

K061655

JUL 10 2006

**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

**Date of Preparation:** June 12, 2005

**Name of Products:**

- Dimension Vista™ Acetaminophen (ACTM) Flex® reagent cartridge
- Dimension Vista™ Amylase (AMY) Flex® reagent cartridge
- Dimension Vista™ Creatine Kinase (CK) Flex® reagent cartridge
- Dimension Vista™ Cholesterol (CHOL) Flex® reagent cartridge
- Dimension Vista™ Gamma-glutamyl transferase (GGT) Flex® reagent cartridge
- Dimension Vista™ Glucose (GLU) Flex® reagent cartridge
- Dimension Vista™ High Density Lipoprotein Cholesterol (HDLC) Flex® reagent cartridge
- Dimension Vista™ Low Density Lipoprotein Cholesterol (LDLC) Flex® reagent cartridge
- Dimension Vista™ Lidocaine (LIDO) Flex® reagent cartridge
- Dimension Vista™ Magnesium (MG) Flex® reagent cartridge
- Dimension Vista™ Pseudocholinesterase (PCHE) Flex® reagent cartridge
- Dimension Vista™ Phosphorus (PHOS) Flex® reagent cartridge
- Dimension Vista™ Procainamide (PROC) Flex® reagent cartridge
- Dimension Vista™ Salicylate (SAL) Flex® reagent cartridge
- Dimension Vista™ Thyroxine (T4) Flex® reagent cartridge
- Dimension Vista™ Tobramycin (TOBR) Flex® reagent cartridge
- Dimension Vista™ Triglyceride (TRIG) Flex® reagent cartridge
- Dimension Vista™ Uric Acid (URCA) Flex® reagent cartridge
- Dimension Vista™ Valproic Acid (VALP) Flex® reagent cartridge
- Dimension Vista™ Vancomycin (VANC) Flex® reagent cartridge

**FDA Classification Name:**

Classification Name:	Common/Usual Name:
862.3030 Acetaminophen test system	Acetaminophen test system
862.1070 Amylase test system	Amylase test system
862.1215 Creatine kinase test system	Creatine kinase test system
862.1175 Cholesterol (total) test system	Cholesterol test system
862.1360 Gamma-glutamyl transpeptidase test system	GGT test system
862.1345 Glucose test system	Glucose test system
862.1475 Lipoprotein test system (HDL)	HDL Cholesterol test system

862.1475 Lipoprotein test system (LDL)	LDL Cholesterol test system
862.3555 Lidocaine test system	Lidocaine test system
862.1495 Magnesium test system	Magnesium test system
862.3240 Cholinesterase test system	Pseudocholinesterase test system
862.1580 Phosphorus (inorganic) test system	Phosphorus test system
862.3320 Digoxin test system ( Procainamide)	Procainamide test system
862.3830 Salicylate test system	Salicylate test system
862.1700 Total thyroxine test system	Total T4 test system
862.3900 Tobramycin test system	Tobramycin test system
862.1705 Triglyceride test system	Triglyceride test system
862.1775 Uric acid test system	Uric acid test system
862.3645 Neuroleptic drugs radioreceptor assay test system	Valproic Acid test system
862.3950 Vancomycin test system	Vancomycin test system

**Predicate Device:**

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

<b>New Product</b>	<b>Predicate</b>	<b>Predicate 510(k) #</b>	<b>Device Class</b>	<b>Regulation</b>	<b>Product Code</b>
Dimension Vista™ ACTM Flex® reagent cartridge	Dimension® ACTM Flex® reagent cartridge	K963244	II	862.3030	LDP
Dimension Vista™ AMY Flex® reagent cartridge	Dimension® AMY Flex® reagent cartridge	K942640	II	862.1070	JFJ
Dimension Vista™ CK Flex® reagent cartridge	Dimension® CK Flex® reagent cartridge	K941584	II	862.1215	JHS
Dimension Vista™ CHOL Flex® reagent cartridge	Dimension® CHOL Flex® reagent cartridge	K861700	I*	862.1175	CHH
Dimension Vista™ GGT Flex® reagent cartridge	Dimension® GGT Flex® reagent cartridge	K861700	I*	862.1360	JQB
Dimension Vista™ GLU Flex® reagent cartridge	Dimension® GLUC Flex® reagent cartridge	K031135	II	862.1345	CFR
Dimension Vista™ HDL Flex® reagent cartridge	Dimension® HDL Flex® reagent cartridge	K053157	I*	862.1475	LBS
Dimension Vista™ LDL Flex® reagent cartridge	Dimension® LDL Flex® reagent cartridge	K020724	I*	862.1475	MRR

