K061020

510(k) Summary of Safety and Effectiveness Information

MAY 10 2006

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

Date of Preparation: April 12, 2005

Name of Product:

Dimension Vista™ Albumin (ALB) Flex® reagent cartridge
Dimension Vista™ Aspartate amino transferase (AST) Flex® reagent cartridge
Dimension Vista™ Carbamazepine (CRBM) Flex® reagent cartridge
Dimension Vista™ Alanine amino transferase (ALT) Flex® reagent cartridge
Dimension Vista™ Total Iron-binding capacity (TIBC) Flex® reagent cartridge

FDA Classification Name:

Methods (Class II)
Albumin, Aspartate amino transferase, and Carbamazepine test systems.

Methods (Class I)
Alanine amino transferase and Iron-binding capacity test systems

Predicate Device:

The following table describes the predicate devices, device classification, regulation and product code associated with this pre-market notification:

Product	Dade Behring Predicate	Predicate 510(k) #	Device class	Regulation	Product Code
Dimension Vista™ ALB Flex® reagent cartridge	Dimension® ALB Flex® reagent cartridge	K861700	II	862.1035	CJW
Dimension Vista™ AST Flex® reagent cartridge	Dimension® AST Flex® reagent cartridge	K860021	II	862.1100	CIT

Dimension Vista™ CRBM Flex® reagent cartridge	Dimension® CRBM Flex® reagent cartridge	K962820	II	862.3645	KLT
Dimension Vista™ ALT Flex® reagent cartridge	Dimension® ALT Flex® reagent cartridge	K862359	I*	862.1030	CKA
Dimension Vista™ TIBC Flex® reagent cartridge	Dimension® IBCT Flex® reagent cartridge	K994115	I	862.1415	JMO

* Not exempt when indications include diagnosis of cardiovascular (heart) diseases

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 (K 051087).

This Special 510(k) is submitted for a packaging modification to *in-vitro* diagnostic devices that have been cleared under the 510(k) process for use on Dimension® clinical chemistry systems. The packaging change is to allow use on the Dimension Vista™ system.

The ALB, AST, CRBM, ALT, and TIBC reagents contained in the Dimension Vista™ Flex® reagent cartridges are the same as those contained in the 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 devices, nor does it alter the fundamental scientific technology of the devices.

Intended Use:

Dimension Vista™ Albumin (ALB) Flex® reagent cartridge:
The ALB method is an *in vitro* diagnostic test for the quantitative measurement of albumin in human serum and plasma on the Dimension Vista™ System.

Dimension Vista™ Aspartate amino transferase (AST) Flex® reagent cartridge:
The AST method is an *in vitro* diagnostic test for the quantitative measurement of aspartate aminotransferase in human serum and plasma on the Dimension Vista™ System.

Dimension Vista™ Carbamazepine (CRBM) Flex® reagent cartridge:
The CRBM method is an *in vitro* diagnostic test for the quantitative measurement of carbamazepine in human serum and plasma on the Dimension Vista™ System. Carbamazepine measurements may be used in the diagnosis and treatment of carbamazepine overdose and in therapeutic drug monitoring.

Dimension Vista™ Alanine amino transferase (ALT) Flex® reagent cartridge:

The ALT method is an *in vitro* diagnostic test for the quantitative measurement of alanine aminotransferase in human serum and plasma on the Dimension Vista™ System.

Dimension Vista™ Total Iron-binding capacity (TIBC) Flex® reagent cartridge:
The TIBC method is an *in vitro* diagnostic test for the quantitative measurement of total iron binding capacity in human serum and plasma on the Dimension Vista™ System.

Comparison to Predicate Device:

Both the Dimension Vista™ Flex® reagent cartridges and the predicate Dimension® 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™ Flex® reagent cartridge	Dimension® Analyzer Flex® reagent cartridge
Reagents	Prepackaged, 12-well plastic, Dade Behring Flex® reagent cartridges	Prepackaged, 6 & 8 well plastic, Dade Behring Flex® reagent cartridges
Intended Use	*in vitro* diagnostic use	*in vitro* diagnostic use
Indications for Use	Same as Dimension® analyzer	As described in 510(k)s for each previously cleared method.
Final concentration of sample/reagent ratio in test milieu	Same as Dimension® analyzer	As described in 510(k)s for each previously cleared method
Tablet Sizes	7/32"	7/32" & 9/32"
Total tests contained in each Flex® cartridge	Approximately three times more than contained in Dimension® Flex® reagent cartridges	As described in 510(k)s for each previously cleared method.
Calibration	30 to 90 days (determined for each method)	30 to 90 days As described in 510(k)s for each previously cleared method.

