K051087

DADE BEHRING

DADE BEHRING INC.
P.O. Box 6101
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JUL 1 1 2005

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

Date of Preparation: April 27, 2005

Name of Product:

Dimension Vista™ Integrated system
Dimension Vista™ Urea Nitrogen Flex® reagent cartridge (BUN)
Dimension Vista™ Chemistry 1 Calibrator
Dimension Vista™ Immunoglobulin G Flex® reagent cartridge (IGG)
Dimension Vista™ Protein 1 Calibrator
Dimension Vista™ Protein 1 Controls, H, M, L
Dimension Vista™ Phenobarbital Flex® reagent cartridge (PHNO)
Dimension Vista™ Drug 1 Calibrator
Dimension Vista™ Mass creatine kinase MB isoenzyme Flex® reagent cartridge (MMB)
Dimension Vista™ MMB Calibrator
Dimension Vista™ V-LYTE™ Integrated Multisensor (Na^+/K^+/Cl^-)
Dimension Vista™ V-LYTE™ Standard A and Standard B

FDA Classification Name:

Discrete photometric chemistry analyzer for clinical use (Class I)

Urea Nitrogen, immunoglobulin G, phenobarbital, mass creatine kinase MB isoenzyme, sodium, potassium and chloride test systems, their associated calibrators, and controls (Class II).

Predicate Device:

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

New Product	Predicate Device	Predicate 510(k)	Device Class	Regulation	Product Code
Dimension Vista ™ 1500 Integrated chemistry system	Dimension® XL/RxL clinical chemistry analyzer	K944093	I	862.2160	JJE
Dimension Vista™ BUN Flex® reagent cartridge	Dimension® BUN Flex® reagent cartridge	K860021	II	862.1770	CDQ
Dimension Vista™ Chemistry 1 Calibrator	Dimension® Chem 1 Calibrator	K860021	II	862.1150	JIX
Dimension Vista™ IGG Flex® reagent cartridge	Dimension ® IGG Flex® reagent cartridge	K990551	II	866.5510	CFQ
Dimension Vista™ Protein 1 Calibrator	N Protein Standard SL	K012470	II	862.1150	JIX
Dimension Vista™ Protein 1 Controls H, M, L	N/T Protein Controls SL	K012468	II	862.1660	JJY
Dimension Vista™ PHNO Flex® reagent cartridge	Dimension ® PHNO Flex® reagent cartridge	K944932	II	862.3660	DLZ
Dimension Vista™ Drug 1 Calibrator	Dimension® Drug Calibrator	K011035	II	862.1150	JIX
Dimension Vista™ MMB Flex® reagent cartridge	Dimension® MMB Flex® reagent cartridge	K970343	II	862.1215	JHY
Dimension Vista™ MMB Calibrator	Dimension® MMB Calibrator	K970336	II	862.1150	JIT
Dimension Vista™ V-LYTE™ Integrated Multisensor $Na^+/K^+/Cl^-$	Dimension® Indirect IMT system (QuikLYTE®) $Na^+/K^+/Cl^-$	K970330	II	K -862.1600 Na-862.1665 Cl-862.1170	CEM JGS CGZ
Dimension Vista™ V-LYTE™ Standard A & Standard B	Dimension® QuikLYTE® Standard A & Standard B	K860021	II	852.1150	JIT

Device Description:

The Dade Behring Dimension Vista™ Integrated system is a floor model, fully automated, microprocessor-controlled, integrated instrument system that uses prepackaged Dade Behring Flex® reagent test cartridges to measure a variety of analytes in human body fluids. The system is a multi-functional analytical tool that processes chemical and immunochemical methodologies, utilizing photometric, turbidimetric, chemiluminesence, nephelometric, and integrated ion selective multisensor detection technologies for clinical use. The Vista™ system includes a communications and connectivity workstation (Easy Link™) for interaction with laboratory information system (LIS) networks, monitoring the usage of the system to suggest preventive maintenance, and QC result management.

Intended Use:
The Dade Behring Dimension Vista™ Integrated system is an *in vitro* diagnostic device intended to duplicate manual analytical procedures such as pipetting, mixing, heating, and measuring spectral intensities to determine a variety of analytes in human body fluids. Vista™ system chemical and immunochemical applications utilize photometric, turbidimetric, chemiluminescence, nephelometric and integrated ion selective multisensor technology for clinical use.

