March 5, 2025

Beckman Coulter, Inc.
Mary Beth Tang
Senior Staff Regulatory Affairs
250 South Kraemer Boulevard
Brea, California 92821

Re: K242190
Trade/Device Name: Access Cortisol; DxC 500i Clinical Analyzer
Regulation Number: 21 CFR 862.1205
Regulation Name: Cortisol (Hydrocortisone and Hydroxycorticosterone) Test System
Regulatory Class: Class II
Product Code: CGR, JJE
Dated: January 24, 2025
Received: January 24, 2025

Dear Mary Beth Tang:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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 V. Caposino, Ph.D.
Deputy Division Director
Division of Chemistry and
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OHT7: Office of In Vitro Diagnostics
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K242190

Device Name
Access Cortisol;
DxC 500i Clinical Analyzer

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.

The DxC 500i Clinical Analyzer combines the DxC 500 AU Clinical Chemistry Analyzer and the Access 2 Immunoassay System into a single instrument presentation. The system is for in vitro diagnostic use only.
The chemistry module of the DxC 500i Clinical Analyzer is an automated chemistry analyzer that measures analytes in samples, in combination with appropriate reagents, calibrators, quality control (QC) material and other accessories. The immunoassay module of the DxC 500i Clinical Analyzer is an in-vitro diagnostic device used for the quantitative, semi-quantitative, or qualitative determination of various analyte concentrations found in human body fluids.

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.

K242190 510(k) Summary
Access Cortisol on DxC 500i

Submitted By:

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Date of Preparation:

March 4, 2025

Device Name(s):

Proprietary Name:	Access Cortisol
Common Name:	Cortisol (hydrocortisone and hydroxycorticosterone) test system
Classification Name:	Radioimmunoassay, Cortisol
Class:	Class II
Regulation Number:	21 CFR 862.1205
Product Code:	CGR

Proprietary Name:	DxC 500i Clinical Analyzer
Common Name:	Discrete photometric analyzer for clinical use
Classification Name:	Analyzer, Chemistry (Photometric, Discrete), For Clinical Use
Class:	Class I
Regulation Number:	21 CFR 862.2160
Product Code:	JJE

Predicate Device:

Candidate Test System	Predicate Test System	Predicate Docket
Access Cortisol on the DxC 500i Clinical Analyzer	Access Cortisol on the Access 2 Immunoassay System	K050202

Device Description:

The Access Cortisol assay is a competitive binding immuno-enzymatic assay designed for use on Beckman Coulter's Access immunoassay analyzers in a clinical laboratory setting. Table 1 summarizes the device characteristics of the Access Cortisol assay on the DxC 500i Clinical Analyzer.

The DxC 500i Clinical Analyzer is an integrated chemistry-immunoassay work cell that combines Beckman Coulter's DxC 500 AU Clinical Chemistry Analyzer and the Access 2 Immunoassay System into a single instrument presentation. The DxC 500i instrument has a single user interface and common point of entry for sample racks; the sample handling unit operates as a parallel processor and sample manager for both sides of the instrument. The DxC 500i operates in conjunction with the existing reagents, calibrators, controls, and system solutions for the AU and Access instrument families.

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. 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.

The DxC 500i Clinical Analyzer combines the DxC 500 AU Clinical Chemistry Analyzer and the Access 2 Immunoassay System into a single instrument presentation. The system is for in vitro diagnostic use only. The chemistry module of the DxC 500i Clinical Analyzer is an automated chemistry analyzer that measures analytes in samples, in combination with appropriate reagents, calibrators, quality control (QC) material and other accessories. The immunoassay module of the DxC 500i Clinical Analyzer is an in-vitro diagnostic device used for the quantitative, semi-quantitative, or qualitative determination of various analyte concentrations found in human body fluids.

Comparison to the Predicate:

The Access Cortisol assay run on the DxC 500i Clinical Analyzer was compared to the Access Cortisol assay run on the stand-alone Access 2 Immunoassay System. Tables 1 and 2 compare the assay and instrument platform characteristics, respectively. The information from the predicate device was derived from the predicate device 510(k) Summary and product labeling.