<b>New Product</b>	<b>Predicate</b>	<b>Predicate 510(k)</b>	<b>Device class</b>	<b>Regulation</b>	<b>Product Code</b>
Dimension Vista™ LIDO Flex® reagent cartridge	Dimension® LIDO Flex® reagent cartridge	K033809	II	862.3555	KLR
Dimension Vista™ MG Flex® reagent cartridge	Dimension® MG Flex® reagent cartridge	K861700	I*	862.1495	JGJ
Dimension Vista™ PCHE Flex® reagent cartridge	Dimension® PCHE Flex® reagent cartridge	K950180	I*	862.3240	DIH
Dimension Vista™ PHOS Flex® reagent cartridge	Dimension® PHOS Flex® reagent cartridge	K861700	I*	862.1580	CEO
Dimension Vista™ PROC Flex® reagent cartridge	Dimension® PROC Flex® reagent cartridge	K032573	II	862.3320	LAR
Dimension Vista™ SAL Flex® reagent cartridge	Dimension® SAL Flex® reagent cartridge	K904301	II	862.3830	DKJ
Dimension Vista™ T4 Flex® reagent cartridge	Dimension® T4 Flex® reagent cartridge	K862359	II	862.1700	KLI
Dimension Vista™ TOBR Flex® reagent cartridge	Dimension® TOBRA Flex® reagent cartridge	K962818	II	862.3900	LCR
Dimension Vista™ TRIG Flex® reagent cartridge	Dimension® TGL Flex® reagent cartridge	K010871	I*	862.1705	CDT
Dimension Vista™ URCA Flex® reagent cartridge	Dimension® URCA Flex® reagent cartridge	K862359	I*	862.1775	KNK
Dimension Vista™ VALP Flex® reagent cartridge	Dimension® VALP Flex® reagent cartridge	K982880	II	862.3645	LEG
Dimension Vista™ VANC Flex® reagent cartridge	Dimension® VANC Flex® reagent cartridge	K963267	II	862.3950	LEH

\* 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:**

Acetaminophen

The ACTM method is an *in vitro* diagnostic test for the quantitative measurement of acetaminophen, an analgesic and antipyretic, in human serum and plasma on the Dimension Vista™ System. Acetaminophen measurements may be used in the diagnosis and treatment of acetaminophen overdose.

Amylase

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

Creatine Kinase

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

Cholesterol

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

Gamma-glutamyl transferase

The GGT method is an *in vitro* diagnostic test for the quantitative measurement of gamma-glutamyl transferase in human serum and plasma on the Dimension Vista™ System.

Glucose

The GLU method is an *in vitro* diagnostic test for the quantitative measurement of glucose in human serum, plasma, urine and cerebrospinal fluid on the Dimension Vista™ System.

High-Density Lipoprotein Cholesterol

The HDLC method is an *in vitro* diagnostic test for the quantitative measurement of high-density lipoprotein cholesterol in human serum and plasma on the Dimension

Vista™ System. Measurements of high-density lipoprotein cholesterol are used as an aid to diagnose lipid disorders.

#### Low-Density Lipoprotein Cholesterol

The LDLC method is an *in vitro* diagnostic test for the quantitative measurement of low-density lipoprotein cholesterol in human serum and plasma on the Dimension Vista™ System. Measurements of low-density lipoprotein cholesterol are used in the diagnosis and treatment of lipid disorders such as diabetes mellitus, atherosclerosis and various liver and renal diseases.

