February 8, 2023

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

Re: K223038
Trade/Device Name: Access Cortisol
Regulation Number: 21 CFR 862.1205
Regulation Name: Cortisol (hydrocortisone and hydroxycorticosterone) test system
Regulatory Class: Class II
Product Code: CGR
Dated: September 29, 2022
Received: September 29, 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: 2023.02.08 17:08:10 -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)*
k223038

Device Name
Access Cortisol

Indications for Use *(Describe)*
The Access Cortisol assay is a paramagnetic particle, chemiluminescent immunoassay for the quantitative determination of cortisol levels in human serum, plasma (heparin, EDTA) and urine using the Access Immunoassay Systems.
A cortisol (hydrocortisone and hydroxycorticosterone) test system is a device intended to measure the cortisol hormones secreted by the adrenal gland in serum, plasma and urine. Measurements of cortisol are used in the diagnosis and treatment of disorders of the adrenal gland.

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.

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Access Cortisol Assay
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: k223038

Submitted By:
Beckman Coulter, Inc.
1000 Lake Hazeltine Drive
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Date Prepared: January 30, 2023

Device Common Name: Access Cortisol Assay
Trade Name: Access Cortisol
Classification Name: Cortisol (hydrocortisone and hydroxycorticosterone) test system
Classification Regulation: 21 CFR 862.1205

Predicate Device: Access Cortisol
510(k) Number: k050202

Device Description:

The Access Cortisol assay is a competitive binding immunoenzymatic assay. The Access Cortisol reagent kit is in a liquid ready-to-use format designed for optimal performance on Beckman Coulter's immunoassay analyzers. Each reagent kit contains two reagent packs. Other items needed to run the assay include Calibrators, substrate, and wash buffer. The Access Cortisol assay reagent pack, Access Cortisol 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 Us

The Access Cortisol assay is a paramagnetic particle, chemiluminescent immunoassay for the quantitative determination of cortisol levels in human serum, plasma (heparin, EDTA) and urine using the Access Immunoassay Systems.

A cortisol (hydrocortisone and hydroxycorticosterone) test system is a device intended to measure the cortisol hormones secreted by the adrenal gland in serum, plasma and urine. Measurements of cortisol are used in the diagnosis and treatment of disorders of the adrenal gland.

Comparison of Technological Characteristics to the Predicate

System Attribute/Characteristic	Predicate Access Cortisol on Access Immunoassay System	Candidate Access Cortisol on Dxl 9000 Access Immunoassay Analyzer
Intended Use/ Indications for Use	The Access Cortisol assay is a paramagnetic particle, chemiluminescent immunoassay for the quantitative determination of cortisol levels in human serum, plasma (heparin, EDTA) and urine using the Access Immunoassay Systems.	Same
Solid Phase	Paramagnetic particles coated with goat anti-rabbit IgG	Same
Conjugate	Cortisol-alkaline phosphatase (bovine) conjugate	Same
Calibrators	Human serum containing cortisol (purified chemical compound) at levels of 0 and approximately 2, 5, 10, 25, and 60 µg/dL 60 µg/dL	Same
Analyte Measured	Cortisol	Same
Traceability	USP Reference Material	Same
Technology	Competitive binding Immunoassay System	Same
Format	Chemiluminescent	Same
Method	Automated	Same
Calibration	Utilizes a stored calibration curve	Same
Sample Type	Serum, plasma, or urine	Same

System Attribute/Characteristic	Predicate Access Cortisol on Access Immunoassay System	Candidate Access Cortisol on DxI 9000 Access Immunoassay Analyzer
Stability	Stable at 2 to 10°C for 14 days after initial use	Same
Reagent Pack formulation and packaging	Access Reagent Pack formulation and packaging.	Same
Measuring Range	0.4 - 60 µg/dL	0.8 - 60 ug/dL
Instrument	Access Immunoassay system	DxI 9000 Access Immunoassay Analyzer
Substrate	Access Substrate	Lumi-Phos PRO substrate

Summary of Studies:

Method Comparison: A method comparison study was completed to compare the Access Cortisol assay on the DxI 9000 Access Immunoassay Analyzer to the Access Cortisol assay on the Access Immunoassay System using a protocol based on CLSI EP09c-A3. The results of the within range method comparison study met the acceptance criteria of R2 ≥ 0.90 and slope 1.00 ± 0.12 and supports the equivalence of the Access Cortisol assay on DxI 9000 to the predicate device, the Access Cortisol assay on Access 2 Instrument.

N	Concentration Range (ug/dL)	Slope	Slope 95% CI	Intercept	Intercept 95% CI	Correlation Coefficient R^2
116	1.6 - 59	1.01	0.99 -1.03	-0.20	-0.41 - 0.056	1.00

Imprecision: Verification studies were performed to determine the imprecision of the Access Cortisol assay on the DxI 9000 Access Immunoassay Analyzer using a protocol based on CLSI EP-05-A3. The study was performed within one internal site over twenty days. Three DxI 9000 Immunoassay Analyzers were used in the study design. There were three reagent pack lots and three calibrator lots. Five (5) serum samples, with Cortisol concentrations spanning the assay range were used for this study. The within-laboratory (total) % CV ranged from 2% to 9.3%, for Cortisol

concentrations > 5.0 ug/dL. The within-laboratory (total) SD was 0.1 for Cortisol concentrations ≤ 5.0 ug/dL. The results from a representative lot are as follows:

Sample	N	Mean Concentration (ug/dL)	Repeatability (Within-run)		Between-run		Between-day		Within-Laboratory	
			SD	%CV	SD	%CV	SD	%CV	SD	%CV
Sample 1	80	0.90	0.1	10.2	0.1	8.2	0.0	0.0	0.1	13.1
Sample 2	80	5.7	0.2	3.4	0.3	5.5	0.2	2.7	0.4	7.1
Sample 3	80	19	0.5	2.6	1.1	6.0	1.1	5.5	1.6	8.6
Sample 4	80	29	0.8	2.7	2.0	6.7	1.7	5.8	2.7	9.3
Sample 5	80	49	1.1	2.3	0.0	0.0	1.6	3.2	1.9	3.9

Linearity: A verification study was performed to evaluate the linearity of the Access Cortisol assay on the DxI 9000 Access Immunoassay Analyzer based on CLSI EP06-Ed2. Acceptance criteria for non-linearity within ± 1 ug/dL for values ≤ 5.0 ug/dL and ± 20% for values > 5.0 ug/dL was met and indicate that the Access Cortisol assay is linear on the DxI 9000 Immunoassay System across the analytical measuring interval of 0.8 - 60 ug/dL (22 - 1,655 nmol/L).

LoB/LoD: Verification studies were performed to determine the Limit of Blank (LoB) and Limit of Detection (LoD) for the Access Cortisol assay on the DxI 9000 Access Immunoassay Analyzer using a protocol based on CLSI EP17-A2. The assay is designed to meet the claimed LoB of 0.4 ug/dL and LoD of 0.4 ug/dL.

LoQ: Verification studies were performed to determine the Limit of Quantitation (LoQ) of the Access Cortisol assay on the DxI 9000 Access Immunoassay Analyzer using a protocol based on CLSI EP17- A2. The LoQ for Access Cortisol designed to meet the claimed LoQ of 0.8 ug/dL based on a 20% CV.

Other claims: The claims for the analytical specificity, reference intervals, matrix comparison are being transferred from file k050202.

Substantial Equivalence Comparison Conclusion

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