K061792

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

JUL 18 2006

Date of Preparation: June 23, 2006

Name of Products:
Dimension Vista™ Ethyl Alcohol (ALC) Flex® reagent cartridge
Dimension Vista™ Alkaline phosphatase (ALP) Flex® reagent cartridge
Dimension Vista™ Calcium (CA) Flex® reagent cartridge
Dimension Vista™ Lactic Acid (LA) Flex® reagent cartridge
Dimension Vista™ Lithium (LI) Flex® reagent cartridge

FDA Classification Name:

Classification Name:	Common/Usual Name:
862.3040 Alcohol Dehyrdogenase, specific reagent for Ethanol Enzyme method	Alcohol test system
862.1050 Alkaline phosphatase	Alkaline phosphatase test system
862.1145 Calcium	Calcium test system
862.1450 Lactic acid	Lactic acid test system
862.3560 Lithium	Lithium test system

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

New Product	Predicate	Predicate 510(k) #	Device Class	Regulation	Product Code
Dimension Vista™ ALC Flex® reagent cartridge	Dimension® ALC Flex® reagent cartridge	K904302	II	862.3040	DIC
Dimension Vista™ ALP Flex® reagent cartridge	Dimension® ALP Flex® reagent cartridge	K860021	II	862.1050	CJE
Dimension Vista™ CA Flex® reagent cartridge	Dimension® CA Flex® reagent cartridge	K860021	II	862.1145	CIC

New Product	Predicate	Predicate 510(k) #	Device Class	Regulation	Product Code
Dimension Vista™ LA Flex® reagent cartridge	Dimension® LA Flex® reagent cartridge	K914508	I*	862.1450	KHP
Dimension Vista™ LI Flex® reagent cartridge	Dimension® LI Flex® reagent cartridge	K011033	II	862.3560	JIH

* Not exempt from premarket notification per 862.9 or per Reserved Medical Devices list

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 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:

Alcohol (Ethyl)
The ALC method is an *in vitro* diagnostic test for the measurement of ethyl alcohol in serum on the Dimension Vista™ System. Ethyl alcohol test results may be used in the diagnosis and treatment of alcohol intoxication and poisoning.

Alkaline Phosphatase
The ALP method is an *in vitro* diagnostic test for the quantitative measurement of alkaline phosphatase in human serum and plasma the Dimension Vista™ System.

Calcium
The CA method is an *in vitro* diagnostic test for the quantitative measurement of calcium in serum, plasma, and urine on the Dimension Vista™ System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUL 18 2006

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

Re: k061792
Trade/Device Name: Dimension Vista™ Ethyl Alcohol (ALC) Flex® reagent cartridge
Dimension Vista™ Alkaline phoshatase (ALP) Flex® reagent cartridge
Dimension Vista™ Calcium (CA) Flex® reagent cartridge
Dimension Vista™ Lactic Acid (LA) Flex® reagent cartridge
Dimension Vista™ Lithium (LI) Flex® reagent cartridge
Regulation Number: 21 CFR§862.3040
Regulation Name: Alcohol test system
Regulatory Class: Class II
Product Code: DIC, CJE, CIC, JIH, KHP
Dated: June 23, 2006
Received: June 26, 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): K061792

Device Name: Dimension Vista™ Ethyl Alcohol (ALC) Flex® reagent cartridge

Indications For Use:

The Dimension Vista™ Ethyl Alcohol (ALC) Flex® reagent cartridge is a device intended to measure ethyl alcohol in human serum. Measurements obtained by this device are used in the diagnosis and treatment of alcohol intoxication and poisoning.

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)

Carol C. Benson

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K061792

Indications for Use

510(k) Number (if known): K061792

Device Name: Dimension Vista™ Alkaline phosphatase (ALP) Flex® reagent cartridge

Indications For Use:

The Dimension Vista™ Alkaline phosphatase (ALP) Flex® reagent cartridge is a device intended to measure alkaline phosphatase in serum and plasma. Measurements of alkaline phosphatase are used primarily in the diagnosis and treatment of liver, bone, parathyroid and intestinal diseases.

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

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Carol C Benson
Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K061792

Indications for Use

510(k) Number (if known): K061792

Device Name: Dimension Vista™ Calcium (CA) Flex® reagent cartridge

Indications For Use:

The Dimension Vista™ Calcium (CA) Flex® reagent cartridge is a device intended to measure the total calcium level in serum, plasma, and urine. Calcium measurements are used in the diagnosis and treatment of parathyroid disease, a variety of bone diseases, chronic renal disease and tetany (intermittent muscular contractions or spasms).

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

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Office of In Vitro Diagnostic Device Evaluation and Safety

(K) K061792

Indications for Use

510(k) Number (if known): K061792

Device Name: Dimension Vista™ Lactic Acid (LA) Flex® reagent cartridge

Indications For Use:

The Dimension Vista™ Lactic Acid (LA) Flex® reagent cartridge is a device intended to measure lactic acid in plasma. Lactic acid measurements that evaluate the acid-base status are used in the diagnosis and treatment of lactic acidosis (abnormally high acidity of the blood).

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

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(Optional) K061792

Indications for Use

510(k) Number (if known): K061792

Device Name: Dimension Vista™ Lithium (LI) Flex® reagent cartridge

Indications For Use:

The Dimension Vista™ Lithium (LI) Flex® reagent cartridge is a device intended to measure lithium in serum and plasma. Measurements of lithium are used to assure the proper drug dosage is administered in the treatment of patients with mental disturbances, such as manic-depressive illness (bipolar disorder).

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

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