July 17, 2025

Roche Diagnostics
Chunhong (Emma) Tao
Regulatory Affairs Manager
9115 Hague Road
Indianapolis, Indiana 46250

Re: K242505
Trade/Device Name: Elecsys Cortisol III
Regulation Number: 21 CFR 862.1205
Regulation Name: Cortisol (Hydrocortisone And Hydroxycorticosterone) Test System
Regulatory Class: Class II
Product Code: JFT
Dated: July 17, 2025
Received: July 17, 2025

Dear Chunhong (Emma) Tao:

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 Caposino, Ph.D.
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)*
K242505

Device Name
Elecsys Cortisol III

Indications for Use *(Describe)*
Immunoassay for the in vitro quantitative determination of cortisol in human urine. The determination of cortisol is used for the recognition and treatment of functional disorders of the adrenal gland.

The electrochemiluminescence immunoassay "ECLIA" is intended for use on cobas e immunoassay analyzers.

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.

510k Summary
Elecsys Cortisol III (K242505)

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

In accordance with 21 CFR 807.87, Roche Diagnostics hereby submits official notification as required by Section 510(k) of the Federal Food, Drug and Cosmetics Act of our intention to market the device described in this Traditional 510(k) Premarket Notification.

The purpose of this Traditional 510(k) Premarket Notification is to obtain FDA review and clearance for Elecsys Cortisol III.

Submitter Name:	Roche Diagnostics
Address:	9115 Hague Road Indianapolis, IN 46250-0457
Contact:	Emma Tao Phone: (317) 260-1427 Email: emma.tao@roche.com
Date Prepared:	July 15, 2025
Proprietary Name:	Elecsys Cortisol III
Common Name:	Fluorometric, Cortisol
Classification Name:	Cortisol (hydrocortisone and hydroxycorticosterone) test system
Product Code:	JFT
Regulation Number:	21 CFR 862. 1205

Predicate Device:	ARCHITECT Cortisol (K062204)
Establishment Registration	Roche Diagnostics GmbH Mannheim, Germany: 9610126 Roche Diagnostics GmbH Penzberg, Germany: 9610529 Roche Diagnostics Indianapolis, IN United States: 1823260

1. DEVICE DESCRIPTION

The Elecsys Cortisol III immunoassay employs a competitive test principle using a cortisol-specific biotinylated monoclonal antibody and a cortisol-derivative labeled with a ruthenium complex. The Elecsys Cortisol III immunoassay is intended for the *in vitro* quantitative determination of cortisol in human urine. The determination of cortisol is used for the recognition and treatment of functional disorders of the adrenal gland on the **cobas e** immunoassay analyzers.

Results are determined via a calibration curve which is instrument-specifically generated by a two-point calibration and a master curve provided via the **cobas** link.

The Elecsys Cortisol III immunoassay reagent Rack Pack comprises the following:

M Streptavidin-coated microparticles (transparent cap), 1 bottle, 12.4 mL:

Streptavidin-coated microparticles 0.72 mg/mL; preservative.

R1 Anti-cortisol-Ab~biotin (gray cap), 1 bottle, 21.0 mL:

Biotinylated monoclonal anti-cortisol antibody (mouse) 18 ng/mL; danazol 20 µg/mL; MES buffer 100 mmol/L, pH 6.0; preservative.

R2 Cortisol-peptide~Ru(bpy) (black cap), 1 bottle, 21.0 mL:

Cortisol derivative (synthetic), labeled with ruthenium complex, 5 ng/mL; danazol 20 µg/mL; MES buffer 100 mmol/L, pH 6.0; preservative.

MES = 2-morpholino-ethane sulfonic acid

2. INDICATIONS FOR USE

Immunoassay for the *in vitro* quantitative determination of cortisol in human urine. The determination of cortisol is used for the recognition and treatment of functional disorders of the adrenal gland.

The electrochemiluminescence immunoassay "ECLIA" is intended for use on **cobas e** immunoassay analyzers.

3. TECHNOLOGICAL CHARACTERISTICS

The following table compares Elecsys Cortisol III with its predicate device, ARCHITECT Cortisol (K062204).

