K062334

510(k) Summary for the
Dimension Vista™ System Chemistry 3 Calibrator
(CHEM 3 CAL – KC130)

SEP 22 2006

A. 510(k) Number:

B. Analytes: Alcohol (ALC), ammonia (AMON) and carbon dioxide (CO2).

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 Chemistry 3 Calibrator
(CHEM 3 CAL – KC130)

F. Regulatory Information:

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

G. Intended Use: The CHEM 3 CAL is an *in vitro* diagnostic product for the calibration of alcohol (ALC), ammonia (AMON) and carbon dioxide (CO2) methods on the Dimension Vista™ System.

H. Device Description:

CHEM 3 CAL is a multi-analyte, aqueous product containing ethyl alcohol, ammonium bicarbonate and sodium carbonate. The kit consists of six vials, three vials of Calibrator A, and three vials of Calibrator B which are ready for use (no preparation is required). The volume per vial is 2.5 mL.

I. Substantial Equivalence Information:

	New Device	Predicate Devices		
Item	**Dimension Vista™ System Chemistry 3 Calibrator**	**Dimension® AMON Calibrator K863840**	**Dimension® ALC Calibrator K904308**	**Dimension® ECO2 Calibrator K010208**
Intended Use	The CHEM 3 CAL is an *in vitro* diagnostic product for the calibration of Alcohol (ALC), Ammonia (AMON) and Carbon Dioxide (CO2) methods on the Dimension Vista™ System.	Ammonia Calibrator is an in vitro diagnostic product to be used for calibrating the Dimension® clinical chemistry system for the ammonia (AMON) method.	The Alcohol Calibrator is an in vitro diagnostic product to be used to calibrate the Dimension® clinical chemistry system for the Ethyl Alcohol (ALC) method.	The Dimension® EC02 Calibrator is an in vitro diagnostics product to be used to calibrate the Dimension® clinical chemistry system for the Enzymatic Carbonate (EC02) method.
Analytes	Alcohol (ALC), Ammonia (AMON) and Carbon Dioxide (CO2).	Ammonia.	Alcohol.	Carbon Dioxide.
Form	Liquid.	Liquid.	Liquid.	Liquid.
Traceability	ALC – USP[1] Grade Ethyl Alcohol. AMON – ACS[2] Grade Ammonium Sulfate. CO2 – NIST SRM[3] 351.	ACS Grade Ammonium Chloride.	USP Grade Ethyl Alcohol.	NIST SRM 351.
Matrix	Aqueous product containing ethyl alcohol, ammonium bicarbonate and sodium carbonate.	Aqueous product containing ammonium chloride.	Aqueous product containing ethanol.	Aqueous product containing sodium carbonate.
Number of Levels	Two levels.	Three levels.	Four levels.	Three levels.

[1] United States Pharmacopeia.
[2] American Chemical Society
[3] 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 Chemistry 3 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 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 24 hours.
An open vial not on instrument, but recapped and stored in a refrigerator is stable for 30 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 1, 3, and 32 versus freshly opened vials.

2. Traceability: The assigned values of the Chemistry 3 Calibrator are standardized to the enclosed table of assigned values:

Constituent	Traceability
ALC	USP[1] Grade Ethyl Alcohol
AMON	ACS[2] Grade Ammonium Sulfate
CO2	NIST SRM[3] 351

[1]USP: United States Pharmacopeia
[2]ACS: American Chemical Society
[3]NIST-SRM: National Institute of Standards and Technology – Standard Reference Material.

3. Bottle Value Assignment:

Carbon dioxide reference material is weighed into purified water at three levels and stored at -70°C. Ammonia and alcohol reference materials are weighed into purified water at three levels respectively and stored at 4°C. The Master Pool values are verified by comparing against previously approved Master Pool values.

The stock solution is made by adding alcohol, ammonia and carbon dioxide reference materials gravimetrically to stock solution at target concentrations. The stock solution values are verified on an instrument calibrated with a previously approved Master Pool.

The commercial lot is made by adding calculated quantities of stock solution to purified water in appropriate concentrations for each of the calibrator levels. The concentration of each level is verified by using an instrument calibrated with Master Pools.

The final bottle values for each level of the commercial lot is assigned using multiple instruments by testing N = 45 replicates per level.

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.
P.O. Box 6101, M/S 514
Newark, DE 19714

SEP 2 2 2006

Re: k062334
Trade/Device Name: Dimension Vista™ Chem 3 Calibrator (KC130)
Regulation Number: 21 CFR 862.1150
Regulation Name: Calibrator
Regulatory Class: Class II
Product Code: JIX
Dated: August 9, 2006
Received: August 10, 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): K062334

Device Name:

Dimension Vista™ Chem 3 Calibrator (KC130)

Indications for Use:

The CHEM 3 CAL is an *in vitro* diagnostic product for the calibration of alcohol (ALC), ammonia (AMON) and carbon dioxide (CO2) methods 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)

for Carol Benson
Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K062334