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

A. 510(k) Number:

k093732

B. Purpose for Submission:

New calibrator materials

C. Measurand:

Not applicable for calibrator materials.

D. Type of Test:

Not applicable for calibrator materials.

E. Applicant:

Siemens Healthcare Diagnostics Inc.

F. Proprietary and Established Names:

Advia Chemistry Drug Calibrator I

G. Regulatory Information:

1. Regulation section:

   21 CFR 862.3200

2. Classification:

   Class II

3. Product code:

   DLJ

4. Panel:

   91 Clinical toxicology

H. Intended Use:

1. Intended use(s):
   See indications for use, below.

2. Indication(s) for use:

   The ADVIA® Chemistry DRUG Calibrator I is for *in vitro* diagnostic use in the calibration of Phenobarbital_2 (PHNB_2), Phenytoin_2 (PHNY_2), and Theophylline_2 (THEO_2) methods on the ADVIA Chemistry Systems.

3. Special conditions for use statement(s):

   For prescription use.

4. Special instrument requirements:

   The 510(k) describes value assignment based on the Advia.

I. Device Description:

ADVIA Chemistry TDM DRUG Calibrator I is a liquid, human serum based product containing multiple drugs, provided as ready to use. Phenobarbital, Phenytoin, and Theophylline are value assigned for ADVIA Chemistry Systems.
Assigned analyte concentrations are shown below:

	Analyte Concentration (µg/mL)				
Analyte	Level 1	Level 2	Level 3	Level 4	Level 5
Phenobarbital	0.0	10.0	20.0	40.0	80.0
Phenytoin	0.0	4.5	9.0	18.0	36.0
Theophylline	0.0	5.0	10.0	20.0	40.0

The manufacturer includes the following as a caution in the product insert:
POTENTIAL BIOHAZARD: 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):

   Dade Behring Dimension Drug Calibrator

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

   k011035

3. Comparison with predicate:

   The new device is physically the same as the predicate device. However the two devices are for use on two different instrument systems. In addition the predicate device has assigned values for lithium and digoxin (as well as phenobarbital, phenytoin, and theophylline; the new device does not.

New Device – The ADVIA Chemistry Drug I Calibrator	**Predicate Device -** (formerly) Dade Behring Dimension Drug Calibrator (DC22B)
The ADVIA Chemistry Drug I Calibrator is for *in vitro* diagnostic use in the calibration of Phenobarbital_2 (PHNB_2), Phenytoin_2 (PHNY_2), and Theophylline_2 (THEO_2) methods on the ADVIA® Chemistry Systems	DRUG CAL I is an *in vitro* diagnostic product to be used to calibrate digoxin, lithium, phenobarbital, phenytoin and theophylline methods on the Dimension® System

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

FDA Guidance for Industry - Abbreviated 510(k) Submissions for In Vitro Diagnostic Calibrators

L. Test Principle:

Not applicable; the submission is for calibrator materials only.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

Only item c- traceability and stability is applicable for this submission for calibrator materials only.

a. Precision/Reproducibility:

b. Linearity/assay reportable range:

c. Traceability, Stability, Expected values (controls, calibrators, or methods):

Traceability and value assignment

The calibrator value is described as traceable to USP materials. The process for value assignment, and the uncertainty in measurement, was described in the 510(k). Initial value assignments involve alignment with a master lot of a previously cleared Siemens calibrator, and confirmation by method comparisons using patient samples.

The table below shows results for USP reference materials and Siemens Master Lot calibrators measured as test samples after calibration with a representative lot of ADVIA Chemistry DRUG Cal I .

ADVIA Chemistry DRUG Cal I			**Master lot as test samples**		**USP-spike reference samples as test**	
	Target values (µg/mL)	**Assigned values for the lot**	**Measured value**	**%-difference in recovery (%CV)**	**Measured value**	**%-difference (recovery vs. USP target with a rep. lot for calibration)**
Phenobarbital (µg/mL)						
Level 1	0	0	< LOD	NA	< LOD	NA
Level 2	10	10.2	10.2	2.00%	10.9	9.00%
Level 3	20	21.4	20.8	4.00%	20.9	4.50%
Level 4	40	40.5	43.3	8.30%	43.5	8.70%
Level 5	80	83.4	79.6	-0.50%	82.8	3.50%
Phenytoin (µg/mL)						
Level 1	0	0	< LOD	NA	< LOD	NA
Level 2	4.5	4.5	4.9	-2.00%	4.6	-8.00%
Level 3	9	9	10.4	4.00%	9.6	-4.00%
Level 4	18	18.8	20	0.00%	19.2	-4.00%
Level 5	36	36.6	42	5.00%	38.6	-3.50%
Theophylline (µg/mL)						
Level 1	0	0	< LOD	NA	< LOD	NA

Level 2	5	5	4.9	-2.00%	5.3	6.00%
Level 3	10	10	10	0.00%	10.5	5.00%
Level 4	20	20	21	5.00%	21.6	8.00%
Level 5	40	40	42.8	7.00%	42	9.00%

Stability

The ADVIA Chemistry DRUG Calibrator I is the same product as the Dade Behring Dimension DRUG Calibrator I (which was cleared previously under k011035 and k861786). The manufacturer's claimed shelf-life stability (of 18 months) and open-vial stability (of 3 months) are assigned based on the same protocols and criteria as for the original cleared products.

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 reviewed for this device type.

b. Clinical specificity:

Not reviewed for this device type.

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

4. Clinical cut-off**:**

   Not applicable

5. Expected values/Reference range:

   The assigned 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.