

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

A. 510(k) Number:

k061703

B. Purpose for Submission:

Premarket Notification (510(k)) of intention to manufacture and market the CHEM 2 CAL calibrator.

C. Measurand:

Calibrator for Phosphorus, salicylate, and triglycerides.

D. Type of Test:

Not applicable to this submission.

E. Applicant:

Dade Behring Inc.

F. Proprietary and Established Names:

CHEM 2 CAL

G. Regulatory Information:

1. Regulation section:

21 CFR § 862.1150: Calibrator, Multi-Analyte Mixture

2. Classification:

Class II

3. Product code:

JIX

4. Panel:

H. Intended Use:

1. Intended use(s):

Please see indications for use.

2. Indication(s) for use:

The CHEM 2 CAL is an in vitro diagnostic product for the calibration of Phosphorus (PHOS), Salicylate (SAL), and Triglycerides (TRIG) methods on the Dimension Vista™ System.

3. Special conditions for use statement(s):

For prescription use.

4. Special instrument requirements:

Dimension Vista™ System

I. Device Description:

CHEM 2 CAL is a liquid, multi-analyte, bovine serum albumin based product containing phosphorus, salicylate and glycerol. 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 2.0 mL.

J. Substantial Equivalence Information:

1. Predicate device name(s):

CHEM II Calibrator

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

k861700

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Intended Use	The CHEM 2 CAL is an in vitro diagnostic product for the	CHEM II Calibrator is an in vitro diagnostic product

Similarities		
Item	Device	Predicate
	calibration of Phosphorus, Salicylate, and Triglycerides methods on the Dimension Vista™ System.	to be used to calibrate the Dimension® clinical chemistry system for the magnesium, phosphorus and triglycerides methods.
Form	Liquid	Liquid
Traceability	Phosphorus - NIST SRM 2186I Triglycerides – Anhydrous Glycerol, ACS grade	Same

Differences		
Item	Device	Predicate
Matrix	Aqueous Bovine Serum Albumin	Phosphate buffered saline
Analytes	Phosphorus, Salicylate , and Triglycerides	Phosphorus and Triglycerides
Levels	2	3

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

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

CEN 13640: Stability testing of In-Vitro Diagnostic Devices.

ISO 14971:2000 Medical devices - Application of risk management to medical devices.

L. Test Principle:

Not applicable to this submission.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

Not applicable to this submission.

b. Linearity/assay reportable range:

Not applicable to this submission.

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

The sponsor demonstrated the stability of their device using real-time data. To assess the shelf life of their device, the company compared concentration measurements made on unopened material stored at 4°C to material stored at -20°C. The company made 5 replicate measurements at each level on days 0, 3, 7, 35, 98, 189, 280, 325, and 371. Data supplied by the company supports the claimed shelf life of 12 months.

To demonstrate the stability of their opened, refrigerated device, the company punctured vials on day zero, removed material, and returned the device to storage at 2 – 8 °C. The company performed 5 replicate measurements on each level of calibrator. Material stored at -20°C was used as a comparator. The company performed subsequent measurements on days 8, 15, 22 and 32. The data supplied by the company supports the claimed opened, refrigerated shelf life of 30 days.

The company verifies the target concentration of the calibrator material following an internally established manufacturing procedure: the new calibrator is made by adding by weight aqueous solutions of potassium dihydrogen phosphate, sodium salicylate, and glycerol reference materials to a stock solution at target concentrations. The company validates the traceability and expected value of the device through 45 replicate measurements across multiple instruments calibrated with primary standards. A previously released lot of calibrator is used as control material.

d. *Detection limit:*

Not applicable to this submission.

e. *Analytical specificity:*

Not applicable to this submission.

f. *Assay cut-off:*

Not applicable to this submission.

2. Comparison studies:

a. *Method comparison with predicate device:*

Not applicable to this submission.

b. *Matrix comparison:*

Not applicable to this submission.

3. Clinical studies:

a. *Clinical Sensitivity:*

Not applicable to this submission.

b. *Clinical specificity:*

Not applicable to this submission.

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

Not applicable to this submission.

4. Clinical cut-off:

Not applicable to this submission.

5. Expected values/Reference range:

Not applicable to this submission.

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.