Representative Methods Intended Use:
The Urea Nitrogen Flex® reagent cartridge (BUN) is intended for the quantitative measurement of urea nitrogen (an end product of urea nitrogen metabolism) in human serum, plasma, and urine on the Dimension Vista™ system.

The Immunoglobulin G Flex® reagent cartridge (IGG) is intended for the quantitative measurement of immuoglobulin G (IgG) in human serum and plasma on the Dimension Vista™ system.

The Phenobarbital Flex® reagent cartridge (PHNO) is intended for the quantitative measurement of phenobarbital in human serum and plasma on the Dimension Vista™ system.

The Mass creatine kinase MB isoenzyme Flex® reagent cartridge (MMB) is intended for the quantitative measurement of mass creatine kinase MB isoenzyme in human serum and plasma on the Dimension Vista™ system for the confirmation of acute myocardial infarction.

The V-LYTE™ Integrated Multisensor is intended for the quantitative measurement of sodium, potassium, and chloride in human serum, plasma, and urine on the Dimension Vista™ system.

The Chemistry 1 calibrator is intended for the calibration of the Urea Nitrogen (BUN) method on the Dimension Vista™ system.

The Protein 1 calibrator is intended for the calibration of the Immunoglobulin G (IGG) method on the Dimension Vista™ system.

The Protein 1 controls, H, M, & L are intended for use as an assayed intralaboratory quality control for assessment of precision and analytical bias in the determination of Immunoglobulin G (IGG) results on the Dimension Vista™ system.

The Drug 1 calibrator is intended for the calibration of the Phenobarbital (PHNO) method on the Dimension Vista™ system.

The Mass CKMB Isoenzyme calibrator is intended for the calibration of the creatine kinase MB isoenzyme (MMB) method on the Dimension Vista™ system.

The V-LYTE™ Standard A & B are intended for the calibration of the $Na^+/K^+/Cl^-$ methods on the Dimension Vista™ system.

Comparison to Predicate Device:

Both the Dimension Vista™ Integrated system and the predicate Dimension® RxL clinical chemistry system employ prepackaged reagents in flexible plastic, Dade Behring Flex® reagent cartridges. Both systems automatically process and analyze clinical samples using a variety of *in vitro* diagnostic test methods. Both systems utilize integrated, ion selective multisensor detection technology for analysis of sodium, potassium and chloride electrolytes. A comparison of the important similarities and differences of these two automated analyzer systems is provided in the following table:

Feature	Dimension Vista™ System	Dimension® RxL Analyzer
Intended Use	*in vitro* diagnostic use	*in vitro* diagnostic use
System Control	Fully automatic, microprocessor controlled	Fully automatic, microprocessor controlled
User Interface	Keyboard control Hand held barcode reader Stationary barcode scanners Graphical user interface On line help	Keyboard control --- Stationary barcode scanners Graphical user interface On line help
Detection Technologies	photometric turbidimetric chemiluminescence nephelometric multisensor electrodes, ion selective	photometric turbidimetric --- --- multisensor electrodes, ion selective
Reagents	Prepackaged, 12-well plastic, Dade Behring Flex® reagent cartridges, stored on board	Prepackaged, 6 & 8 well plastic, Dade Behring Flex® reagent cartridges stored on board
Calibrators	Stored on board	User places on system as needed
System fluids and Supplies	Stored on board	Stored on board
Reaction Vessels	hard plastic cuvettes & plastic reaction vessels	soft, plastic cuvettes & plastic reaction vessels
Temperature control	Reactions are controlled at 37°C Reagents are stored at 2 to 8 °C	Reactions are controlled at 37°C Reagents are stored at 2 to 8 °C
Spectral Selection	Interference filters - xenon flash lamp source	Interference filters - quartz/halogen lamp source
Test Throughput (typical)	Up to 1500 tests/hr	Up to 500 tests/hr
LIS external connectivity capability	Yes	Yes

Feature	Dimension Vista™ System	Dimension® RxL Analyzer
System Performance Monitoring	Automatic preventive maintenance (usage - based)	Traditional preventative maintenance (time-based)
Sample Level Detection Capability	Automatic	Automatic
Calibration/QC	Automatic and Manual calibration/QC	Manual calibration/QC
Sample Integrity (hemolysis, icterus, lipemia) Monitoring	Yes - spectral interference monitoring (optional)	Yes- spectral interference monitoring (optional)

Comments on Substantial Equivalence:

The automated Dade Behring Dimension® RxL and Dimension Vista™ Integrated systems are designed similarly for the same purpose. Both are floor model units that are microprocessor-controlled, integrated instrument systems that use prepackaged, Dade Behring Flex® reagent cartridges and integrated ion selective multisensor technology to analyze a variety of analytes in human body fluids. Both systems spectrally analyze processed clinical samples using chemical and immunochemical methodologies. Split sample comparative data demonstrates equivalent performance in evaluations of the representative methods.

