

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

A. 510(k) Number:

k083579

B. Purpose for Submission:

New device

C. Measurand:

Creatine Kinase, Creatine Kinase MB fraction

D. Type of Test:

Calibrator

E. Applicant:

Siemens Healthcare Diagnostics Inc.

F. Proprietary and Established Names:

Dimension Vista® Enzyme 6 Calibrator

G. Regulatory Information:

1. Regulation section:

21 CFR § 862.1150, Calibrator

2. Classification:

Class II (calibrator)

3. Product code:

JIX, Calibrator, Multi-Analyte Mixture

4. Panel:

Clinical Chemistry (75)

H. Intended Use:

1. Intended use(s):

See Indication(s) for use below.

2. Indication(s) for use:

The ENZ 6 CAL is an in vitro diagnostic product for the calibration of the Creatine Kinase (CKI) and Creatine Kinase MB (MBI) methods on the Dimension Vista® System.

3. Special conditions for use statement(s):

For prescription use.

4. Special instrument requirements:

For use with the Siemens Dimension Vista® System

I. Device Description:

The Dimension Vista® System Enzyme 6 Calibrator (Enz 6 CAL) is a liquid, multi-analyte, human serum albumin based product containing creatine kinase MM (human source) and creatine kinase MB (porcine source). The kit consists of three vials of Calibrator A, 2.0 ml per vial.

Contains human source material. Each donor unit used in the preparation of this product was tested by FDA-approved methods for the presence of antibodies to Human Immunodeficiency Virus Type 1 (HIV-1) and Type 2 (HIV-2), as well as for Hepatitis B Surface Antigen (HBsAg) and antibody to Hepatitis C Virus (HCV), and found to be negative (not repeatedly reactive). Because no testing can offer complete assurance that these or other infectious agents are absent, this material should be handled using good laboratory practice to avoid skin contact and ingestion.

J. Substantial Equivalence Information:

1. Predicate device name(s):

Dimension® CKI/MBI Calibrator

2. Predicate K number(s):

k081731

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Analyte	Creatine kinase (human source) and creatine kinase-MB (porcine source)	Creatine kinase (human source) and creatine kinase-MB (porcine source)
Matrix	Human serum albumin	Human serum albumin
Form	Liquid	Liquid

Differences		
Item	Device	Predicate
Intended Use	The ENZ 6 CAL is an in vitro diagnostic product for the calibration of the Creatine Kinase (CKI*) and Creatine Kinase MB (MBI*) methods on the Dimension Vista® System.	The CKI/MBI CAL is an <i>in vitro</i> diagnostic product for the calibration of the Creatine Kinase (CKI) and Creatine Kinase MB (MBI) methods on the Dimension® clinical chemistry system.
Levels	CKI – One level MBI – One level	CKI - Two levels MBI – Two levels

* CKI and MBI are the sponsor's nomenclature to indicate that the devices are traceable to IFCC Reference material. See section M.1.c.

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

FDA Guidance for Industry - Abbreviated 510(k) Submissions for In Vitro Diagnostic Calibrators; Final

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):*

The Dimension Vista® Enzyme 6 Calibrator is a one level calibrator containing CK (CKMM) and CKMB. The zero level calibrator is deionized water which is provided by the user. Both CKI and MBI are traceable to IFCC Reference methods or materials.

Traceability:

The sponsor prepares an Anchorpool by combining normal and high levels of Creatine Kinase from human serum. The value for this pool is assigned by analyzing it using the IFCC Reference Method.

Masterpools for CK or CKMB are created using gravimetrically prepared CK or CKMB stock solutions added to the sponsor's base material to establish prespecified concentrations of the analytes. Value assignments for the CKI Masterpools are determined using the IFCC Reference Method and verified against the Anchorpool using multiple Dimension instruments, testing 45 replicates. CKMB Masterpool values are assigned from IFCC reference standard ERM AD455/IFCC calibration curves using multiple instruments, testing multiple replicates.

CKI and CKMB antigens are added gravimetrically to the stock base at appropriate amounts to the target calibrator levels. Final bottle values are assigned against Masterpools using multiple instruments and reagent lots.

Stability: The shelf life, open and punctured vial stabilities of the CKI MBI calibrator have been demonstrated using real time data. The predetermined acceptance criteria and protocols were reviewed and found to be acceptable. The CKI/MBI calibrator has a target shelf life of 12 months when stored at -20°C. The calibrator must be thawed at room temperature before use. Once the cap is removed, or punctured, the assigned values are stable for 7 days when recapped immediately and stored at 2-8 °C.

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):*

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.