February 8, 2024

Beckman Coulter Inc.
Kate Oelberg
Senior Staff Quality and Regulatory Affairs
1000 Lake Hazeltine Drive
Chaska, Minnesota 55318

Re: K233480
Trade/Device Name: Access SHBG
Regulation Number: 21 CFR 862.1680
Regulation Name: Testosterone Test System
Regulatory Class: Class I, reserved
Product Code: CDZ
Dated: December 14, 2023
Received: December 14, 2023

Dear Kate Oelberg:

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 (the 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Paula V. Caposino -S

Paula Caposino, Ph.D.
Acting Deputy Director
Division of Chemistry
and Toxicology Devices
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
k233480

Device Name
Access SHBG

Indications for Use *(Describe)*
The Access SHBG assay is a paramagnetic particle, chemiluminescent immunoassay for the quantitative determination of Sex Hormone Binding Globulin levels in human serum and plasma using the Access Immunoassay Systems.
The Access SHBG assay is indicated for use in the assessment 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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510 (k) Summary
This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

510(k) Number K233480 **Date Prepared: 1/30/2024**

Submitted By:
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Device Name

Common Name: Access SHBG
Trade Name: Access SHBG
Classification Name: Alkaline phosphatase or isoenzymes test system.
Classification Code: CDZ (Class 1) - Radioimmunoassay, Testosterones and Dihydrotestosterone
Classification Regulation: 21 CFR 862.1680

Predicate Device

Device Name: Access Sex Hormone Binding Globulin Reagent
510(k) Numbers: K083867

Device Description

The Access SHBG assay is a sequential two-site immunoenzymatic (“sandwich”) assay. The Access SHBG assay consists of the reagent pack, calibrators and QCs. Other items needed to run the assay include substrate and wash buffer. The Access SHBG assay reagent pack, Access SHBG assay calibrators, Access SHBG QCs, along with the UniCel DxI Wash Buffer II are designed for use with the DxI 9000 Access Immunoassay Analyzer in a clinical laboratory setting.

Intended Use

The Access SHBG assay is a paramagnetic particle, chemiluminescent immunoassay for the quantitative determination of Sex Hormone Binding Globulin levels in human serum and plasma using the Access Immunoassay Systems.

Indications for Use

The Access SHBG assay is indicated for use in the assessment of androgen disorders.

Comparison of Technological Characteristics to the Predicate

Parameter	Access Sex Hormone Binding Globulin Reagent Access UniCel DxI 800 Immunoassay System (Predicate)	Access SHBG on DxI 9000 Access Immunoassay System
Intended use	The Access SHBG assay is a paramagnetic particle, chemiluminescent immunoassay for the quantitative determination of Sex Hormone Binding Globulin levels in human serum and plasma using the Access Immunoassay Systems.	Same
Technology	Two-step immunoenzymatic assay	Same
Format	Chemiluminescent	Same
Calibration	Utilizes a stored calibration curve	Same
Sample Type	Serum and lithium heparin plasma	Same
Measuring Range	Approximately 0.33 - 200 nmol/L	Same
Instrument	Access UniCel DxI 800 Immunoassay System	DxI 9000 Access Immunoassay Analyzer
Substrate	Access Substrate	Lumi-Phos Pro Substrate

Standard/Guidance Document Referenced (if applicable):

CLSI EP05-A3: Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline – Third Edition
CLSI EP06-2nd Edition-: Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach; Approved Guideline

CLSI EP17-A2: Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; Approved Guideline – Second Edition
CLSI EP09c 3rd Edition: Measurement Procedure Comparison and Bias Estimation Using Patient Samples; Third Edition

Summary of Studies

Method Comparison: Method comparison study was performed to compare the Access SHBG assay on DxI 9000 Access Immunoassay Analyzer to a previously cleared system. Method comparison and bias estimation experiments were designed in accordance with the CLSI EP09c-A3 "*Method Procedure Comparison and Bias Estimation Using Patient Samples; Approved Guideline – Third Edition"*. A total of one hundred and fifty-one (151) samples were evaluated in the method comparison study. The results of the method comparison study met the acceptance criteria of $R^2 \geq 0.95$ with a slope equal to 1.00 ± 0.09 and supports the equivalence of the Access SHBG assay on DxI 9000 Access Immunoassay Analyzer to the Access SHBG on the Access 2 instrument.

