

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

A. 510(k) Number:

k092993

B. Purpose for Submission:

New device

C. Measurand:

Calibration verification materials

D. Type of Test:

N/A

E. Applicant:

Siemens Healthcare Diagnostics, Inc.

F. Proprietary and Established Names:

ADVIA Centaur Cyclosporine Master Curve Material

G. Regulatory Information:

1. Regulation section:

21 CFR 862.1660 Single, specified controls (assayed and unassayed)

2. Classification:

Class I, reserved

3. Product code:

JJX

4. Panel:

Clinical Chemistry (75)

H. Intended Use:

1. Intended use(s):

See indications for use below

2. Indication(s) for use:

The ADVIA Centaur® Cyclosporine Master Curve Material is for *in vitro* diagnostic use in the verification of calibration and reportable range in the ADVIA Centaur® Cyclosporine (CsA) assay.

3. Special conditions for use statement(s):

For prescription use only

4. Special instrument requirements:

ADVIA Centaur® Systems

I. Device Description:

The ADVIA Centaur® Cyclosporine Master Curve Material are 5 level human serum based solutions containing varying concentrations of cyclosporine in human serum, detergents, glycerol, anti-foam and preservatives. The Cyclosporine Master Curve Materials have expected values (lot specific) of approximately 0, 100, 500, 900 and 1400 ng/mL. The Cyclosporine Master Curve Material (1.0 mL/vial) is liquid and ready to use. Storage is at 2 -8° C.

The labeling contains the following information:

“Contains human source material. While each human serum or plasma donor unit used in the manufacture of this product was tested by FDA-approved methods and found nonreactive for hepatitis B surface antigen (HBsAg), antibody to hepatitis C (HCV) and antibody to HIV-1/2, all products manufactured using human source material should be handled as potentially infectious. Because no test method can offer complete assurance that hepatitis B or C viruses, HIV, or other infectious agents are absent, these products should be handled according to established good laboratory practices.”

J. Substantial Equivalence Information:

1. Predicate device name(s):

VALIDATE Thyroid Calibration Verification Test Set

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

k062501

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Intended use	For in vitro diagnostic use in the verification of calibration and reportable range in the ADVIA Centaur Cyclosporine Assay	For in vitro diagnostic use in the quantitative determination of linearity, calibration verification, and verification of reportable range in automated, semi-automated and manual chemistry systems
Form	liquid	liquid
Storage	2 -8° C	-10 to -20 ° C
Matrix	human serum	human serum

Differences		
Item	Device	Predicate
Analyte list	Cyclosporine only	Multi-analytes including triiodothyronine, thyroxine, TSH and cortisol

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

None referenced

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):

The Master Curve Material is traceable to an internal standard manufactured using USP grade cyclosporine.

The ADVIA Centaur® Cyclosporine Master Curve Material is prepared utilizing various amounts of a cyclosporine positive stock solution and negative basepool. The assigned values are established by comparison studies to a reference lot of master curve materials using the ADVIA Centaur Cyclosporine Assay. Value assignment is performed using one ADVIA Centaur instrument with one lot of ADVIA Centaur Cyclosporine reagent assaying the material and reference material in multiple replicates and multiple runs. The within run CV of the 20 replicates met the sponsor's acceptance criteria of $\leq 8\%$. The acceptance criteria of the test lot assigned value to the reference lot met the acceptance criteria of $\pm 15\%$. The ranges for the assigned values were established by calculating $\pm 25\%$ of the assigned value.

The labeling includes a statement that if results do not fall within expected values, technical support should be contacted.

The protocol for establishing shelf-life for the Master Curve Material was reviewed and is adequate. The shelf stability is 2 years when properly stored at 2-8 ° C. Open stability was established to be up to 21 weeks when stored at 2-8 ° 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:
Lot specific target values are provided in the labeling.

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.