FEB 16 2006

510(k) Summary
Emit® 2000 Cyclosporine Specific Assay

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(k) number is: K053108

1. Manufacturer's Name, Address, Telephone, and Contact Person, Date of Preparation

Manufacturer:	Dade Behring Inc. P.O. Box 6101. Newark, DE 19714-6101
Contact Information:	Dade Behring Inc. P.O. Box 6101 Newark, DE 19714-6101 Attn: Yuk-Ting Lewis Tel: 302-631-7626
Date of Preparation:	Oct. 27, 2005

2. Device Name / Classification

Dimension® CSAE Cyclosporine Extended Range Calibrator / Class II

3. Identification of the Predicate Device

Dimension® CSAE Cyclosporine Extended Range Calibrator, K052015

4. Device Description

The Dimension® CSAE Cyclosporine Extended Range Calibrator contains cyclosporine in a preserved whole blood hemolysate. The kit consists of one vial of each calibrator level 0-5. The target concentrations of the calibrator levels are approximately 0, 200, 400, 800, 1400 and 2000 ng/mL of cyclosporine.

Level 0 is used 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 through 5 are used for calibration of the CSAE Cyclosporine Extended range method for the Dimension® clinical chemistry system or the Syva® Emit® 2000 Cyclosporine Specific Assay.

5. Device Intended Use

The Dimension® CSAE Cyclosporine Extended Range 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 or the Syva® Emit® 2000 Cyclosporine Specific Assay.

6. Medical device to which equivalence is claimed and comparison information

The Dimension® CSAE Cyclosporine Extended Range Calibrator is equivalent to the calibrator previously cleared under K052015. The intended use of this product has been modified to include use of the calibrator with the Emit® 2000 Cyclosporine Specific Assay. No changes were made to the formulation or operating principle to allow its use with the Emit® 2000 Cyclosporine Specific Assay. The Dimension® CSAE Cyclosporine Extended Range Calibrator with the modified intended use is substantially equivalent to the cleared Dimension® CSAE Cyclosporine Extended Range Calibrator (K052015).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

FEB 16 2006

Ms. Yuk-Ting Lewis
Regulatory Affairs & Compliance Manager
Dade Behring Inc.
PO Box 6101, M/S 514
Newark DE 19714-6101

Re: k053108
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: February 8, 2006
Received: February 9, 2006

Dear Ms. Lewis:

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,

Alberto Gutierrez, Ph.D.
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

510(k) Number (if known): K053108

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 A, Extended Range (CSAE) method for the Dimension® clinical chemistry system or the Syva® Emit® 2000 Cyclosporine Specific Assay.

Prescription Use ___x___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801)

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

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

Ann Chappie

...sion Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

K053108