Table 1 Predicate Device Comparison (Assay)

Feature	Predicate Device: Access Cortisol assay on the Access 2 Immunoassay System (K050202)	Candidate Device: Access Cortisol assay on the DxC 500i Clinical 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. 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.	Same
Methodology	Competitive binding immunoassay with chemiluminescence detection (automated)	Same
Solid Phase	Paramagnetic particles coated with goat anti-rabbit IgG	Same
Conjugate	Cortisol-alkaline phosphatase (bovine) conjugate	Same
Substrate	Access Substrate	Same
Calibrators	Human serum containing cortisol (purified chemical compound) at levels of 0 and approximately 2, 5, 10, 25, and 60 µg/dL	Same
Traceability	USP Reference Material	Same
Calibration Stability	28 days	Same
Reagent Open-Pack Stability	Stable at 2 to 10°C for 14 days after initial use	Same
Sample Type	Serum, plasma, urine	Same
Measuring Range	0.4 to 60.0 µg/dL	2.3 to 60.0 µg/dL
Instrument	Access 2	Access 2 and DxC 500i Clinical Analyzer
Reagent IFU	A33262	D12398A

Table 2 Predicate Device Comparison (Instrument)

Feature	Predicate Device: K121214, Access 2 Immunoassay System	Candidate Device: DxC 500i Clinical Analyzer
Intended Use	The Access 2 Analyzer is an in-vitro diagnostic device used for the quantitative, semi-quantitative, or qualitative determination of various analyte concentrations found in human body fluids.	The DxC 500i Clinical Analyzer combines the DxC 500 AU Clinical Chemistry Analyzer and the Access 2 Immunoassay System into a single instrument presentation. The system is for in vitro diagnostic use only. The chemistry module of the DxC 500i Clinical Analyzer is an automated chemistry analyzer that measures analytes in samples, in combination with appropriate reagents, calibrators, quality control (QC) material and other accessories. The immunoassay module of the DxC 500i Clinical Analyzer is an in-vitro diagnostic device used for the quantitative, semi-quantitative, or qualitative determination of various analyte concentrations found in human body fluids.
Analytical Modules	Access 2 Immunoassay Analyzer with closed chemiluminescence module	A modified Access 2 system serves as the immunoassay module in the DxC 500i work cell configuration. Beckman Coulter's DxC 500 AU Clinical Chemistry Analyzer serves as the chemistry module in the DxC 500i work cell configuration. The analytical processes on both analytical modules are identical to those on the respective stand-alone analyzers; technological characteristics, sample and reagent dispensing, chemistry analysis, and data reduction modules are all unchanged.
Test Systems	Menu of cleared and exempt Access assays; user-enabled system configuration.	Menu of cleared and exempt Access (immunoassay) and AU (chemistry) assays; user-enabled system configuration.
Assay Parameters	Database of Access Assay Protocol Files for Access 2 Systems	Same for immunoassay module; chemistry module uses current AU assay settings.
System Console	Access 2 console for hardware configuration as currently marketed	Shared console for the integrated hardware configuration; manages combined chemistry and immunoassay module operations.

Feature	Predicate Device: K121214, Access 2 Immunoassay System	Candidate Device: DxC 500i Clinical Analyzer
GUI Application	User interface unique to Access 2 Systems	User interface common to new Beckman Coulter analyzers
Specimen Types	Serum, plasma, urine, amniotic fluid, whole blood hemolysate (off-line preparation)	Same; chemistry module includes whole blood (online hemolysate preparation)
Sample Input	Sample rack load area with a sample wheel that accommodates all sample types (routine, STAT, QC, calibration)	Shared sample input area: Continuous sample loading (routine, STAT, QC, calibration, maintenance) from single point of entry on the shared sample handler.
Sample Handling	Open primary tubes/cups loaded in a unique 10-tube rack, continuous loading (patient, STAT, QC, calibration, maintenance samples)	Open primary tubes/cups loaded in a 7-tube rack common to new Beckman Coulter analyzers, continuous loading (patient, STAT, QC, calibration, maintenance samples)
Sample Identification	Stationary internal barcode reader	Dynamic barcode reader attached to the rack shuttle on the shared sample handler
Reagent Loading	Internal fixed barcode reader with refrigerated onboard storage; reagents can be loaded during instrument measurement cycle.	Same
Results Management	The analytical module collects and sends the response data to the instrument console and calculates the final test results for reporting	Same; the shared console collates the chemistry and immunoassay test results.
Track Connectivity	No	Same

