

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

**A. 510(k) Number:**

k062122

**B. Purpose for Submission:**

New device

**C. Measurand:**

Calibrator materials for Alcohol and Carbon Dioxide assays

**D. Type of Test:**

Not applicable. This submission is for clearance of calibrator materials

**E. Applicant:**

Dade Behring, Inc.

**F. Proprietary and Established Names:**

Dimension Vista™ System Chem 3 Calibrator (CHEM 3 CAL - KC130)

**G. Regulatory Information:**

<b>Product Code</b>	<b>Classification</b>	<b>Regulation Section</b>	<b>Panel</b>
<u>JIX</u>	<u>II</u>	<u>21 CFR 862.1150</u>	<u>Clinical Chemistry</u> <u>(75)</u>

**H. Intended Use:**

1. Intended use(s):

The CHEM 3 CAL is an *in vitro* diagnostic product for the calibration of alcohol (ALC) and carbon dioxide (CO2) methods on the Dimension Vista™ System.

2. Indication(s) for use:

The CHEM 3 CAL is an *in vitro* diagnostic product for the calibration of alcohol (ALC) and carbon dioxide (CO2) 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:**

CHEM 3 CAL is a multi-analyte, aqueous product containing ethyl alcohol and sodium carbonate. 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.

**J. Substantial Equivalence Information:**

<b>Predicate</b>	k904308 – Dade Behring Dimension ALC Calibrator		
<b>Predicate</b>	k010208 – Dade Behring Dimension ECO2 Calibrator		
<b>Comparison</b>			
<b>Item</b>	<b>New Device</b>	<b>Predicate (ALC Calibrator)</b>	<b>Predicate (ECO2 Calibrator)</b>
Intended Use	The CHEM CAL 3 is an in vitro diagnostic product for the calibration of Alcohol (ALC) and Carbon Dioxide (CO2) methods on the Dimension Vista™ System	The Alcohol Calibrator is an in vitro diagnostic product to be used to calibrate the Dimension clinical chemistry system for the Ethyl Alcohol (ALC) method.	The Dimension ECO2 Calibrator is an in vitro diagnostic product to be used to calibrate the Dimension clinical chemistry system for the Enzymatic Carbonate (ECO2) method.
Analytes	Alcohol and carbon dioxide	Alcohol	Carbon Dioxide
Form	Liquid	Liquid	Liquid
Traceability	ALC – USP Grade Ethyl Alcohol CO2 – NIST SRM 351	USP Grade Ethyl Alcohol	NIST SRM 351
Number of Levels	Two	Four	Three

**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)

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

**L. Test Principle:**

Not applicable. This submission is for calibrator materials.

**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 calibrator is prepared by adding calculated quantities of analytes into purified water. 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=45 replicates with multiple reagent lots on multiple instruments.

The assigned values of the alcohol are traceable to USP Grade Alcohol and of the Carbon Dioxide are traceable to NIST SRM 351.

The calibrator materials 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.