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 ALB, AST, CRBM, ALT, and TIBC reagents contained in the Dimension Vista™ Flex® reagent cartridges are the same as those contained in the 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 devices, nor do they alter the fundamental scientific technology of the devices.

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

Conclusion:
The Flex® reagent cartridges, containing reagents for testing ALB, AST, ALT, CRBM, and TIBC on the Dimension® Vista™ Integrated system are substantially equivalent in design, principle, and performance to the Dimension® system 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
April 27, 2006

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

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

MAY 10 2006

Re: k061020
Trade/Device Name: Dimension Vista™ Albumin (ALB) Flex® reagent cartridge
Dimension Vista™ Aspartate amino transferase (AST) Flex reagent cartridge
Dimension Vista™ Carbarmazepine (CRBM) Flex® reagent cartridge
Dimension Vista™ Alanine amino transferase (ALT) Flex® reagent cartridge
Dimension Vista™ Total Iron-binding capacity (TIBC) Flex® reagent cartridge
Regulation Number: 21 CFR§ 862.1035
Regulation Name: Albumin test system
Regulatory Class: Class II
Product Code: CJW, CIT, KLT, CKA, JMO
Dated: April 12, 2006
Received: April 13, 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).

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): K061020

Device Name: Dimension Vista™ Albumin (ALB) Flex® reagent cartridge

Indications For Use:

The Dimension Vista™ Albumin Flex® reagent cartridge (ALB) is a device intended to measure the albumin concentration in serum and plasma. Measurements obtained by this device are used in the diagnosis and treatment of numerous diseases involving primarily the liver or kidneys.

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)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

(Optional) K061020

Indications for Use

510(k) Number (if known): K061020

Device Name: Dimension Vista™ Aspartate amino transferase (AST) Flex® reagent cartridge

Indications For Use:

The Dimension Vista™ Aspartate amino transferase (AST) Flex® reagent cartridge is a device intended to measure the activity of the enzyme aspartate amino transferase (AST) in serum and plasma. Aspartate amino transferase measurements are used in the diagnosis and treatment of certain types of liver and heart disease.

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

Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K061020

Indications for Use

510(k) Number (if known): K061020

Device Name:

Dimension Vista™ Carbamazepine (CRBM) Flex® reagent cartridge

Indications For Use:

The Dimension Vista™ Carbamazepine (CRBM) Flex® reagent cartridge is a device intended to measure carbamazepine, an anticonvulsant drug, in plasma and serum. Measurements obtained by this device are used in the diagnosis and treatment of carbamazepine overdose and in monitoring levels of carbamazepine to ensure appropriate therapy.

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)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

(Optional Format 1-2-96) K061020

Indications for Use

510(k) Number: (if known): K061020

Device Name: Dimension Vista™ Alanine amino transferase (ALT) Flex® reagent cartridge

Indications For Use:

The Dimension Vista™ Alanine amino transferase (ALT) Flex® reagent cartridge is intended to measure the activity of the enzyme pyruvic transaminase (ALT) in serum and plasma. Alanine amino transferase measurements are used in the diagnosis and treatment of certain liver diseases (e.g. viral hepatitis and cirrhosis) and heart diseases.

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

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K061020

Indications for Use

510(k) Number: (if known): K061020

Device Name: Dimension Vista™ Total Iron-binding capacity (TIBC) Flex® reagent cartridge

Indications For Use:

The Dimension Vista™ Total Iron-binding capacity (TIBC) Flex® reagent cartridge is intended to quantitatively measure total iron binding capacity in human serum and plasma. Measurements of total iron binding capacity are used in the diagnosis and treatment of iron deficiency anemia and chronic inflammatory disorders.

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

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

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K061020