

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

A. 510(k) Number:

k062199

B. Purpose for Submission:

510(k) premarket notification to manufacture and market the Dimension Vista™ System Drug 3 Calibrator (DRUG 3 CAL-KC430).

C. Measurand:

Calibrator materials for cyclosporine (CSA)

D. Type of Test:

Calibrator materials

E. Applicant:

Dade Behring, Inc.

F. Proprietary and Established Names:

Dimension Vista™ System Drug 3 Calibrator

G. Regulatory Information:

1. Regulation section:

862.3200 Clinical toxicology calibrator

2. Classification:

Class II

3. Product code:

DLJ – Calibrator, drug specific

4. Panel:

H. Intended Use:

1. Intended use(s):

See indication(s) for use below.

2. Indication(s) for use:

The DRUG 3 CAL is an in vitro diagnostic product for the calibration of cyclosporine (CSA) method on the Dimension Vista™ System.

3. Special conditions for use statement(s):

For prescription use

4. Special instrument requirements:

Dade Behring Dimension Vista System

I. Device Description:

DRUG 3 CAL is a frozen, liquid, human whole blood hemolysate containing cyclosporine. The kit consists of six vials, three vials of Calibrator A, and three vials of Calibrator B which are frozen. The volume for Calibrator A is 2.0 mL per vial and for Calibrator B is 1.5 mL per vial. Intermediate levels are automatically prepared and corresponding values calculated by the Dimension Vista™ System. Each donor unit used in the preparation of this material was tested by FDA approved methods for the presence of antibodies to HIV-1, HIV-2, Hepatitis B Surface Antigen and antibody to HCV and found to be negative.

J. Substantial Equivalence Information:

1. Predicate device name(s):

Dimension® CSA Calibrator

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

k011112

3. Comparison with predicate:

Similarities		
Item	Device: Dimension Vista™ System Drug 3 Calibrator	Predicate: Dimension® CSA Calibrator k011112
Analyte	Cyclosporine	Cyclosporine
Form	Frozen	Frozen
Traceability	USP Cyclosporine A.	USP Cyclosporine A
Matrix	Human whole blood containing cyclosporine.	Human whole blood containing cyclosporine.

Differences		
Item	Device: Dimension Vista™ System Drug 3 Calibrator	Predicate: Dimension® CSA Calibrator k011112
Intended use	The DRUG 3 CAL is an <i>in vitro</i> diagnostic product for the calibration of Cyclosporine (CSA) method on the Dimension Vista™ System.	The CSA Calibrator is an <i>in vitro</i> diagnostic product intended to be used to calibrate the Cyclosporine (CSA) method for the Dimension® clinical chemistry system.
Number of Levels	Two levels. Intermediate levels are automatically prepared and corresponding values calculated by the Dimension Vista™ System.	Five Levels.

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

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

FDA Guidance for Industry and FDA Staff - Use of Symbols on Labels and in Labeling of In Vitro Diagnostic Devices Intended for Professional Use

FDA Guidance for Industry and FDA - Class II Special Controls Guidance Document: Cyclosporine and Tacrolimus Assays

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 DRUG 3 CAL are traceable to United States Pharmacopeia Cyclosporine A Reference Material.

Value Assignment

Cyclosporine Reference Material is weighed into drug free whole blood hemolysate to prepare master pools at five levels and stored at -70°C. The verification of the Master Pool values is performed against weighed in Master Pool values and LC/MS testing. The stock solution is made by adding cyclosporine gravimetrically to stock solution at target concentrations. The commercial lot is made by adding calculated quantities of stock solution to drug free whole blood hemolysate to target concentrations for each of the calibrator levels. The concentration of each level is verified by using an instrument. Nominal values are assigned to the commercial lot.

The nominal values for each level of the commercial lot are verified using an instrument calibrated with Master Pools.

Stability

Target shelf life for the Dimension Vista™ System Drug 3 Calibrator is 12 months. Calibrator shelf life is determined by comparing results of the product stored at -20°C with the reference (control) stored at -70°C. The method is calibrated from this stored reference. The -20°C material values are recovered versus the calibration. Recovery versus time is monitored and percent change over time is determined. Shelf-life stability (expiration) dating assignment at commercialization reflects the real-time data on file at Dade Behring, Inc.

A vial punctured by the instrument and stored on board is stable for seven days. An open vial not on instrument, but recapped and stored in a refrigerator is stable for 31 days. For testing, vials are opened /punctured on day zero. A quantity sufficient for multiple calibrations is removed and the vials are recapped and stored at 2 – 8 °C. Opened/punctured vials are tested on days 8, 15, 22 and 32 versus freshly opened vials.

- 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.