and ARCHITECT SHBG labeling will be updated to include the %FTI or %FAI expected values generated using these assays.