N	Concentration Range* (nmol/L)	Slope	Slope 95% CI	Intercept	Intercept 95% CI	Correlation Coefficient R	R^2
151	0.63 - 235	1.01	1.00-1.03	-0.019	-0.46 - 0.29	1.00	0.99

*Range is Access 2 values

Imprecision: Repeatability (within-run) and within-laboratory (total) precision studies were designed in accordance with the CLSI Guideline EP05-A3 *"Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline - Third Edition"*. The study was run on three DxI 9000 Access Immunoassay Analyzer systems, three reagent lots, and three calibrator lots. Five (5) serum samples with varying SHBG concentrations, were assayed in duplicate with two runs per day, over 20 days. The assay was designed to have within-laboratory imprecision as listed below:

≤ 0.14 nmol/L SD at concentrations ≤ 2 nmol/L

≤ 7.0% CV at concentrations > 2 nmol/L

The results from a representative lot are as follows:

Concentration (nmol/L)			Repeatability (Within-run)		Between-run		Between-day		Within-Laboratory (Total)	
Sample	N	Mean	SD	%CV	SD	%CV	SD	%CV	SD	%CV
Sample 1	80	0.82	0.02	2.3	0.01	1.5	0.03	3.7	0.04	4.6
Sample 2	80	18	0.3	1.4	0.2	1.4	0.4	1.9	0.5	2.7
Sample 3	80	47	0.7	1.6	0.6	1.6	0.8	1.8	1.3	2.7

Sample 4	80	90	1.4	1.5	1.4	1.5	1.7	1.9	2.6	2.9
Sample 5	80	198	3.0	1.5	3.4	1.5	2.3	1.2	5.1	2.6

Linearity: A verification study was performed to evaluate the linearity of the Access SHBG assay on the DxI 9000 Access Immunoassay Analyzer based on CLSI EP06-Ed2 "*Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach; Approved Guideline"*. A native sample was obtained at the low end of the assay's measuring range. A high sample was created by spiking a low serum sample with SHBG antigen to achieve a concentration at or above the highest calibrator. In addition to the high and low SHBG concentration samples, seven mixtures were tested in this study. The Access SHBG assay is linear on the DxI 9000 Access Immunoassay Analyzer throughout the analytical measuring interval of 0.33 nmol/L – 200 nmol/L.

LoB, LoD, and LoQ: Limit of Blank (LoB), Limit of Detection (LoD), and Limit of Quantitation (LoQ) studies were designed from the CLSI guideline EP17-A2 "Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures Approved Guideline – Second Edition". Four distinct blank samples (calibrator matrix were used for the LoB determination. For estimation of LoD, six to seven samples containing low levels of SHBG analyte were measured. For estimation of LoQ, 12-13 serum samples containing low levels of SHBG analyte were measured. The LoB study included multiple reagent lots and 3 DxI 9000 Access Immunoassay Analyzers over a minimum of 3 days. The LoD and LoQ studies included multiple reagent lots and 3 DxI 9000 Access Immunoassay Analyzers over a minimum of 5 days. The maximum observed results for LoB for Access SHBG assay is 0.005 nmol/L, LoD is 0.01 nmol/L and LoQ is 0.06 nmol/L on DxI 9000 Access Immunoassay Analyzer.

Other claims: The claims for the analytical specificity and reference intervals are being transferred from file K083867.

Substantial Equivalence Comparison Conclusion

Beckman Coulter's Access SHBG on the DxI 9000 Access Immunoassay Analyzer is substantially equivalent to the Access Sex Hormone Binding Globulin Reagent on the Access Immunoassay System as demonstrated through the information and data provided in this submission. The performance testing presented in this submission provides evidence that the device is safe and effective in its intended use.