

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

A. 510(k) Number:

k072204

B. Purpose for Submission:

New device

C. Measurand:

Not applicable – calibrator for Microalbumin

D. Type of Test:

Calibrators for ADVIA® Chemistry Microalbumin and Microalbumin_2 test systems

E. Applicant:

Siemens Medical Solutions Diagnostics

F. Proprietary and Established Names:

ADVIA® Chemistry Microalbumin Calibrators

ADVIA® Chemistry Microalbumin_2 Calibrators

G. Regulatory Information:

1. Regulation section:
21 CFR Section 862.1150, Calibrator
2. Classification:
Class II
3. Product code:
JIX, Calibrator, Multi-analyte mixture
4. Panel:
Chemistry (75)

H. Intended Use:

1. Intended use(s):
See Indications for use below.
2. Indication(s) for use:
The ADVIA® Chemistry Microalbumin Calibrators are for *in vitro* diagnostic use in the calibration of ADVIA Chemistry systems for the ADVIA Chemistry Microalbumin method (this method is used for *in vitro* quantitation of albumin in

urine).

The ADVIA[®] Chemistry Microalbumin_2 Calibrators are for *in vitro* diagnostic use in the calibration of ADVIA Chemistry systems for the ADVIA Chemistry Microalbumin_2 method (this method is used for *in vitro* quantitation of albumin in urine).

3. Special conditions for use statement(s):

For prescription use

4. Special instrument requirements:

For use with ADVIA Chemistry systems

I. Device Description:

The ADVIA[®] Chemistry Microalbumin Calibrators and ADVIA[®] Chemistry Microalbumin_2 Calibrators are aqueous, buffered solutions containing varying concentrations of human serum albumin. Five (5) vials of each calibrator level are provided (2 mL each). The Microalbumin Calibrators have expected values (lot specific) of 1, 2.5, 5, 10, and 20 mg/dL, and the Microalbumin_2 Calibrators have expected values (lot specific) of 1, 4, 10, 20, and 40 mg/dL.

The calibrators are liquid and ready to use.

The human blood used in the manufacture of these calibrators has been tested using FDA approved methods and found to be nonreactive for HBsAg and antibodies to HCV and HIV-1/2.

J. Substantial Equivalence Information:

1. Predicate device name(s):

DCL Microalbumin Multi-Calibrator Set

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

k042243

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Intended use	For <i>in vitro</i> diagnostic use in the calibration of ADVIA Chemistry systems for the Microalbumin method or Microalbumin_2 method (for quantitation of albumin in urine)	For <i>in vitro</i> diagnostic use as a calibrator for the DCL Microalbumin Assay for quantitation of albumin in human urine
Matrix	same	Liquid, ready-to-use

Differences		
Item	Device	Predicate
Calibrator levels	5 levels, values are lot specific	6 levels, values are lot specific
Stability	Shelf life 2 years when unopened and stored at 2-8°C. Microalbumin: Once opened, stable for 28 days at 2-8°C. Microalbumin_2: Once opened, stable for 60 days at 2-8°C.	Unopened calibrators are stable until expiration date when stored at 2-8°C Once opened, stable for 30 days at 2-8°C.

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

FDA/CDRH Guidance for Industry: Abbreviated 510(k) Submissions for In Vitro Diagnostic Calibrators (issued February 22, 1999)

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 Microalbumin and Microalbumin_2 calibrators are traceable to Master lots of the Microalbumin and Microalbumin_2 calibrators which are assayed against an internally prepared, highly purified human serum albumin standard.

The value assignment process consists of assaying and comparing new lots of calibrators and Master lots in a nested test protocol using the appropriate ADVIA Chemistry Microalbumin reagent on the ADVIA1650 analyzer. The final value assigned to each analyte is lot specific and is found on the Assigned Calibrator Value sheet that is provided with the product.

Stability: The shelf-life and open-vial stability of Microalbumin and Microalbumin_2 calibrators when stored at 2-8°C have been demonstrated using real time and accelerated stability data and predetermined acceptance criteria. The protocols were reviewed and found to be acceptable.

For both the Microalbumin and Microalbumin_2 calibrators, the sponsor claims a shelf life of 2 years when unopened and stored at 2-8°C. Once opened the Microalbumin and Microalbumin_2 calibrators are stable for 28 days and for 60 days respectively 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:
Not applicable

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 substantial equivalence decision.