

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

A. 510(k) Number:

k052015

B. Purpose for Submission:

New device

C. Measurand:

Cyclosporine

D. Type of Test:

Calibrator

E. Applicant:

Dade Behring, Inc.

F. Proprietary and Established Names:

Dimension® CSAE Cyclosporine Calibrator (DCC108)

G. Regulatory Information:

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

H. Intended Use:

1. Intended use(s):
See below.
2. Indication(s) for use:
The CSAE Calibrator is an in vitro diagnostic product is intended to be used to calibrate the Cyclosporine Extended Range method for the Dimension® clinical chemistry system.
3. Special conditions for use statement(s):
None
4. Special instrument requirements:
None

I. Device Description:

The Dimension® CSAE Cyclosporine Extended Range Calibrator contains cyclosporine in a preserved whole blood hemolysate. The kit consists of 2 sets of the following: one vial of sample diluent (0.0 ng/ml of cyclosporine) and one vial of levels 1 through 5. Target concentrations for the five calibrator levels are approximately 200, 400, 800, 1400 and 2000 ng/ml 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. Levels 1 thru 5 are used for calibration of the CSAE method. Refer to the method insert sheet for instructions on calibration and making appropriate manual dilutions.

J. Substantial Equivalence Information:

1. Predicate device name(s):
Dade Behring Dimension CSA Calibrator
2. Predicate 510(k) number(s):
k011112
3. Comparison with predicate:
The two devices have the same composition, manufacturing, and intended use. Cyclosporine calibrator levels are higher than in the predicate in order to accommodate an extended assay range.

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

- Class II Special Controls Guidance Document: Cyclosporine and Tacrolimus Assays; Guidance for Industry and FDA, Document issued on: September 16, 2002.
- Stability Testing of In Vitro Diagnostic Reagents (13640)
- Medical devices - Risk management - Part 1: Application of risk analysis (14971-1)
- EN 1441:1997, Medical Devices - Risk Analysis (EN 1441:1997)
- Medical Devices - Symbols to be used with medical device labels, labeling and information to be supplied (15223)
- Continuous Quality Improvement: Essential Management Approaches; Approved Guideline (GP 22-A)

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):*
Stability
Product is stored at -20°C throughout testing cycle and tested at days 0, 7, 14, 30, 90, 120, 150, 180, 210, 240, 270, 300, 330, 360, 390. The control material is stored at -70 °C and tested at the same frequency. The shelf life of the calibrators is 12 months (unopened).

Traceability:

Commercially available CSA powder is used to formulate a reference stock solution. The concentration of the stock solution is determined by HPLC. A reference lot is formulated by diluting the stock into whole blood hemolysate with preservatives at six different levels and stored -20° C. The reference lot values are assigned by LC/MS/MS.

Value Assignment

A cyclosporine stock solution is prepared using standard gravimetric procedure and the concentration of the stock solution is established with high performance liquid chromatography (HPLC). Aliquots of the stock solution are added to measured amounts of calibrator matrix to yield the desired concentration for each calibrator level. Cyclosporine calibrators are prepared in preserved whole blood hemolysate. The recovery of the six levels are verified versus a control calibrator lot (control calibrator = any approved calibrator lot) and versus a frozen 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 a substantial equivalence decision.