Table 1: Technical Characteristics Comparison between Elecsys Cortisol III and ARCHITECT Cortisol (K062204)

Item	Elecsys Cortisol III (Candidate Device)	ARCHITECT Cortisol (K062204, Predicate Device)
Intended Use	Immunoassay for the *in vitro* quantitative determination of cortisol in human urine. The determination of cortisol is used for the recognition and treatment of functional disorders of the adrenal gland.	The ARCHITECT Cortisol is a chemiluminescent microparticle immunoassay (CIMA) for the quantitative determination of cortisol in human serum, plasma or urine on the ARCHITECT *i* System. The ARCHITECT Cortisol assay is intended for use as an aid in the diagnosis and treatment of adrenal disorders.
Indications for Use	The results obtained are used for the recognition and treatment of functional disorders of the adrenal gland.	The results obtained are used as an aid in the diagnosis and treatment of adrenal disorders.
Detection Method	electrochemiluminescence immunoassay "ECLIA"	chemiluminescent microparticle immunoassay (CMIA)
Instrument Platform	**cobas e** immunoassay analyzers	ARCHITECT *i* System
Sample Type	Urine	Serum, plasma or urine
Expected Range	8.98 – 86.2 µg/24 h (24.8 – 238 nmol/24 h)	4.3 – 176 µg/24 h
Reportable Range	0.725 – 18.1 µg/dL (20.0 – 500 nmol/L)	0.8 – 59.8 µg/dL

4. NON-CLINICAL PERFORMANCE EVALUATION

The following performance data are provided in support of the substantial equivalence determination. All performance specifications were met.

4.1. Precision

4.1.1. Repeatability and Intermediate Precision

Precision was evaluated with human urine samples (24-hour urine) and controls by testing two replicates per run, two runs per day for 21 days. Repeatability and Intermediate precision were calculated according to CLSI EP05-A3. All data met the predefined acceptance criteria.

cobas e 801 analyzer					
Sample	Mean nmol/L	Repeatability		Intermediate Precision	
		SD nmol/L	CV %	SD nmol/L	CV %
Human Urine 1	88.7	2.41	2.7	3.34	3.8
Human Urine 2	236	5.46	2.3	6.90	2.9
Human Urine 3	296	5.86	2.0	9.37	3.2
Human Urine 4	453	9.39	2.1	14.5	3.2
Control 1	204	4.04	2.0	5.00	2.5
Control 2	374	8.98	2.4	11.3	3.0

cobas e 801 analyzer					
Sample	Mean µg/dL	Repeatability		Intermediate Precision	
		SD µg/dL	CV %	SD µg/dL	CV %
Human Urine 1	3.22	0.0873	2.7	0.121	3.8
Human Urine 2	8.56	0.198	2.3	0.250	2.9
Human Urine 3	10.7	0.212	2.0	0.340	3.2
Human Urine 4	16.4	0.340	2.1	0.525	3.2
Control 1	7.39	0.147	2.0	0.181	2.5
Control 2	13.6	0.325	2.4	0.408	3.0

4.1.2. Reproducibility

Lot-to-lot reproducibility was performed using three reagent lots according to CLSI EP05-A3. All data met the predefined acceptance criteria.

4.2. Analytical Sensitivity

4.2.1. Limit of Blank (LoB)

The Limit of Blank (LoB) was determined according to CLSI EP17-A2. The LoB claim in the labeling will be set to 4.00 nmol/L (0.145 µg/dL).

4.2.2. Limit of Detection (LoD)

The Limit of Detection (LoD) was determined according to CLSI EP17-A2. The LoD claim in the labeling will be set to 7.50 nmol/L (0.272 µg/dL).

4.2.3. Limit of Quantitation (LoQ)

The Limit of Quantitation (LoQ) was determined according to CLSI EP17-A2. The LoQ claim in the labeling will be set to 10.0 nmol/L (0.363 µg/dL).

4.3. Linearity/Assay Reportable Range

Linearity was evaluated on the **cobas e** 801 analyzer according to CLSI EP06-Ed2. The dilution series contained a minimum of 9 concentrations throughout the measuring range. A measuring range of 20.0-500 nmol/L or 0.725-18.1 µg/dL will be claimed in the labeling.

4.4. Human Anti-Mouse Antibodies (HAMA)

The effect of the presence of human anti-mouse antibodies (HAMA) was assessed on the **cobas e** 801 analyzer. The differentiation between HAMA-negative and HAMA-positive samples was assessed. Data met the predefined acceptance criteria.

4.5. Endogenous Interferences

The effect on quantitation of Cortisol in the presence of thirteen endogenous interfering substances (lipemia, biotin, bilirubin, hemoglobin, rheumatic factor, human serum albumin, human IgG, human IgM, human IgA, Sodium Chloride, Urea, glucose, and creatinine) was tested using human urine samples (24-hour urine). No significant interference for the assay was observed up to the concentrations of the potential interfering substances tested as shown in the table below.

Compound	Concentration tested
Bilirubin	≤ 1130 µmol/L or ≤ 66 mg/dL
Hemoglobin	≤ 0.621 mmol/L or ≤ 1000 mg/dL
Intralipid	≤ 2000 mg/dL
Biotin*	≤ 204658 nmol/L or ≤ 50000 ng/mL
Rheumatoid Factor	≤ 1200 IU/mL
Human IgG	≤ 7.0 g/dL
Human IgA	≤ 1.6 g/dL
Human IgM	≤ 1.0 g/dL
Human serum albumin	≤ 4.9 g/dL
Creatinine	≤ 5 mmol/L
Glucose	≤ 5 mmol/L
NaCl	≤ 750 mmol/L
Urea	≤ 350 mmol/L

* Biotin was tested at 100,000 ng/mL. The data supports no interference up to 50,000 ng/mL.

