

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

A. 510(k) Number:

k062121

B. Purpose for Submission:

New device

C. Measurand:

Calibrator for acetaminophen, carbamazepine, digitoxin, gentamicin, lidocaine, N-acetylprocainamide, procainamide, tobramycin, valproic acid, and vancomycin assays.

D. Type of Test:

Not applicable. This submission is for clearance of a calibrator.

E. Applicant:

Dade Behring, Inc.

F. Proprietary and Established Names:

Dimension Vista™ System Drug 2 Calibrator (DRUG 2 CAL – KC420)

G. Regulatory Information:

Product Code	Classification	Regulation Section	Panel
<u>DKB</u>	<u>II</u>	<u>862.3200</u>	<u>91</u>

H. Intended Use:

1. Intended use(s):

The DRUG 2 CAL is an *in vitro* diagnostic product for the calibration of acetaminophen (ACTM), carbamazepine (CRBM), digitoxin (DGTX), gentamicin (GENT), lidocaine (LIDO), N-acetylprocainamide (NAPA), procainamide (PROC), tobramycin (TOBR), valproic acid (VALP), and vancomycin (VANC) methods on the Dimension Vista™ System.

2. Indication(s) for use:

The DRUG 2 CAL is an *in vitro* diagnostic product for the calibration of acetaminophen (ACTM), carbamazepine (CRBM), digitoxin (DGTX), gentamicin (GENT), lidocaine (LIDO), N-acetylprocainamide (NAPA), procainamide (PROC), tobramycin (TOBR), valproic acid (VALP), and vancomycin (VANC) methods on the Dimension Vista™ System.

3. Special conditions for use statement(s):

For prescription use

4. Special instrument requirements:

Dade Behring Dimension Vista™ System

I. Device Description:

DRUG 2 CAL is a multi-analyte, liquid, bovine serum based product containing acetaminophen, carbamazepine, digitoxin, gentamicin, lidocaine, N-acetylprocainamide, procainamide, tobramycin, valproic acid, and vancomycin.

The kit consists of six vials, three vials of Calibrator A, and three vials of Calibrator B which are ready for use (no preparation is required). The volume per vial is 2.5 mL. Intermediate levels are automatically prepared and corresponding values calculated by the Dimension Vista™ System.

J. Substantial Equivalence Information:

Predicate k033809 – Dade Behring Dimension Drug Calibrator II		
Comparison		
Item	New Device	Predicate Device
Intended Use	DRUG 2 CAL is an in vitro diagnostic product for the calibration of acetaminophen, carbamazepine, digitoxin, gentamicin, lidocaine, N-acetylprocainamide, procainamide, tobramycin, valproic acid, and vancomycin methods on the Dimension Vista™ System.	Drug Calibrator II is an in vitro diagnostic product intended for the calibration of the following methods packaged in 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).

Comparison		
Item	New Device	Predicate Device
Analytes	acetaminophen (ACTM), carbamazepine (CRBM), digitoxin (DGTX), gentamicin (GENT), lidocaine (LIDO), N-acetylprocainamide (NAPA), procainamide (PROC), tobramycin (TOBR), valproic acid (VALP), and vancomycin (VANC).	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 for all analytes except NAPA NAPA - All-Tech Applied Sciences Reference Standard.	USP for all analytes except NAPA NAPA - All-Tech Applied Sciences Reference Standard.
Matrix	Bovine	Bovine
Number of Levels	Two	Five

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

STANDARDS
Title and Reference Number
Stability Testing of In Vitro Diagnostic Reagents (CEN 13640)
Medical devices - Application of risk management to medical devices (ISO 14971:2000)

GUIDANCE			
Document Title	Office	Division	Web Page
Guidance for Industry - Abbreviated 510(k) Submissions for In Vitro Diagnostic Calibrators; Final	OIVD		http://www.fda.gov/cdrh/ode/calibrator.html
Guidance for Industry and FDA Staff - Use of Symbols on Labels and in Labeling of In Vitro Diagnostic Devices Intended for Professional Use			http://www.fda.gov/cdrh/ocd/guidance/4444.html

L. Test Principle:

Not applicable. This submission is for calibrators.

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 new calibrator is prepared by adding calculated quantities of analytes to the base matrix (bovine serum). The concentration is verified using an instrument calibrated with the master calibrator pools. The final bottle assignment is assigned for the level of the commercial lot by testing N=20 replicates with multiple reagent lots on multiple instruments.

The assigned values of DRUG 2 CAL are traceable to USP Reference Materials except for NAPA which is traceable to All-Tech Applied Sciences Reference Standard.

Assigned values for a typical lot of DRUG 2 CAL is presented in the following table:

Level	Units	ACTM	CRBM	DGTX	GENT	LIDO	NAPA	PROC	TOBR	VALP	VANC
1	ug/mL	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
5	ug/mL	302.1	22.0	83.0	11.6	12.5	33.4	21.2	13.4	164.1	48.6

The Calibrators are stable for 12 months when stored at 2 to 8 °C. A vial punctured by the instrument and stored on board the analyzer is stable for 24 hours. Opened vials stored at 2 to 8 °C are stable for 31 days. Protocols and acceptance criteria for stability testing were described and found to be acceptable.

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):

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.