

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

A. 510(k) Number:

k053108

B. Purpose for Submission:

New calibrator

C. Measurand:

Cyclosporine

D. Type of Test:

Calibrator

E. Applicant:

Dade Behring Inc.

F. Proprietary and Established Names:

Dimension® CSAE Cyclosporine Extended Range Calibrator

G. Regulatory Information:

1. Regulation section:
21 CFR §862.3200, Clinical toxicology calibrator
2. Classification:
Class II
3. Product code:
DLJ
4. Panel:
91 Clinical Toxicology

H. Intended Use:

1. Intended use(s):
See item 2 below.
2. Indication(s) for use:
The CSAE Calibrator is an in vitro diagnostic product intended to be used to calibrate the Cyclosporine A, Extended Range (CSAE) method for the Dimension® clinical chemistry system and the Syva® Emit® 2000 Cyclosporine Specific Assay.
3. Special conditions for use statement(s):
None
4. Special instrument requirements:
To be used only on the Dimension® or Syva® Emit® 2000 analyzers

I. Device Description:

The Dimension® CSAE Cyclosporine Extended Range Calibrator contains cyclosporine in a preserved whole blood hemolysate. The kit consists of one vial each of Calibrator 0 (0 ng/mL of cyclosporine) and one vial each of Levels 1 through 5. Target concentrations for the five calibrator are approximately 200 (Level 1), 400 (Level 2), 800 (Level 3), 1400 (Level 4) and 2000 ng/ml (Level 5) of cyclosporine. Level 0 is included for dilution of over-range samples (>2000 ng/mL) in order to obtain results within the assay range; it is not used in calibration. Refer to the method insert sheet for instructions on calibration and making appropriate manual dilutions.

J. Substantial Equivalence Information:

1. Predicate device name(s):
Dimension® CSAE Cyclosporine Extended Range
2. Predicate 510(k) number(s):
k052015
3. Comparison with predicate:
The two devices have the same formulation and operating principle. Only the intended use has changed to allow the calibrator to be used with the Syva® Emit® 2000 Cyclosporine Specific Assay, Extended Range.

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

None

L. Test Principle:

The Dimension® CSAE Cyclosporine Extended Range Calibrator contains cyclosporine in a preserved whole blood hemolysate. It is intended to be used to calibrate the extended range cyclosporine assay on the Dimension® clinical chemistry systems or the Syva® Emit® 2000 Cyclosporine Specific Assay.

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):*

Stability: The unopened product is stored frozen between -17°C and -27°C. The shelf life of the product is stated to be 12 months. Once thawed, the calibrators are stable for 30 days, when stored at 2-8°C. The labeling states that the calibrators should not be refrozen. Two different stability studies were performed to support these claims.

For the shelf-life claim, the product is stored between -17°C and -27°C for 0, 7, 14, 30, 90, 120, 150, 180, 210, 240, 270, 300, 360, and 390 days. The control material is stored at -70°C and tested at the same frequency. The maximum allowable drift at each testing point compared to the control is as follows: Levels 1, 2, and 5 \leq 8%, Levels 3 and 4 \leq 6%.

For the opened product claim, the product is stored at 2-8°C for 0, 1, 2, 3, 7, 14, and 35 days. The control material is stored at -70°C and tested at the same frequency. The maximum allowable drift at each testing point compared to the control is as follows: Levels 1, 2, and 5 \leq 8%, Levels 3 and 4 \leq 6%.

Traceability and Value Assignment: For the Reference Lot of calibrators, pharmaceutical grade Cyclosporine A is used to formulate a reference stock solution. The concentration of the stock solution is assigned by HPLC. Reference lot calibrators are prepared by diluting the stock into whole blood hemolysate with preservatives at six different target levels. The value of the reference lot calibrators is assigned by LC/MS/MS.

For new lots of Dimension® CSAE Cyclosporine Extended Range Calibrator, a cyclosporine stock solution is first prepared using standard gravimetric procedure and the concentration is assigned by HPLC. Aliquots of the stock solution are added to measured amounts of calibrator matrix to yield the desired concentrations for each level. The calibrators are prepared in preserved whole blood hemolysate.

The recovery of the six calibrator levels is verified against a control calibrator lot and against a frozen reference lot. The new calibrator lot must be within $\pm 10\%$ of the reference lot.

- 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 and substantial equivalence decision.