Comparison Testing:

Substantial equivalence was demonstrated through non-clinical (bench) studies. CLSI study protocols were used to ensure that the technological differences between the candidate and predicate analyzer models did not adversely affect safety and effectiveness; these performance evaluations included method comparison, linearity, imprecision, and detection limit studies. Additional studies were conducted for carryover and thermal sensitivity.

Summary of Performance Data:

The method comparison studies between the Access Cortisol assay on the DxC 500i Clinical Analyzer and the Access Cortisol assay on the Access 2 Immunoassay System were designed in accordance with CLSI Guideline EP09C-ED3, *Measurement Procedure Comparison and Bias Estimation Using Patient Samples; Third Edition*. The study evaluated both serum and urine using test samples that spanned the measuring range of the assay (2.3 – 60.0 µg/dL). The test results met the slope criteria of 1.00 ± 0.12 using Weighted Deming regression analysis.

Sample Type	Concentration Range (µg/dL)	N	Slope	Slope 95% CI	Intercept (µg/dL)	Correlation Coefficient (r)
Serum	2.3 – 56.2	104	0.974	0.952 – 0.996	0.33	0.993
Urine*	3.1 – 59.0	115	1.002	0.976– 1.029	0.18	0.992

*Unextracted, random collection

Linearity studies were designed in accordance with CLSI Guideline EP06-ED2:2020, *Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach; Approved Guideline, 2nd Edition.* The Access Cortisol assay was determined to be linear throughout the analytical measuring range on the DxC 500i analyzer.

Repeatability (within-run) and within-laboratory (total) precision studies followed CLSI guideline EP05-A3, *Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline - Third Edition*. The Access Cortisol assay met the established performance specification for allowable imprecision of <12% at approximately 5 µg/dL and <10% for higher concentrations for all test samples when run on the DxC 500i analyzer.

DxC 500i Instrument	Test Sample	N	Mean Value (µg/dL)	Repeatability (Within-run)		Total (Within-laboratory)	
				SD (µg/dL)	CV (%)	SD (µg/dL)	CV (%)
1	Control L1	80	3.04	0.15	4.8	0.19	6.4
	Control L2	80	17.7	0.56	3.2	0.63	3.6
	Control L3	80	27.0	0.80	3.0	1.00	3.7
	Serum Pool	80	49.3	1.33	2.7	1.88	3.8
2	Control L1	80	2.95	0.16	5.6	0.21	7.2
	Control L2	80	17.7	0.50	2.8	0.72	4.1
	Control L3	80	26.8	0.77	2.9	0.98	3.6
	Serum Pool	80	47.2	1.40	3.0	2.34	5.0

Detection capability studies followed the CLSI guideline EP17-A2 "*Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures Approved Guideline - Second Edition*". The Access Cortisol assay on the DxC 500i Clinical Analyzer produced the following results:

Parameter	µg/dL	nmol/L
Limit of Blank (LoB)	≤ 0.4	≤ 11
Limit of Detection (LoD)	≤ 0.4	≤ 11
Limit of Quantitation (LoQ) ≤ 20% within-lab CV	≤ 0.8	≤ 22

Substantial Equivalence Conclusion

The data contained in the Premarket Notification supports a finding of substantial equivalence to the measurand test systems already in commercial distribution. The performance testing presented in this submission provides evidence that the device is safe and effective in its Intended Use.