510(k) Summary for the
Dimension Vista™ System Urinary/Cerebrospinal Fluid Protein Calibrator
(UCFP CAL – KC260)

JUL 13 2005

A. 510(k) Number: **k061751**

B. Analyte: Urinary/Cerebrospinal Fluid Protein (UCFP)

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 Urinary/Cerebrospinal Fluid Protein Calibrator (UCFP CAL – KC260)

F. Regulatory Information:

1. Regulation section: 21 CFR § 862-1150 – Calibrator
2. Classification: Class II
3. Product Code: JIT – Calibrator, Secondary
4. Panel: Clinical Chemistry

G. Intended Use: The UCFP CAL is an *in vitro* diagnostic product for the calibration of Urinary/Cerebrospinal Fluid Protein (UCFP) method on the Dimension Vista™ System.

H. Device Description:

UCFP CAL is an aqueous product containing dilute human serum. The kit consists of three vials of Calibrator A. The volume per vial is 1.5 mL. UCFP CAL is ready for use, where no preparation is required. System water is used as the UCFP zero calibrator (Level 1) for the Dimension Vista™ System.

I. Substantial Equivalence Information:

1. Predicate Device: k934843 – Dimension® Urinary/Cerebrospinal Fluid Protein Calibrator.

2. Comparison with Predicate:

	Device	Predicate
Item	**Dimension Vista™ System UCFP Calibrator**	**Dimension® UCFP Calibrator**
Intended Use	The UCFP CAL is an *in vitro* diagnostic product for the calibration of Urinary/Cerebrospinal Fluid Protein (UCFP) method on the Dimension Vista™ System.	The Dimension® Urinary/Cerebrospinal Fluid Protein is an in vitro diagnostic product to be used to calibrate the Dimension® clinical chemistry system for the Urinary/Cerebrospinal Fluid Protein (UCFP) method.
Analytes	Urinary/Cerebrospinal Fluid Protein	Urinary/Cerebrospinal Fluid Protein
Form	Liquid	Liquid
Traceability	NIST SRM 927(1)	NIST SRM 927(1)
Matrix	Aqueous product containing dilute human serum.	Saline solution containing human serum albumin and IgG.
Levels	One level (Level 2). Level 1 is system water.	Five levels.

1. National Institute of Standards and Technology, Standard Reference Material

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

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 Urinary/Cerebrospinal Fluid Protein Calibrator is 12 months. Calibrator shelf life is determined by comparing results of the product stored at 4°C with control stored at -20°C. The method is calibrated from this stored material. The 4°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 3%. 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 stored on board of the 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 Urinary/Cerebrospinal Fluid Protein Calibrator are traceable to the National Institute of Standards and Technology- Standard Reference Material 927.

3. Value Assignment:

Purified human IgG and human serum albumin are weighed into an aqueous solution to form a stock solution which is assayed and further diluted to create four more levels. The Master Pool is stored at 2 – 8 °C. The Master Pool recovered values are verified using an instrument calibrated with a previously approved Master Lot as a control. The control Master Pool values were assigned with an instrument calibrated with the standard reference material. The purified human IgG and human serum albumin are added gravimetrically to stock solution at target concentrations and verified using an instrument calibrated with Master Pool assigned values. Calculated quantities of human serum stock solution are added to base matrix (aqueous solution) in appropriate concentrations for one calibrator level. The test calibrator level is verified using an instrument calibrated with the Master Pool assigned values. The final bottle assignment for test calibrator level of the commercial lot is tested N = 90 replicates, with multiple reagent lots on multiple instruments.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Mr. Victor M. Carrio
RA/QS Compliance Manager
Dade Behring, Inc.
500 GBC Drive,
PO Box 6101, M/S 514
Newark DE 19714-6101

JUL 13 2006

Re: k061751
Trade/Device Name: Dimension Vista™ UCFP Calibrator (KC260)
Regulation Number: 21 CFR§862.1150
Regulation Name: Calibrator
Regulatory Class: Class II
Product Code: JIT
Dated: June 20, 2006
Received: June 21, 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): K061751

Device Name:

Dimension Vista™ UCFP Calibrator (KC260)

Indications for Use:

The UCFP CAL is an *in vitro* diagnostic product for the calibration of Urinary/Cerebrospinal Fluid Protein (UCFP) 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

K061751