#### Lidocaine

The LIDO method is an *in vitro* diagnostic test for the quantitative measurement of lidocaine in human serum and plasma on the Dimension Vista™ System. Lidocaine measurements may be used in the diagnosis and treatment of lidocaine overdose, and in therapeutic drug monitoring.

#### Magnesium

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

#### Pseudocholinesterase

The PCHE method is an *in vitro* diagnostic test for the quantitative measurement of pseudocholinesterase activity in human serum and plasma on the Dimension Vista™ System. PCHE measurements may be used in the diagnosis and treatment of cholinesterase inhibition disorders.

#### Phosphorus

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

#### Procainamide

The PROC method is an *in vitro* diagnostic test for the quantitative measurement of procainamide in human serum and plasma on the Dimension Vista™ System. Procainamide measurements may be used in the diagnosis and treatment of procainamide overdose, and in therapeutic drug monitoring.

#### Salicylate

The SAL method is an *in vitro* diagnostic test for the quantitative measurement of salicylate in human serum on the Dimension Vista™ System. Salicylate test results may be used in the diagnosis and treatment of salicylate overdose and for monitoring salicylate levels during therapy.

#### Thyroxine

The T4 method is an *in vitro* diagnostic test for the quantitative measurement of total thyroxine in human serum and plasma on the Dimension Vista™ System.

### Tobramycin

The TOBR method is an *in vitro* diagnostic test for the quantitative measurement of tobramycin, an aminoglycoside antibiotic, in human serum and plasma on the Dimension Vista™ System. Tobramycin measurements may be used in the diagnosis and treatment of tobramycin overdose and in monitoring levels of tobramycin to ensure appropriate therapy.

### Triglyceride

The TRIG method is an *in vitro* diagnostic test for the quantitative measurement of triglycerides in human serum and plasma on the Dimension Vista™ System. Measurements obtained are used in the diagnosis and treatment of patients with diabetes mellitus, nephrosis, liver obstruction, other diseases involving lipid metabolism or various endocrine disorders.

### Uric Acid

The URCA method is an *in vitro* diagnostic test for the quantitative measurement of uric acid in human serum, plasma, and urine on the Dimension Vista™ System.

### Valproic Acid

The VALP method is an *in vitro* diagnostic test for the quantitative measurement of valproic acid in human serum and plasma on the Dimension Vista™ System. Valproic acid measurements may be used in the diagnosis and treatment of valproic acid overdose and in monitoring levels of valproic acid to ensure appropriate therapy.

### Vancomycin

The VANC method is an *in vitro* diagnostic test for the quantitative measurement of vancomycin, a glycopeptide antibiotic, in human serum and plasma on the Dimension Vista™ System. Vancomycin measurements may be used in the diagnosis and treatment of vancomycin overdose and in monitoring levels of vancomycin to ensure appropriate therapy.

**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	<i>in vitro</i> diagnostic use	<i>in vitro</i> 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 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 substantially equivalent performance.

**Conclusion:**

The Flex® reagent cartridges, containing reagents for testing ACTM, AMY, CK, CHOL, GGT, GLU, HDLC, LDLC, LIDO, MG, PCHE, PHOS, PROC, SAL, T4, TOBR, TRIG, URCA, VALP, and VANC 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  
June 12, 2006





DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

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

**JUL 10 2006**

Re: k061655  
Trade/Device Name: See attached list of device trade names  
Regulation Number: 21 CFR§862.3030  
Regulation Name: Acetaminophen test system  
Regulatory Class: Class II  
Product Code: LDP, JFJ, JHS, CHH, JQB, CFR, LBS, MRR, KLR, JGJ, DIH, CEO,  
LAR, DKJ, KLI, LCR, CDT, KNK, LEG, LEH  
Dated: June 12, 2006  
Received: June 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.

