SEP 1 2 2005

K 052.015

510(k) Summary for the
Dimension® Extended Range Cyclosporine Calibrator Catalog # DC108

A. 510(k) Number:

B. Analyte: Cyclosporine Calibrator

C. Type of Test: Calibrator Material

D. Applicant: Dade Behring Inc., P.O. Box 6101, Newark, DE 19714-6101
(302) 631-9454
Contact: Andrea M. Tasker, Regulatory Affairs and Compliance Manager

E. Proprietary and Established Names:
Dimension® Extended Range Cyclosporine Calibrator (DC108)

F. Regulatory Information:
1. Regulation section: 862.3200 - CLINICAL TOXICOLOGY CALIBRATOR

2. Classification: Class II

3. Product Code: DLJ - CALIBRATORS, DRUG SPECIFIC

4. Panel: CLINICAL TOXICOLOGY

G. Intended Use:
1. Intended use(s):
The Dimension® CSAE Cyclosporine Extended Range Calibrator is an in vitro diagnostic product intended to be used to calibrate the CSAE Cyclosporine Extended range method for the Dimension® clinical chemistry system.

2. Indication(s) for use:
The Dimension® CSAE Cyclosporine Extended Range Calibrator is an in vitro diagnostic product intended to be used to calibrate the CSAE Cyclosporine Extended range method for the Dimension® clinical chemistry system.

3. Special condition for use statement(s): none

4. Special instrument Requirements: none

H. 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.

I. Substantial Equivalence Information:

1. Predicate device name(s): Dimension Cyclosporine Calibrator Catalog # DC89

2. Predicate K number(s): K011112

3. Comparison with predicate:

Item	Device Dimension® CSAE Cyclosporine Calibrator	Predicate Dimension® CSA Cyclosporine Calibrator
Intended Use	To calibrate the CSAE Cyclosporine Extended range method for the Dimension® clinical chemistry system.	To calibrate the CSA Cyclosporine method for the Dimension® clinical chemistry system.
Matrix	Preserved whole blood hemolysate	Preserved whole blood hemolysate
Number of levels	5	5
Target Concentrations	200, 400, 800, 1400 and 2000 ng/ml of cyclosporine[a]	0, 80, 180, 300 and 500 ng/ml of cyclosporine

a. This calibrator material is similar to the predicate in terms of intended use, matrix, and number of levels. Cyclosporine calibrator levels are different compared to the predicate in order to accommodate a higher assay range.

J. Standard/Guidance Document Referenced:
Class II Special Controls Guidance Document: Cyclosporine and Tacrolimus Assays; Guidance for Industry and FDA, Document issued on: September 16, 2002.

K. 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 high range cyclosporine assay on the Dimension® clinical chemistry systems.

L. Performance Characteristics:
1. Stability
Product is stored at -20°C and 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.
Acceptance Criteria: Allowable drift is less than or equal to the total precision % CV at the test concentration.

2. Traceability:
Novartis Pharmaceutical Grade CSA powder used to formulate a reference stock solution. The concentration of the stock solution is assigned 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 is assigned by LC/MS/MS.

3. 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 verses a control calibrator lot (control calibrator = any approved calibrator lot) and verses a frozen reference lot.

Final: September 2, 2005

DEPARTMENT OF HEALTH & HUMAN SERVICES

SEP 12 2005

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ms. Andrea M. Tasker
Regulatory Affairs and Compliance Manager
Dade Behring, Inc.
P.O. Box 6101
Glasgow Bldg. 500
Newark, DE 19714

Re: k052015
Trade/Device Name: Dimension® CSAE Cyclosporine Extended Range Calibrator
Regulation Number: 21 CFR 862.3200
Regulation Name: Clinical toxicology calibrator
Regulatory Class: Class II
Product Code: DLJ
Dated: August 30, 2005
Received: September 1, 2005

Dear Ms. Tasker:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Carol C. Benson

Carol C. Benson, M.A.
Acting Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications For Use Statement

510(k) Number (if known): K052015

Device Name:
Dimension® CSAE Cyclosporine Extended Range Calibrator

Indications for Use:

The CSAE Calibrator is an in vitro diagnostic product intended to be used to calibrate the Cyclosporine Extended Range (CSAE) method for the Dimension® clinical chemistry system.

Andrea M. Tasker
Regulatory Affairs and Compliance Manager
June 27, 2005

Prescription Use X **AND/OR** **Over-the-counter Use** _____
(Per 21 CFR 801 Subpart D) **(21 CFR 801 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of -In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K052015