January 13, 2023

Beckman Coulter, Inc.
Kuljeet Kaur
Regulatory Affairs Manager
1000 Lake Hazeltine Drive
Chaska, MN 55318

Re: K223405
Trade/Device Name: Access Testosterone
Regulation Number: 21 CFR 862.1680
Regulation Name: Testosterone test system
Regulatory Class: Class I, reserved
Product Code: CDZ
Dated: November 7, 2022
Received: November 9, 2022

Dear Kuljeet Kaur:

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. 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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 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 Caposino -S
Digitally signed by Paula Caposino -S
Date: 2023.01.13 17:18:55 -05'00'

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)*
k223405

Device Name
Access Testosterone

Indications for Use *(Describe)*
The Access Testosterone assay is a paramagnetic particle, chemiluminescent immunoassay for the quantitative determination of total testosterone levels in human serum and plasma using the Access Immunoassay Systems.

Measurement of testosterone are used in the diagnosis and treatment of disorders involving the male sex hormones (androgens), including primary and secondary hypogonadism, delayed or precocious puberty, impotence in males and, in females hirsutism (excessive hair) and virilization (masculinization) due to tumors, polycystic ovaries, and adrenogenital syndromes.

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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Access Testosterone

510(k) Summary

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

510(k) number: k223405

Submitted By:
Beckman Coulter, Inc.
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Date Prepared:
January 5, 2023

Common Name: Access Testosterone Assay
Trade Name: Access Testosterone
Classification Name: Testosterone test system
Product Code: CDZ
Classification Regulation: 21 CFR 862.1680

Predicate Device:

Predicate Device	Manufacturer	510(k) No.
Access Testosterone assay	Beckman Coulter, Inc.	K001935

Device Description:

The Access Testosterone assay is a competitive binding immunoenzymatic assay. The Access Testosterone assay consists of the reagent pack and calibrators. Other items needed to run the assay include substrate and wash buffer. The Access Testosterone assay reagent pack, Access Testosterone assay calibrators, 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 Testosterone assay is a paramagnetic particle, chemiluminescent immunoassay for the quantitative determination of total testosterone levels in human serum and plasma using the Access Immunoassay Systems.

Measurement of testosterone are used in the diagnosis and treatment of disorders involving the male sex hormones (androgens), including primary and secondary hypogonadism, delayed or precocious puberty, impotence in males and, in females hirsutism (excessive hair) and virilization (masculinization) due to tumors, polycystic ovaries, and adrenogenital syndromes.

Comparison to the Predicate

Attribute/Characteristic	Predicate Access Testosterone on Access Immunoassay System	Access Testosterone on DxI 9000 Access Immunoassay Analyzer
Intended Use/Indications for Use	The Access Testosterone assay is a paramagnetic particle, chemiluminescent immunoassay for the quantitative determination of total testosterone levels in human serum and plasma using the Access Immunoassay Systems.	Same
Analyte Measured	Testosterone	Same
Standardization	USP Reference Material	Same
Technology	One-step competitive binding	Same

Attribute/Characteristic	Predicate Access Testosterone on Access Immunoassay System	Access Testosterone on DxI 9000 Access Immunoassay Analyzer
	Immunoassay System	
Format	Chemiluminescent	Same
Method	Automated	Same
Calibration	Utilizes a stored calibration curve	Same
Traceability	USP reference material	Same
Sample Type	Serum, plasma (heparin)	Same
Stability	Stable at 2 to 10°C for 28 days after initial use	Same
Reagent Pack formulation and packaging	Access Reagent Pack formulation and packaging.	Same
Measuring Range	0.1 – 16.0 ng/mL	0.4 – 16.0 ng/mL
Instrument	Access Immunoassay system	DxI 9000 Access Immunoassay Analyzer
Substrate	Access Substrate	Lumi-Phos PRO substrate

Summary of Studies:

Method Comparison: Method comparison study was performed to compare the Access Testosterone 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 eight (108) serum samples were evaluated in the method comparison study. The results of the method comparison study met the acceptance criteria of R2 ≥ 0.90 and slope of 1.00 ± 0.14 and support the equivalence of the Access Testosterone assay on DxI 9000 Access Immunoassay Analyzer to the Access Testosterone assay on the Access 2 instrument.

N	Concentration Range (ng/mL)	Slope	Slope 95% CI	Intercept	Intercept 95% CI	Correlation Coefficient R2
108	0.48, 14	0.95	0.93, 0.98	0.028	-0.015, 0.071	0.98

Linearity: A verification study was performed to evaluate the linearity of the Access Testosterone 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"*. The low sample was a native serum sample. The high sample was created by spiking a native serum sample with Testosterone antigen. All other samples tested were mixtures of the low and high sample. The Access Testosterone assay is linear on the DxI 9000 Access Immunoassay Analyzer throughout the analytical measuring interval of 0.4 - 16.0 ng/mL.

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 Analyzers, three reagent lots, and three calibrator lots. Six (6) serum samples with Testosterone concentrations spanning the range of the assay were each tested in replicates of two (2) per run with two (2) runs per day with a minimum of 20 days on each instrument and reagent lot combination. Two (2) samples were native serum samples from individual donors, three (3) were native pooled serum samples and one (1) sample was prepared by spiking native serum samples with an antigen to achieve adequate coverage at the high end of the analytical range. The assay was designed to have within-laboratory imprecision as listed below:

• ≤ 0.14 ng/mL (0.49 nmol/L) SD at concentrations ≤ 1.4 ng/mL (4.9 nmol/L)

• ≤ 10.0% CV at concentrations > 1.4 ng/mL (4.9 nmol/L)

The results from a representative lot are as follows:

Concentration (ng/mL)			Repeatability (Within-run)		Between-run		Between-day		Within-Laboratory	
Sample	**N**	**Mean**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**
Sample 1	88	0.71	0.03	3.6	0.02	3.4	0.02	3.4	0.04	6.0
Sample 2	88	2.0	0.05	2.6	0.05	2.6	0.05	2.3	0.09	4.4
Sample 3	88	4.8	0.09	1.9	0.08	1.7	0.14	3.0	0.19	3.9

Concentration (ng/mL)			Repeatability (Within-run)		Between-run		Between-day		Within-Laboratory	
Sample 4	88	7.1	0.13	1.8	0.09	1.2	0.29	4.0	0.33	4.6
Sample 5	88	8.6	0.18	2.1	0.25	2.9	0.40	4.7	0.51	5.9
Sample 6	88	14	0.3	2.2	0.2	1.6	1.0	7.3	1.1	7.8

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 blank samples (Matrix lacking Testosterone antigen) were used for LoB determination. For estimation of LoD, seven serum samples containing low levels of Testosterone analyte were measured. For estimation of LoQ, 12 serum samples containing low levels of Testosterone 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 assay has an LoB of 0.2 ng/mL (0.7 nmol/L), LoD of 0.4 ng/mL (1.39 nmol/L) and 20% Within-Laboratory CV LoQ of 0.4 ng/mL (1.39 nmol/L).

Other claims: The claims for the analytical specificity, reference intervals, matrix comparison are being transferred from file k001935.

Substantial Equivalence Comparison Conclusion

Beckman Coulter's Testosterone Assay on the DxI 9000 Access Immunoassay Analyzer is substantially equivalent to the Access Testosterone Assay 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.