

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

A. 510(k) Number:

k062034

B. Purpose for Submission:

New Device

C. Measurand:

Calibrator materials for Digoxin (DIG), Lithium (LI), Phenobarbital (PHNO), Phenytoin (PTN) and Theophylline (THEO)

D. Type of Test:

Not Applicable

E. Applicant:

Dade Behring, Inc.

F. Proprietary and Established Names:

Dimension Vista System Drug 1 Calibrator (DRUG 1 CAL - KC410)

G. Regulatory Information:

Product Code	Classification	Regulation Section	Panel
<u>Calibrator, Multi-Analyte Mixture (JIX)</u>	<u>Class II</u>	<u>21 CFR 862.1150, Calibrator.</u>	<u>75 CLINICAL CHEMISTRY (CH)</u>

H. Intended Use:

1. Intended use(s):

See below indications(s) for use below.

2. Indication(s) for use:

The DRUG 1 CAL is an in vitro diagnostic product for the calibration of Digoxin (DIG), Lithium (LI), Phenobarbital (PHNO), Phenytoin (PTN) and Theophylline (THEO) 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 1 CAL is a liquid, multi-analyte, human serum based product containing digoxin, lithium, phenobarbital, phenytoin, and theophylline. 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). This same product, the Dimension Vista™ System Drug 1 Calibrator (KC410), was previously cleared (k051087) for the calibration of the Phenobarbital (PHNO) method on the Dimension Vista™ System. The calibrator formulation has not changed. However, additional analytes are being assigned values and included in the intended use. The volume in the vials has also changed from 2.0 mL to 2.5 mL and the claim for punctured vial shelf life is reduced to one day. Each donor unit used in the preparation of this material was tested by FDA approved methods for the presence of antibodies to HIV-1, HIV-2, Hepatitis B Surface Antigen and antibody to HCV and found to be negative.

J. Substantial Equivalence Information:

	Device	Predicate
Item	Dimension Vista™ System Drug 1 Calibrator ¹	Dimension® Drug Calibrator (k011035)
Intended Use	The DRUG 1 CAL is an in vitro diagnostic product for the calibration of Digoxin (DIG), Lithium (LI), Phenobarbital (PHNO), Phenytoin (PTN) and Theophylline (THEO) methods on the Dimension Vista™ System.	The Drug Calibrator is an in vitro diagnostic product to be used to calibrate the Digoxin (DGNA), Lithium (LI), Phenobarbital (PHNO), Phenytoin (PTN), and Theophylline (THEO) methods on the Dimension® clinical chemistry system.
Analytes	Digoxin (DIG), Lithium (LI), Phenytoin (PTN), Theophylline (THEO), and Phenobarbital (PHNO) ¹ .	Digoxin (DGNA), Lithium (LI), Phenobarbital (PHNO), Phenytoin (PTN), and Theophylline (THEO).
Form	Liquid	Liquid
Traceability	DIG, PHNO, PTN, THEO – USP ² . LI – NIST SRM ³ .	DIG, PHNO, PTN, THEO – USP ² . LI – NIST SRM ³ .
Matrix	Human serum based product	Human serum based product
Number of Levels	Two Levels	Five Levels

¹ The Dimension Vista™ System Drug 1 Calibrator was previously cleared for the calibration of Phenobarbital (PHNO) method in the Dimension Vista™ System under k051087.

² USP – United States Pharmacopeia.

³ NIST SRM – National Institute of Standards and Technology Standard Reference Material.

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

Standards:

CEN 13640 Stability testing of In-Vitro Diagnostic Devices

ISO 14971:2000 Medical devices -Application of Risk Management to Medical Devices

Guidance:

Guidance for Industry - Abbreviated 510(k) Submissions for In Vitro Diagnostic Calibrators; Final, 02/22/1999

Guidance for Industry and FDA Staff - Use of Symbols on Labels and in Labeling of In Vitro Diagnostic Devices Intended for Professional Use, 11/30/2004

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 assigned values of the Drug 1 Calibrator are standardized to the enclosed table of assigned values:

Analyte	Reference Material
Digoxin	USP ² 120000
Phenytoin	USP 1535507
Theophylline	USP 1653004
Lithium	NIST SRM ³ 924
Phenobarbital ¹	USP 1524001

¹ The Dimension Vista™ System Drug 1 Calibrator was previously cleared for the calibration of Phenobarbital (PHNO) method in the Dimension Vista™

System under k051087

² United States Pharmacopeia.

³ National Institute of Standards and Technology – Standard Reference Material.

Stability: The target life for the Dimension Vista™ Drug 1 Calibrator is 12 months. A vial punctured by the instrument and stored on board has a stability claim of one day. An open vial not on the instrument, but recapped and stored in the refrigerator had a stability claim of 31 days. Stability study protocols and acceptance criteria 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.