

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

A. 510(k) Number:

k090900

B. Purpose for Submission:

New device

C. Measurand:

Carbamazepine, Gentamicin, Tobramycin, Valproic Acid, Vancomycin

D. Type of Test:

Calibrator Materials

E. Applicant:

Siemens Healthcare Diagnostics Inc.

F. Proprietary and Established Names:

ADVIA Chemistry DRUG Calibrator II

G. Regulatory Information:

| Product Code | Classification | Regulation Section | Panel |
|--------------|----------------|--------------------|-----------------|
| DKB | Class II | 21 CFR§ 862.3200 | Toxicology (91) |

H. Intended Use:

1. Intended use(s):

See Indications for Use below.

2. Indication(s) for use:

The ADVIA Chemistry TDM DRUG Calibrator II is for *in vitro* diagnostic use in the calibration of Carbamazepine₂ (CARB₂), Gentamicin₂ (GENT₂), Tobramycin₂ (TOBR₂), Valproic Acid₂ (VPA₂), and Vancomycin₂ (VANC₂) methods on the ADVIA Chemistry Systems.

3. Special conditions for use statement(s):

For prescription use only

4. Special instrument requirements:

ADVIA Clinical Chemistry Systems

I. Device Description:

ADVIA Chemistry TDM DRUG Calibrator II is a multi-analyte, liquid, bovine serum based product containing multiple analytes. The kit consists of 2 vials of each of 5 calibrator levels which are ready for use (no preparation is required). The volume per vial is 5.0 mL. Tobramycin, Carbamazepine, Valproic Acid, Vancomycin and Gentamicin analytes are value assigned for ADVIA Chemistry systems.

J. Substantial Equivalence Information:

1. Predicate device name(s):
Dade Behring Dimension DRUG Calibrator II

2. Predicate 510(k) number(s):
k033809

3. Comparison with predicate:

| SIMILARITIES | | |
|---------------------|--|--|
| Item | Candidate Device | Predicate Device |
| Intended Use | For <i>in vitro</i> diagnostic use in the calibration of Carbamazepine_2 (CARB_2), Gentamicin_2 (GENT_2), Tobramycin_2 (TOB_2), Valproic Acid_2 (VPA_2), and Vancomycin_2 (VANC_2) methods on the ADVIA Chemistry systems. | DRUG CAL II is an in vitro diagnostic product for the calibration of the following methods packaged in the Flex reagent cartridges: acetaminophen (ACTM), carbamazepine (CRBM), digitoxin (DGTX), gentamicin (GENT), lidocaine (LIDO), N-acetylprocainamide (NAPA), procainamide (PROC), tobramycin (TOBR), valproic acid (VALP), and vancomycin (VANC). |
| Form | Liquid | Liquid |
| Traceability | USP | USP |
| Matrix | Bovine | Bovine |
| Number of Levels | Five, 5.0 mL each vial | Five, 5.0 mL each vial |
| Stability | 12 months – shelf-life 30 days open vial | 12 months – shelf-life 30 days open vial |
| Packaging | Ten vials | Ten vials |

| DIFFERENCES | | |
|---|-------------------------|-----------------------------|
| Item | Candidate Device | Predicate Device |
| Measured Analytes (value assigned) | Carbamazepine (CARB_2), | carbamazepine (CRBM) |
| | Tobramycin (TOBR_2) | tobramycin (TOBR) |
| | Valproic Acid_2 (VPA_2) | acetaminophen (ACTM) |
| | Vancomycin_2 (VANC_2). | digitoxin (DGTX) |
| | Gentamicin_2 (GENT_2) | gentamicin (GENT) |
| | | lidocaine (LIDO) |
| | | N-acetylprocainamide (NAPA) |
| | | procainamide (PROC) |
| | | valproic acid (VALP) |
| | | vancomycin (VANC). |

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

- CEN 13640: Stability Testing of In Vitro Diagnostic Reagents
- Guidance for Industry - Abbreviated 510(k) Submissions for In Vitro Diagnostic Calibrators (1999)
- Format for Traditional and Abbreviated 510(k)s - Guidance for Industry and FDA Staff (2005)

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:
All measurands in the calibrator (carbamazepine, gentamicin, tobramycin, vancomycin, valproic acid) are traceable to an internal Anchor Calibrator.

The Anchor Calibrator is in turn traceable to USP material gravimetrically spiked into human serum.

Stability:

The stability of the calibrators is established through real-time data. Testing is conducted at multiple time points and must pass pre-defined acceptance criteria. The unopened product refrigerated at 4°C is stable for 12 months. The opened product is stable for 30 days, refrigerated at 2 - 8 °C.

Value Assignment:

Values are assigned to production lots by using an ADVIA Clinical Chemistry System calibrated with the Anchor Calibrator and adjusted with a ratio derived from the Anchor Calibrator assigned value (target value) and the mean recovery of the Anchor Calibrator values (observed). The table below shows the target values for one specific lot of calibrator material

| Analyte Concentration (ug/mL) | | | | | |
|-------------------------------|---------|---------|---------|---------|---------|
| Analyte | Level 1 | Level 2 | Level 3 | Level 4 | Level 5 |
| Carbamazepine | 0.0 | 2.9 | 6.1 | 12.8 | 21.9 |
| Gentamicin | 0.0 | 1.6 | 3.3 | 6.5 | 12.7 |
| Tobramycin | 0.0 | 1.5 | 3.0 | 6.0 | 12.6 |
| Vancomycin | 0 | 5.2 | 10.5 | 21.1 | 44.4 |
| Valproic Acid | 0 | 18.8 | 37.5 | 75.0 | 157.5 |

- 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 a substantial equivalence decision.