510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY TEMPLATE

A. 510(k) Number:
k091123

B. Purpose for Submission:
New Device

C. Measurand:
Dehydroepiandrosterone sulfate (DHEAS)

D. Type of Test:
Calibration verification material for the ADVIA® Centaur Systems DHEAS assay

E. Applicant:
Siemens Healthcare Diagnostics Inc.

F. Proprietary and Established Names:
ADVIA® Centaur DHEAS Master Curve Materials

G. Regulatory Information:

1. Regulation section:
   21 CFR § 862.1660 Quality control material (assayed and unassayed)
2. Classification:
   Class I (reserved)
3. Product code:
   JJX, Single (specified) analyte controls (assayed and unassayed)
4. Panel:
   Clinical Chemistry (75)

H. Intended Use:

1. Intended use(s):
   See Indication(s) for use below.

2. Indication(s) for use:
   The ADVIA Centaur (DHEAS) Master Curve Materials are for *in vitro* diagnostic use in the verification of calibration and reportable range in the ADVIA Centaur Systems Dehydroepiandrosterone sulfate (DHEAS) assay.

3. Special conditions for use statement(s):
   For *In Vitro* Diagnostic Use; For Prescription Use Only; To be used with the ADVIA Centaur Systems DHEAS assay; Not to be used as routine quality control material or as calibration material

4. Special instrument requirements:
   Not applicable

I. Device Description:

The ADVIA Centaur (DHEAS) Master Curve Materials (MCM) are 5 levels of varying concentrations of DHEAS in delipidated, steroid stripped, human defribrinated plasma with preservative. The MCM have expected values (lot specific) of approximately 0, 60, 300, 900 and 1500 µg/dL. The MCM (1.0 mL per vial) are liquid and ready to use.

All human source materials used in the preparation of the proposed device were tested using FDA-approved methods and found to be non-reactive for hepatitis B surface antigen (HBsAg), antibody to hepatitis C (HCV), and antibody to HIV-1/2.

J. Substantial Equivalence Information:

1. Predicate device name(s):
   Maine Standards Company, VALIDATE Thyroid Calibration Verification Test Set

2. Predicate 510(k) number(s):
   k062501

3. Comparison with predicate:

Item	Device	Predicate (k062501)
Similarities		
Intended use	For *in vitro* diagnostic use in the verification of calibration and reportable range in the ADVIA Centaur Systems Dehydroepiandrosterone sulfate (DHEAS) assay.	For in vitro diagnostic use in the quantitative determination of linearity, calibration verification and verification of reportable range in chemistry systems for the following analytes: Triiodothyronine (T3), Thyroxine (T4), human Thyroid Stimulating Hormone (TSH), and Cortisol.
Form	Liquid	same
Differences		
Analytes	DHEAS	T3, T4, TSH and Cortisol
Matrix	Human plasma	Human serum
Storage	2 to 8 °C	-10 to -20 °C
Stability	Unopened—until expiration date on the vial label Opened—60 days	Unopened—until expiration date on storage container

K. Standard/Guidance Document Referenced (if applicable):

- Guidance for Industry and FDA Staff – Assayed and Unassayed Quality Control Material

L. Test Principle:
Not Applicable

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:
Not Applicable

b. Linearity/assay reportable range:
Not Applicable

c. Traceability, Stability, Expected values (controls, calibrators, or methods):
Traceability: The ADVIA Centaur DHEAS Master Curve Material are traceable to an internal standard manufactured using purified DHEAS.

Value assignment: Each of the five MCM levels is value assigned using one ADVIA Centaur analyzer, one lot of calibrators and one lot of the ADVIA Centaur DHEAS reagent. At least 3 vials are assayed for each level. MCM 1 is assayed in replicates of 10 on 2 separate runs. For MCM 2 through 5, a "nested test" protocol was used where the samples are assayed with alternating samples of the lot to be value assigned "test lot" and the reference lot used to confirm value assignment. Twenty replicates of the test lot and 20 replicates of the reference lot are assayed. The target values are given in the table below:

MCM Level	Concentration (µg/dL)
MCM 1	0
MCM 2	60
MCM 3	300
MCM 4	900
MCM 5	1500

Stability: The unopened stability of the ADVIA Centaur DHEAS MCM was determined using accelerated studies and real-time studies. The sponsor currently has real-time data supporting 108 weeks of closed vial stability when the product is stored at 2 to 8 ^{o}C. The sponsor will claim 18 months of unopened shelf life at 2 to 8 ^{o}C.

The open vial stability was determined using real-time studies. The sponsor currently has data supporting 9 weeks of open-vial stability when the product is stored at 2 to 8 ^{o}C. The sponsor will claim 60 days of open vial stability at 2 to 8 ^{o}C

The sponsor presented data for the in-use stability of the product. The data supports the claim that the ADVIA Centaur DHEAS MCM are stable up to 8

hours when stored at 20 to 25 °C. The sponsor will claim 8 hours of in-use stability at 20 to 25 °C.

d. Detection limit:
Not Applicable

e. Analytical specificity:
Not Applicable

f. Assay cut-off:
Not Applicable

2. Comparison studies:
   a. Method comparison with predicate device:
   Not Applicable

   b. Matrix comparison:
   Not Applicable

3. Clinical studies:
   a. Clinical Sensitivity:
   Not Applicable

   b. Clinical specificity:
   Not Applicable

   c. Other clinical supportive data (when a. and b. are not applicable):
   Not Applicable

4. Clinical cut-off:
   Not Applicable

5. Expected values/Reference range:
   Assigned values for the ADVIA Centaur DHEAS MCM are provided in the DHEAS lot specific target value sheet.

N. Proposed Labeling:
The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

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