

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

A. 510(k) Number:

k062152

B. Purpose for Submission:

Clearance for new intended use

C. Measurand:

Calibrator for Creatine kinase MB isoenzyme

D. Type of Test:

Calibrator

E. Applicant:

Dade Behring, Inc.

F. Proprietary and Established Names:

Dimension Creatine Kinase MB Isoenzyme Verifier, Model DC27

G. Regulatory Information:

Product Code	Classification	Regulation Section	Panel
<u>Calibrator, Secondary (JIT)</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 Indications for Use below.
2. Indication(s) for use:
The Creatine Kinase MB Isoenzyme Verifier is an *in vitro* diagnostic product for verification of the Creatine Kinase MB Isoenzyme (CKMB) method on the Dimension® clinical chemistry system and Dimension Vista™ System.
3. Special conditions for use statement(s):
For professional use.
4. Special instrument requirements:
Dimension® clinical chemistry system and Dimension Vista™ System.

I. Device Description:

CKMB Verifier is a lyophilized human serum base product. Level 1 contains no CKMB, Levels 2 and 3 contain CKMB from a simian heart source. The kit consists of six vials, two vials per level. The volume per vial is 1.0 mL.

All human source material was tested by FDA-approved methods for the presence of antibodies to Human Immunodeficiency Virus Type 1 (HIV-1) and Type 2 (HIV-2), Hepatitis B Surface Antigen (HBsAg) and antibodies to Hepatitis C Virus (HCV) and found to be negative/non-reactive.

J. Substantial Equivalence Information:

1. Predicate device name(s):
Creatine Kinase MB Isoenzyme Verifier
2. Predicate K number (s):
k863840
3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Analyte	Creatine Kinase MB Isoenzyme	Creatine Kinase MB Isoenzyme
Form	Lyophilized	Lyophilized
Traceability	Dimension® clinical chemistry system values.	Dimension® clinical chemistry system values.
Matrix	Human serum based product containing CKMB from simian heart source.	Human serum based product containing CKMB from simian heart source.
Number of levels	Three levels.	Three levels.

Differences		
Item	Device	Predicate
Indications for Use	The Creatine Kinase MB Isoenzyme Verifier is an <i>in vitro</i> diagnostic product for verification of the Creatine Kinase MB Isoenzyme (CKMB) method on the Dimension® clinical chemistry system and Dimension Vista™ System.	The Creatine Kinase MB Isoenzyme Verifier is an <i>in vitro</i> diagnostic product for verification of the Creatine Kinase MB Isoenzyme (CKMB) method on the Dimension® clinical chemistry system.

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

STANDARDS
Title and Reference Number
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 and Value Assignment: Purified cynomolgus monkey heart CK-MB stock solution is added to human serum based matrix. The solution is tested on a Dimension clinical chemistry system with fixed calibration parameters (coefficients) that are determined from the molar absorbdity of NADH. The commercial lot is made by taking calculated quantities of stock solution and adding to human serum base to create the target concentrations for the two calibrator levels. The concentration of each level is verified to be within acceptable range using a Dimension clinical chemistry system with fixed calibration parameters (coefficients) that are determined from the molar absorbdity of NADH.

Stability: Shelf life for the CKMB isoenzyme verifier is 12 months when stored at the recommended conditions. Reconstituted product is stable for 8 hours when stored at 4°C. Stability study protocols and acceptance criteria were described and found to be acceptable.

