

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

A. 510(k) Number:

k061218

B. Purpose for Submission:

New device

C. Measurand:

Calibrator for Albumin (ALB) and Total Protein (TP)

D. Type of Test:

Not Applicable

E. Applicant:

Dade Behring, Inc.

F. Proprietary and Established Names:

Dimension Vista™ System Chemistry Calibrator 4 (CHEM 4 CAL – KC140)

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 indication(s) for use.

2. Indication(s) for use:

The CHEM 4 CAL is an in vitro diagnostic product for the calibration of Albumin (ALB) and Total Protein (TP) 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:

The CHEM 4 CAL is an in vitro diagnostic product for the calibration of Albumin (ALB) and Total Protein (TP) methods on the Dimension Vista™ System. The kit consists of three vials of one level which are ready for use (no preparation is required). The volume per vial is 1.5 mL. System water is used as the TP and LAB zero calibrator (Level 1) for the Dimension Vista™ System. The vials contain sodium azide (less than 0.1%) as a preservative.

J. Substantial Equivalence Information:

Predicate Device: Dimension® TP/ALB Calibrator (DC31)

Predicate 510(k) Number(s): k914917

Comparison with Predicate:

Comparison		
Item	New Device (k061218)	Predicate Device (k914917)
Intended Use	The CHEM 4 CAL is an in vitro diagnostic product for the calibration of Albumin (ALB) and Total Protein (TP) methods on the Dimension Vista™ System.	The CHEM 4 CAL is an in vitro diagnostic product for the calibration of Albumin (ALB) and Total Protein (TP) methods on the Dimension Vista™ System.
Analytes	Albumin (ALB) Total Protein (TP)	Albumin (ALB) Total Protein (TP)
Form	Liquid	Lyophilized
Traceability	ALB – IFCC CRM470 TP – NIST SRM 927	ALB – IFCC CRM470 TP – NIST SRM 927
Matrix	Human serum based product	Human serum based product
Number of Levels	One Level	Three Levels

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

STANDARDS

Title and Reference Number

CEN 13640 Stability testing of In-Vitro Diagnostic Devices

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

GUIDANCE

Document Title	Office	Division	Web Page
Guidance for Industry – Abbreviated 510(k) Submissions for In Vitro Diagnostic Calibrators; Final 02/22/1999			
Guidance for Industry and 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):

Value assignment: The new calibrator is made by adding calculated quantities of albumin to the base matrix (human serum) which already contains total protein. The concentration is verified using an instrument calibrated with the primary and secondary standards. The final bottle assignment is assigned for the level of the commercial lot by testing N=90 replicates with multiple reagent lots on multiple instruments.

The assigned values of the ALB/TP calibrator are standardized to the following reference materials:

Analyte	Reference Material
Albumin	IFCC CRM 470 [i]
Total Protein	NIST SRM 927 [ii]

[i] IFCC: International Federation for Clinical Chemistry

[ii] NIST: National Institute of Standards and Technology

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.