K062199

510(k) Summary for the
Dimension Vista™ System Drug 3 Calibrator
(DRUG 3 CAL – KC430)

SEP – 6 2006

A. 510(k) Number:

B. Analytes: Cyclosporine (CSA)

C. Type of Test: Calibrator Material

D. Applicant: Dade Behring Inc., P.O. Box 6101, Newark, DE 19714-6101
Victor M. Carrio, Regulatory Affairs and Compliance Manager
Office: (302) 631-0376 Fax: (302) 631-6299

E. Proprietary and Established Names:

Dimension Vista™ System Drug 3 Calibrator
(DRUG 3 CAL – KC430)

F. Regulatory Information:

1. Regulation section: 21 CFR § 862-3200 – Clinical Toxicology Calibrator
2. Classification: Class II
3. Product Code: DLJ – Calibrator, Drug Specific
4. Panel: Clinical Chemistry

G. Intended Use: The DRUG 3 CAL is an *in vitro* diagnostic product for the calibration of Cyclosporine (CSA) method on the Dimension Vista™ System.

H. 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.

I. Substantial Equivalence Information:

Item	New Device Dimension Vista™ System Drug 3 Calibrator	Predicate Device Dimension® CSA Calibrator K011112
Intended Use	The DRUG 3 CAL is an *in vitro* diagnostic product for the calibration of Cyclosporine (CSA) method on the Dimension Vista™ System.	The CSA Calibrator is an in vitro diagnostic product intended to be used to calibrate the Cyclosporine (CSA) method for the Dimension® clinical chemistry system.
Analytes	Cyclosporine.	Cyclosporine.
Form	Frozen.	Frozen.
Traceability	USP[1] Cyclosporine A.	USP Cyclosporine A.
Matrix	Human whole blood containing cyclosporine.	Human whole blood containing cyclosporine.
Number of Levels	Two levels[2].	Five levels.

[1] United States Pharmacopeia.
[2] Intermediate levels are automatically prepared and corresponding values calculated by the Dimension Vista™ System.

J. Standard/Guidance Document Referenced:

1. Guidance: Guidance for Industry - Abbreviated 510(k) Submissions for In Vitro Diagnostic Calibrators; Final, 02/22/1999
   Guidance for Industry and FDA Staff - Use of Symbols on Labels and in Labeling of In Vitro Diagnostic Devices Intended for Professional Use, 11/30/2004
   Class II Special Controls Guidance Document: Cyclosporine and Tacrolimus Assays; Guidance for Industry and FDA

2. Standards: CEN 13640 Stability testing of In-Vitro Diagnostic Devices
   ISO 14971:2000 Medical devices -Application of risk management to medical devices

K. Performance Characteristics:

1. 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 control stored at -70°C. The method is calibrated from this stored material. The -20°C material values are recovered versus the calibration. Recovery versus time is monitored and percent change over time is determined. Percent change should be less than or equal to 5%. 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.

2. Traceability: The assigned values of the DRUG 3 CAL are traceable to United States Pharmacopeia Cyclosporine A Reference Material.

3. Bottle Value Assignment:

Cyclosporine Reference Material is weighed into drug free whole blood hemolysate at five levels and stored at -70°C.
The verification of the Master Pool values are compared against weighed in Master Pool values and LC/MS testing.
The stock solution is made by adding Cyclosporine Reference Material 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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Mr. Victor M. Carrio
RAC/QC Compliance Manager
Dade Behring, Inc.
500 GBC Drive
Mailstop 514
Newark, DE 19714

SEP - 6 2006

Re: k062199
Trade/Device Name: Dimension Vista™ System Drug 3 Calibrator (DRUG 3 CAL – KC430)
Regulation Number: 21 CFR 862.3200
Regulation Name: Clinical toxicology calibrator
Regulatory Class: Class II
Product Code: DLJ
Dated: July 28, 2006
Received: August 1, 2006

Dear Mr. Carrio:

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 Statement

510(k) Number (if known):

Device Name:

Dimension Vista™ System Drug 3 Calibrator
(DRUG 3 CAL – KC430)

Indications for Use:

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

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)

Carol C Benson

Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

K062199