Representative Method Comparison Data
Dimension Vista™ vs. Predicate Method

Dimension Vista™	Predicate	Sample Type	Slope	Intercept	Correlation Coefficient (r)	n
BUN	Dimension® BUN	Serum/Plasma Urine	1.03 0.92	0.92 18.6	0.998 0.988	111 75
IGG	Dimension ® IGG	Serum/Plasma	0.92	1.89	0.985	98
PHNO	Dimension ® PHNO	Serum/Plasma	1.04	1.7	0.995	75
MMB	Dimension ® MMB	Serum/Plasma	1.05	1.4	0.997	136
V-LYTE™ Na^+	Dimension ® QuikLYTE™ Na^+	Serum/Plasma Urine	1.02 0.98	-1.3 2.5	0.997 0.998	103 52
V-LYTE™ K^+	Dimension ® QuikLYTE™ K^+	Serum/Plasma Urine	1.01 1.00	-0.06 0.12	0.999 0.999	103 52
V-LYTE™ CL^-	Dimension ® QuikLYTE™ Cl^-	Serum/Plasma Urine	1.02 1.02	-0.3 -3.3	0.998 0.998	104 51

Conclusion:
The automated Dimension® RxL and Dimension Vista™ Integrated systems are substantially equivalent in principle and performance based on the similarity of system design and split-sample comparisons using methods representative of each of the Vista™ system detection technologies. In addition, the representative test methods (BUN, IGG, PHNO, MMB, sodium, potassium and chloride) when compared to their predicates are equivalent in performance and design.

Lorraine H Piestrak
Regulatory Affairs & Compliance Manager
April 27, 2005

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUL 11 2005

Ms. Lorraine H. Piestrak
Regulatory Affairs & Compliance Manager
Dade Behring, Inc.
Chemistry/ Immunochemistry
P.O. Box 6101 Bldg 500; M.S. 514
Newark, DE 19714

Re: k051087
Trade/Device Name: Dimension Vista™ Integrated System
Regulation Number: 21 CFR 862.1770
Regulation Name: Urea nitrogen test system
Regulatory Class: Class II
Product Code: CDQ, CEM, CFQ, CGZ, DLZ, JGS, JHY, JIT, JIX, JJY, CKA, JJE
Dated: July 1, 2005
Received: July 5, 2005

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,

Carol C. Benson

Carol C. Benson, M.A.
Acting 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): K051087

Device Name: Dimension Vista™ Integrated System

Indications For Use:

The Dade Behring Dimension Vista™ Integrated system is an *in vitro* diagnostic device intended to duplicate manual analytical procedures such as pipetting, mixing, heating, and measuring spectral intensities to determine a variety of analytes in human body fluids. Vista™ system chemical and immunochemical applications utilize photometric, turbidimetric, chemiluminescence, nephelometric and integrated ion selective multisensor technology for clinical use.

Lorraine H Piestrak

Lorraine H Piestrak
Regulatory Affairs & Compliance Manager
April 27, 2005

Prescription Use ✓
(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

510(k) 051087

Indications for Use

510(k) Number (if known): K051087

Device Name: Dimension Vista™ Urea Nitrogen Flex® reagent cartridge (BUN)
Dimension Vista™ Chem I Calibrator

Indications For Use:

The Dimension Vista™ Urea Nitrogen Flex® reagent cartridge (BUN) is a device intended to measure urea nitrogen (an end-product of nitrogen metabolism) in serum, plasma, and urine. Measurements obtained by this device are used in the diagnosis and treatment of certain renal and metabolic diseases.

The Dimension Vista™ Chem I Calibrator is intended for medical purposes for use in a test system to establish points of reference that are used in the determination of values in the measurement of urea nitrogen in human specimens.

