

K062316

**510(k) Summary of Safety and Effectiveness Information**

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

**Submitter's Name:** Lorraine H Piestrak  
Dade Behring Inc.  
P.O. Box 6101  
Newark, DE 19714-6101

SEP - 6 2006

**Date of Preparation:** August 8, 2006

**Name of Products:**  
Dimension Vista™ Ammonia (AMON) Flex® reagent cartridge

**FDA Classification Name:**

Classification Name:	Common/Usual Name:
862.1065 Enzymatic Method, Ammonia	Ammonia test system

**Product code:** JIF

**Predicate Device:**  
Dimension® Ammonia (AMON) Flex® reagent cartridge (K863840)

**Device Description:**  
Dade Behring Dimension Vista™ Flex® reagent cartridges are prepackaged in-vitro diagnostic test methods (assays) that are specifically designed to be used on the Dade Behring Dimension Vista™ Integrated system, a floor model, fully automated, microprocessor-controlled, integrated instrument system. The Dimension Vista™ system was previously cleared with seven associated test methods (K051087). This Special 510(k) is submitted for a packaging modification to the Dimension® Ammonia (AMON) Flex® reagent cartridge (K863840), an *in-vitro* diagnostic device that has been cleared under the 510(k) process. The packaging change is to allow use on the Dimension Vista™ system.

The reagents contained in the Dimension Vista™ Ammonia (AMON) Flex® reagent cartridges are the same as those contained in the Ammonia (AMON) Flex® reagent cartridges manufactured for the Dimension® clinical chemistry systems, another family of Dade Behring analyzers. The packaging modification, does not affect the intended use of the device, nor does it alter the fundamental scientific technology of the device.

**Intended Use:**  
The AMON method is an *in vitro* diagnostic test for the quantitative measurement of ammonia in human plasma on the Dimension Vista™ System.

**Comparison to Predicate Device:**

Both the Dimension Vista™ AMON Flex® reagent cartridges and the predicate Dimension® AMON Flex® reagent cartridges contain prepackaged reagents in flexible plastic cartridges. A comparison of the important similarities and differences between the two Flex® cartridges is provided in the following table:

Feature	Dimension Vista™ AMON Flex® reagent cartridge	Dimension® AMON Flex® reagent cartridge K863840
Reagents	Prepackaged, 12-well plastic, Dade Behring Flex® reagent cartridges	Prepackaged, 8 well plastic, Dade Behring Flex® reagent cartridges
Intended Use	<i>in vitro</i> diagnostic use	<i>in vitro</i> diagnostic use
Indications for Use	Same as Dimension® analyzer	The Ammonia (AMON) Flex® reagent cartridge is an <i>in vitro</i> device intended to measure ammonia levels in plasma. Ammonia measurements are used in the diagnosis and treatment of severe liver disorders, such as cirrhosis, hepatitis, and Reye's syndrome.
Tablet Sizes	7/32"	7/32"
Total tests contained in each Flex® cartridge	20	15
Calibration	90 days	90 days
Sample Type	plasma	plasma
Reportable Range	25 - 1000 µmol/L	0 -1000 µmol/L
Sample Size	20 µL	53 µL
Measurement	Bichromatic rate @ 340 & 383 nm	Bichromatic rate @ 340 & 383 nm

**Comments on Substantial Equivalence:**

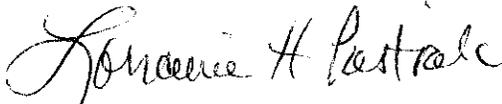
The Dade Behring Dimension Vista™ Flex® reagent cartridges and the Dimension® Flex® reagent cartridges are designed similarly for the same purpose. Both contain prepackaged reagents for *in-vitro* diagnostic tests that are processed on microprocessor-controlled, integrated instrument systems to analyze a variety of analytes in human specimens.

The reagents contained in the Dimension Vista™ Ammonia (AMON) Flex® reagent cartridges are the same as those contained in the Ammonia (AMON) Flex® reagent cartridges manufactured for the Dimension® clinical chemistry systems, another family of Dade Behring analyzers. The packaging modifications do not affect the intended use of the device, nor do they alter the fundamental scientific technology of the device.

Comparative testing described in the protocol included in this submission demonstrates substantially equivalent performance.

**Conclusion:**

The Flex® reagent cartridges, containing reagents for testing AMON on the Dimension® Vista™ Integrated system are substantially equivalent in design, principle, and performance to the Dimension® system AMON Flex® reagent cartridges. They have the same intended use and indications for use. Comparative testing also demonstrates substantially equivalent performance.



Lorraine H Piestrak  
Regulatory Affairs & Compliance Manager  
August 8, 2006



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

Ms. Lorraine Piestrak  
Dade Behring, Inc.  
Glasgow Business Community  
P.O. Box 6101, M/S 514  
Newark, DE 19714-6101

SEP - 6 2006

Re: k062316  
Trade/Device Name: Dimension Vista™ Ammonia (AMON) Flex®  
Regulation Number: 21 CFR 862.1065  
Regulation Name: Ammonia test system  
Regulatory Class: Class I  
Product Code: JIF  
Dated: August 8, 2006  
Received: August 9, 2006

Dear Ms. Piestrak:

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.

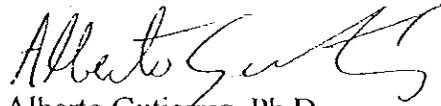
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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).

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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): K062316

Device Name: Dimension Vista™ Ammonia (AMON) Flex® reagent cartridge

### Indications For Use:

The Dimension Vista™ Ammonia (AMON) Flex® reagent cartridge is an *in vitro* device intended to measure ammonia levels in plasma. Ammonia measurements are used in the diagnosis and treatment of severe liver disorders, such as cirrhosis, hepatitis, and Reye's syndrome.

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)

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

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Division Sign-Off

Office of In Vitro Diagnostic Device  
Evaluation and Safety

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