Food and Drug Administration
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510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY

I Background Information:

A 510(k) Number

K192788

B Applicant

Siemens Healthcare Diagnostics, Inc.

C Proprietary and Established Names

ADVIA Centaur Cortisol (COR)

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
JFT	Class II	21 CFR 862.1205 - Cortisol (Hydrocortisone And Hydroxycorticosterone) Test System	CH - Clinical Chemistry

II Submission/Device Overview:

A Purpose for Submission:

Addition of K2-EDTA and lithium heparin plasma sample types.

B Measurand:

Cortisol

C Type of Test:

Chemiluminescent Immunoassay

III Intended Use/Indications for Use:

A Intended Use(s):

See Indication(s) for Use below.

B Indication(s) for Use:

For in vitro diagnostic use in the quantitative determination of cortisol in serum, plasma (EDTA and lithium heparin), and urine using the ADVIA Centaur XP system. Measurements of cortisol are used in the diagnosis and treatment of disorders of the adrenal gland.

C Special Conditions for Use Statement(s):

Prescription use only

D Special Instrument Requirements:

ADVIA Centaur XP

IV Device/System Characteristics:

A Device Description:

The ADVIA Centaur Cortisol (COR) assay is a competitive immunoassay using direct chemiluminescent technology. Results are determined using a calibration curve that is generated specifically on each instrument by a 2-point calibration and a master curve with the reagent bar code.

The ADVIA Centaur COR reagent kit contains the following:
ADVIA Centaur ReadyPack® primary reagent pack contains Lite Reagent and Solid Phase Reagent. Lite reagent consists of 2.5 mL reagent pack with cortisol labeled with acridinium ester in buffered saline with sodium salicylate (~50 mg/mL), sodium azide (0.1%) and preservatives. Solid phase reagent consists of 12.5 mL reagent pack with rabbit anti-cortisol antibody (~1.1 µg/mL) bound to monoclonal mouse anti-rabbit IgG antibody (~56 µg/mL) covalently coupled to paramagnetic particles in buffered saline with sodium azide (0.1%) and preservatives.

B Principle of Operation:

The ADVIA Centaur Cortisol (COR) assay is a competitive immunoassay using direct chemiluminescent technology. Cortisol in the patient sample competes with acridinium ester labeled cortisol in the Lite Reagent for binding to polyclonal rabbit anti-cortisol antibody in the Solid Phase. The polyclonal rabbit anti-cortisol antibody is bound to monoclonal mouse anti-rabbit antibody, which is covalently coupled to paramagnetic particles in the Solid Phase. An inverse relationship exists between the amount of cortisol present in the patient sample and the amount of relative light units (RLUs) detected by the instrument.

V Substantial Equivalence Information:

A Predicate Device Name(s):
ADVIA Centaur Cortisol (COR) Assay

B Predicate 510(k) Number(s):
K142723

C Comparison with Predicate(s):

Device & Predicate Device(s):	K192788	K142723
Device Trade Name	ADVIA Centaur Cortisol (COR) Assay	Same
General Device Characteristic Similarities and differences		
Intended Use/Indications For Use	For in vitro diagnostic use in the quantitative determination of cortisol in serum, plasma (EDTA and lithium heparin), and urine using the ADVIA Centaur Systems. Measurements of cortisol are used in the diagnosis and treatment of disorders of the adrenal gland.	Same
Traceability	Internal Standards traceable to GCMS	Same
Assay Range	Serum and Plasma: 0.50–75 µg/dL Urine: 0.50–53 µg/dL	Serum: 0.50–75 µg/dL Urine: 0.50–53 µg/dL
Sample Type	Serum, Plasma (EDTA and lithium heparin), Urine.	Serum and Urine

VI Standards/Guidance Documents Referenced:

CLSI EP07-Ed3: Interference Testing in Clinical Chemistry

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:
   Previously established in k142723.

2. Linearity:
   Previously established in k142723.

3. Analytical Specificity/Interference:
   Interference testing was conducted according to CLSI EP07-ed3: Interference Testing in Clinical Chemistry. Interfering substances were tested using human K2-EDTA and heparin pools. Various concentration of interferents were spiked into one pool at low and one at high cortisol concentrations for each matrix. The same sample pools with no interferents were used as controls. All samples were run in triplicate using ADVIA Centaur XP instrument and one reagent lot. The sponsor defined non-significant interference as ≤10% difference between the spiked samples and control. Results are summarized below.

Potential Interferent	Highest concentration tested that showed no interference
K2-EDTA	9.0 mg/mL
Lithium heparin	75 U/mL

4. Assay Reportable Range:
   Previously established in k142723.

5. Traceability, Stability, Expected Values (Controls, Calibrators, or Methods):
   Previously established in k142723.

6. Detection Limit:
   Previously established in k142723.

7. Assay Cut-Off:

   Not applicable.

B Comparison Studies:

1. Method Comparison with Predicate Device:
   Previously established in k142723.

2. Matrix Comparison:

A matrix comparison study was performed to demonstrate sample equivalence between serum and plasma (K2-EDTA and lithium heparin). Matched sample sets were tested using one ADVIA Centaur (COR) assay reagent lot and one ADVIA Centaur XP instrument. One replicate was tested for each sample. A total of 83 dipotassium EDTA plasma/serum and 99 lithium heparin plasma/serum sample pairs were tested. Deming linear regression analysis was used to analyze measured values using serum as the comparator. The results are shown in the table below.

Comparison	N*	Correlation Coefficient (r)	Regression Equation	Sample Range
K2EDTA Plasma vs. Serum	83	1.00	y = 0.95x + 0.24	0.29-67.06 µg/dL
Lithium Heparin Plasma vs. Serum	99	1.00	y = 0.96x + 0.54	0.29-67.06 µg/dL

*N=Number of samples tested

C Clinical Studies:

1. Clinical Sensitivity:

Not applicable.

2. Clinical Specificity:

Not applicable.

3. Other Clinical Supportive Data (When 1. and 2. Are Not Applicable):

Not applicable.

D Clinical Cut-Off:

Not applicable.

E Expected Values/Reference Range:

Previously established in k142723.

VIII Proposed Labeling:

The labeling supports the finding of substantial equivalence for this device.

IX Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.