Lorraine H Piestrak
Regulatory Affairs & Compliance Manager
April 27, 2005

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

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Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) 051087

Indications for Use

510(k) Number (if known): K05 1087

Device Name: Dimension Vista™ Immunoglobulin G Flex® reagent cartridge (IGG)
Dimension Vista™ Protein 1 Calibrator
Dimension Vista™ Protein 1 Controls, H, M, L

Indications For Use:

The Dimension Vista™ Immunoglobulin G Flex® reagent cartridge (IGG) is a device that consists of the reagents used to measure by immunochemical techniques the immunoglobulin G (serum antibody) in serum and plasma. Measurement of immunoglobulin G aids in the diagnosis of abnormal protein metabolism and the body's lack of ability to resist infectious agents.

The Dimension Vista™ Protein 1 Calibrator is intended for medical purposes for use in a test system to establish points of reference that are used in the determination of values in the measurement of IgG in human specimens.

The Dimension Vista™ Protein 1 Controls, H, M, L, are intended for medical purposes for use in a test system to estimate test precision and to detect systematic analytical deviations that may arise from reagent or analytical instrument variation.

Lorraine H Piestrak
Regulatory Affairs & Compliance Manager
April 27, 2005

Prescription Use ✓ AND/OR Over-The-Counter Use _____
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510(k) 051087

Indications for Use

510(k) Number (if known): K051087

Device Name: Dimension Vista™ Phenobarbital Flex® reagent cartridge (PHNO)
Dimension Vista™ Drug 1 Calibrator

Indications For Use:

The Dimension Vista™ Phenobarbital Flex® reagent cartridge (PHNO) is a device intended to measure phenobarbital, an antiepileptic and sedative-hypnotic drug, in human serum and plasma. Measurements obtained by this device are used in the diagnosis and treatment of phenobarbital use or overdose and in monitoring levels of phenobarbital to ensure appropriate therapy.

Dimension Vista™ Drug 1 Calibrator is intended for medical purposes for use in a test system to establish points of reference that are used in the determination of values in the measurement of phenobarbital in human specimens.

Lorraine H Piestrak
Regulatory Affairs & Compliance Manager
April 27, 2005

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (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) 051087

Indications for Use

510(k) Number (if known): K051087

Device Name:
Dimension Vista™ Mass creatine kinase MB isoenzyme Flex® reagent cartridge (MMB)
Dimension Vista™ MMB Calibrator

Indications For Use:

The Dimension Vista™ Mass creatine kinase MB isoenzyme Flex® reagent cartridge (MMB) is a device intended to measure the activity of the MB isoenzyme of creatine phosphokinase in plasma and serum. Measurements of creatine phosphokinase and its isoenzymes are used in the diagnosis and treatment of myocardial infarction.

The Dimension Vista™ MMB Calibrator is intended for medical purposes for use in a test system to establish points of reference that are used in the determination of values in the measurement of mass creatine kinase MB isoenzyme in human specimens.

Lorraine H Piestrak

Lorraine H Piestrak
Regulatory Affairs & Compliance Manager
April 27, 2005

Prescription Use ✓
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801)

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Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) 051087

Indications for Use

510(k) Number: K051087

Device Name: Dimension Vista™ V-LYTE™ Integrated Multisensor $Na^+/K^+/Cl^-$
Dimension Vista™ V-LYTE™ Standard A
Dimension Vista™ V-LYTE™ Standard B

Indications For Use:

The Dimension Vista™ V-LYTE ™ Sodium test system is intended to measure sodium in serum, plasma and urine. Measurements obtained by this device are used in the diagnosis and treatment of aldosteronism (excessive secretion of the hormone aldosterone), diabetes insipidus (chronic excretion of large amounts of dilute urine, accompanied by extreme thirst), adrenal hypertension, Addison's disease (caused by destruction of the adrenal glands), dehydration, inappropriate antidiuretic hormone secretion, or other diseases involving electrolyte imbalance.

The Dimension Vista™ V-LYTE ™ Potassium test system is intended to measure potassium in serum, plasma and urine. Measurements obtained by this device are used to monitor electrolyte balance in the diagnosis and treatment of diseases conditions, characterized by low or high blood potassium levels.

The Dimension Vista™ V-LYTE ™ Chloride test system is intended to measure chloride in serum, plasma and urine. Measurements obtained by this device are used in the diagnosis and treatment of electrolyte and metabolic disorders.

The Dimension Vista™ V-LYTE ™ Standard A and Standard B are intended for medical purposes for use in a test system to establish points of reference that are used in the determination of values in the measurement of substances in human specimens.

Lorraine H Piestrak
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Regulatory Affairs & Compliance Manager
April 27, 2005

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