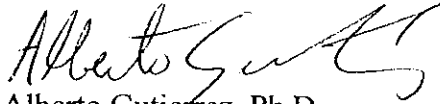
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's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

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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

Device/Trade Names:

Dimension Vista™ Acetaminophen (ACTM) Flex® reagent cartridge  
Dimension Vista™ Amylase (AMY) Flex® reagent cartridge  
Dimension Vista™ Creatine Kinase (CK) Flex® reagent cartridge  
Dimension Vista™ Cholesterol (CHOL) Flex® reagent cartridge  
Dimension Vista™ Gamma-glutamyl transferase (GGT) Flex® reagent cartridge  
Dimension Vista™ Glucose (GLU) Flex® reagent cartridge  
Dimension Vista™ Cholesterol (CHOL) Flex® reagent cartridge  
Dimension Vista™ High Density Lipoprotein Cholesterol (HDL) Flex® reagent cartridge  
Dimension Vista™ Low-Density Lipoprotein Cholesterol Flex(LDLC)® reagent cartridge  
Dimension Vista™ Lidocaine (LIDO) Flex® reagent cartridge  
Dimension Vista™ Magnesium (MG) Flex® reagent cartridge  
Dimension Vista™ Pseudocholinesterase (PCHE) Flex® reagent cartridge  
Dimension Vista™ Phosphorus (PHOS) Flex® reagent cartridge  
Dimension Vista™ Procainamide (PROC) Flex® reagent cartridge  
Dimension Vista™ Salicylate (SAL) Flex® reagent cartridge  
Dimension Vista™ Thyroxine (T4) Flex® reagent cartridge  
Dimension Vista™ Tobramycin (TOBR) Flex® reagent cartridge  
Dimension Vista™ Triglyceride (TRIG) Flex® reagent cartridge  
Dimension Vista™ Uric Acid (URCA) Flex® reagent cartridge  
Dimension Vista™ Valproic Acid (VALP) Flex® reagent cartridge  
Dimension Vista™ Vancomycin (VANC) Flex® reagent cartridge

## Indications for Use

510(k) Number (if known):

Device Name: Dimension Vista™ Acetaminophen (ACTM) Flex® reagent cartridge

Indications For Use:

The Dimension Vista™ Acetaminophen (ACTM) Flex® reagent cartridge is a device intended to measure acetaminophen, an analgesic and antipyretic (fever reducing) drug, in serum and plasma. Measurements obtained by this device are used in the diagnosis and treatment of acetaminophen overdose.

Prescription Use   X    
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801)

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*Carol Benson*

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Evaluation and Safety**

510(k) K061655

## Indications for Use

510(k) Number (if known):

Device Name: Dimension Vista™ Amylase (AMY) Flex® reagent cartridge

Indications For Use:

The Dimension Vista™ Amylase (AMY) Flex® reagent cartridge is a device intended to measure the activity of the enzyme amylase in serum, plasma and urine. Amylase measurements are used primarily for the diagnosis and treatment of pancreatitis (inflammation of the pancreas).

Prescription Use   X    
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801)

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## Indications for Use

510(k) Number (if known):

Device Name: Dimension Vista™ Creatine Kinase (CK) Flex® reagent cartridge

Indications For Use:

The Dimension Vista™ Creatine Kinase (CK) Flex® reagent cartridge is a device intended to measure the activity of the enzyme creatine kinase in serum and plasma. Measurements of creatine kinase are used in the diagnosis and treatment of myocardial infarction and muscle diseases such as progressive Duchenne-type muscular dystrophy.

Prescription Use   X    
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801)

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## Indications for Use

510(k) Number (if known):

Device Name: Dimension Vista™ Cholesterol (CHOL) Flex® reagent cartridge

Indications For Use:

The Dimension Vista™ Cholesterol (CHOL) Flex® reagent cartridge is a device intended to measure cholesterol in serum and plasma. Cholesterol measurements are used in the diagnosis and treatment of disorders involving excess cholesterol in the blood and lipid and lipoprotein metabolism disorders.

Prescription Use   X    
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801)

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## Indications for Use

510(k) Number (if known):

Device Name: Dimension Vista™ Gamma-glutamyl transferase (GGT) Flex® reagent cartridge

Indications For Use:

The Dimension Vista™ Gamma-glutamyl transferase (GGT) Flex® reagent cartridge is a device intended to measure gamma-glutamyl transferase in human serum and plasma. Gamma-glutamyl transferase measurements are used in the diagnosis and treatment of liver diseases such as alcoholic cirrhosis and primary and secondary liver tumors.