4.6. Analytical Specificity/Cross-Reactivity

A cross-reactivity study was conducted on the **cobas e** 801 analyzer to evaluate the potential cross-reacting compounds using human urine (24-hour urine). Samples were measured in the presence and absence of the potential cross-reactants and cross-reactivity was calculated with one lot of reagents. The following cross-reactivities (in %) were found at the respective cross-reactant concentration, tested with a cortisol concentration of approximately 17 nmol/L (0.6 µg/dL).

Cross-Reactant	Concentration tested µg/dL	Cross reactivity %
11-Deoxycorticosterone	100	0.174
11-Deoxycortisol	50	24.3
17α-Hydroxyprogesterone	1000	0.412
21-Deoxycortisol	100	2.33
Corticosterone	750	0.368
Cortisone	500	1.49
Androstenedione	100	n. d.d)
DHEAS	1000	n. d.
DHEA	1000	n. d.
Progesterone	1000	0.00930
Testosterone	1000	n. d.

Cross-Reactant	Concentration tested µg/dL	Cross reactivity %
Estradiol	1000	n. d.
Estriol	1000	n. d.
Estrone	1000	n. d.
Aldosterone	1000	n. d.
Pregnenolone	1000	n. d.
17α-Hydroxypregnenolone	1000	0.0417
11β-Hydroxyprogesterone	1000	0.0173
Pregnanetriol	1000	n. d.
6α-Hydroxycortisol	100	n. d.
6β-Hydroxycortisol	100	0.0698
Cortisol-21 glucuronide	1000	0.0301
Allotetrahydrocortisol	10	11.3
Cortisol-21-sulfate	1000	n. d.
β-Cortol	1000	n. d.
β-Cortolone	1000	n. d.
Pregnanediol	1000	n. d.
Tetrahydrocortisol	10	n. d.

4.7. Exogenous Interferences – Drugs

In vitro tests were performed on 12 commonly used pharmaceuticals. No interference with the assay was found. At concentrations corresponding to the daily therapeutic dose, the special drugs prednisolone and hydrocortisone caused elevated concentrations of cortisol. For the special drug 6 methylprednisolone, no interference was observed for concentrations ≤ 0.157 mg/dL.

In addition, the following special drugs were tested. No interference with the assay was found.

Drug	Concentration tested mg/dL
Amlodipine	0.008
Betamethasone	0.0345
Beclomethasone	0.000631
Budenoside	0.00063
Canrenone	0.075
Dexamethasone	1.20
Fludrocortisone	0.120
Fluticasone propionate	0.0003

Drug	Concentration tested mg/dL
HCT (hydrochlorothiazide)	4.77
Lisinopril	27
Losartan potassium	0.092
Metformin	850
Metoprolol	0.150
Mometasone	0.000045
Prednisone	0.010
Spironolactone	0.0555
Triamterene	0.059
Valsartan	1.17
Verapamil	0.160
Triamcinolone	0.003
Atorvastatin	0.075
Danazol	0.030
Diclofenac	2.40
β-Sitosterol	1.00

4.8. Method Comparison

Method comparison was performed between the candidate device and the predicate device using native 24 h urine samples. Samples span the measuring range. Data was analyzed according to CLSI EP09-A3 and met all predefined acceptance criteria.

4.9. Stability

The stability studies were performed and the predefined acceptance criteria were met. The stability data supports the claims as reported in labeling.

Stability:	
unopened at 2-8 °C	up to the stated expiration date
on the analyzer	16 weeks

5. REFERENCE RANGE STUDY

A study was performed to determine the expected values of the Elecsys Cortisol III assay in 24 h urine samples from an apparently healthy population in the United States. Samples were

collected across three study sites according to the inclusion and exclusion criteria. An additional study site did sample testing. The reference range was computed and reported as the 2.5th and 97.5th percentiles for pooled data from all study sites and with all sites combined according to CLSI EP28-A3c.

2.5th percentile	97.5th percentile	Unite
24.8	238	nmol/24h
8.98	86.2	µg/24h

6. ADDITIONAL INFORMATION

Elecsys Cortisol III is intended to be used with the following calibrators and controls:

- CalSet Cortisol III Urine
- PreciControl Cortisol Urine

7. CONCLUSIONS

The information provided in this 510(k) Premarket Notification supports the determination that Elecsys Cortisol III is equivalent to the predicate device, ARCHITECT Cortisol (K062204).