

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

A. 510(k) Number:

k061390

B. Purpose for Submission:

New Device

C. Measurand:

Calibrator for Alanine aminotransferase (ALT) and Aspartate aminotransferase (AST)

D. Type of Test:

Not Applicable

E. Applicant:

Dade Behring, Inc.

F. Proprietary and Established Names:

Dimension Vista™ Enzyme 2 Calibrator (ENZ 2 Cal –KC320)

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.

2. Indication(s) for use:

The Enzyme 2 Calibrator is an *in vitro* diagnostic product for the calibration of alanine aminotransferase (ALT) and aspartate aminotransferase (AST) 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 Enzyme 2 Calibrator is a liquid, multi-analyte, bovine serum albumin based product containing alanine aminotransferase (ALT) and aspartate aminotransferase (AST) from porcine heart.

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 1.5 mL.

J. Substantial Equivalence Information:

1. Predicate device name(s):

Dimension(R) Clinical Chemistry System calibrator

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

k860021

3. Comparison with predicate:

Item	Similarities	Differences
Analytes	Both device and predicate are to be used on the AST and ALT assays.	Device does not include: Alkaline phosphatase (ALP), Amylase (AMY) g-glutamyl transferase (GGT), or Lactic dehydrogenase (LDH)
Form	None	Device is liquid while predicate is lyophilized.

Item	Similarities	Differences
Intended Use	Both device and predicate are to be used on the AST and ALT assays.	The Enzyme 2 Calibrator is an <i>in vitro</i> diagnostic product for the calibration of alanine aminotransferase (ALT) and aspartate aminotransferase (AST) on the Dimension Vista™ System. Enzyme Verifier is an <i>in vitro</i> diagnostic product to be used to verify alkaline phosphatase (ALP), amylase (AMY), g-glutamyl transferase (GGT), aspartame aminotransferase (AST), alanine aminotransferase (ALT) and lactic dehydrogenase (LDH) method performance on the Dimension® clinical chemistry system.
Traceability	Both device and predicate are traceable to ALT/AST Master pool Dimension® clinical chemistry system values.	None
Matrix	Both device and predicate have porcine heart product in base.	Device - Bovine serum and porcine heart based product. Predicate - Human serum and porcine heart based product
Calibration / Verification Levels	None	Device has two levels where predicate has three levels.

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

STANDARDS
Title and Reference Number
Stability Testing of In Vitro Diagnostic Reagents (13640)
Medical devices - Application of risk management to medical devices (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.

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 Enzyme 2 Calibrator are verified on a Dimension® instrument calibrated with an approved Master Pool. Master Pool values is assigned on multiple Dimension® clinical chemistry instruments.

Stability: Calibrator shelf life for the Dimension Vista™ Enzyme 2 Calibrator was determined to be 12 months. A vial that has been punctured (opened) by the instrument and stored on board has a seven day stability claim. 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.