Prescription Use   X    
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801)

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## Indications for Use

510(k) Number (if known):

Device Name: Dimension Vista™ Glucose (GLU) Flex® reagent cartridge

Indications For Use:

The Dimension Vista™ Glucose (GLU) Flex® reagent cartridge is a device intended to measure glucose in human serum, plasma, urine and cerebrospinal fluid. Glucose measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, neonatal and idiopathic hypoglycemia, and pancreatic islet cell carcinoma.

Prescription Use   X    
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801)

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## Indications for Use

510(k) Number (if known):

Device Name: Dimension Vista™ High Density Lipoprotein Cholesterol  
(HDLC) Flex® reagent cartridge

Indications For Use:

The Dimension Vista™ High-Density Lipoprotein Cholesterol (HDLC) Flex® reagent cartridge is intended to measure high-density lipoprotein cholesterol in serum and plasma. Measurements of high-density lipoprotein cholesterol are used in the diagnosis of lipid disorders (such as diabetes mellitus), atherosclerosis, and various liver and renal diseases.

Prescription Use   X    
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801)

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## Indications for Use

510(k) Number (if known):

Device Name: Dimension Vista™ Low-Density Lipoprotein Cholesterol (LDLC) Flex® reagent cartridge

Indications For Use:

The Dimension Vista™ Low-Density Lipoprotein Cholesterol (LDLC) Flex® reagent cartridge is intended to measure low-density lipoprotein cholesterol in serum and plasma. Measurements of low-density lipoprotein cholesterol are used in the diagnosis of lipid disorders (such as diabetes mellitus), atherosclerosis, and various liver and renal diseases.

Prescription Use   X    
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801)

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## Indications for Use

510(k) Number (if known):

Device Name: Dimension Vista™ Lidocaine (LIDO) Flex® reagent cartridge

Indications For Use:

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

Prescription Use   X    
(Part 21 CFR 801 Subpart D)

AND/OR


Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801)

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## Indications for Use

510(k) Number (if known):

Device Name: Dimension Vista™ Magnesium (MG) Flex® reagent cartridge

Indications For Use:

The Dimension Vista™ Magnesium (MG) Flex® reagent cartridge is intended for the measurement of magnesium levels in serum and plasma. Magnesium measurements are used in the diagnosis and treatment of hypomagnesemia (abnormally low plasma levels of magnesium) and hypermagnesemia (abnormally high plasma levels of magnesium).

Prescription Use  (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_ (21 CFR 801)

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\_\_\_\_\_  
Director, OIVD

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## Indications for Use

510(k) Number (if known):

Device Name: Dimension Vista™ Pseudocholinesterase (PCHE) Flex® reagent cartridge

Indications For Use:

The Dimension Vista™ Pseudocholinesterase (PCHE) Flex® reagent cartridge is a device intended to measure pseudocholinesterase activity in human serum and plasma. Measurements obtained by this device are used in the diagnosis and treatment of cholinesterase inhibition disorders (e.g., insecticide poisoning and succinylcholine poisoning).

Prescription Use   X    
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801)

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## Indications for Use

510(k) Number (if known):

Device Name: Dimension Vista™ Phosphorus (PHOS) Flex® reagent cartridge

Indications For Use:

The Dimension Vista™ Phosphorus (PHOS) Flex® reagent cartridge is a device intended to measure inorganic phosphorus in serum, plasma, and urine. Measurements of phosphorus (inorganic) are used in the diagnosis and treatment of various disorders, including parathyroid gland and kidney diseases, and vitamin D imbalance.

Prescription Use   X    
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801)

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*Carol Bensen*

Director, OIVD

Office of In Vitro Diagnostic Device  
Evaluation and Safety

K061655

## Indications for Use

510(k) Number (if known):

Device Name: Dimension Vista™ Procainamide (PROC) Flex® reagent cartridge

Indications For Use:

The Dimension Vista™ Procainamide (PROC) Flex® reagent cartridge is a device intended to measure procainamide in serum and plasma. Measurements obtained may be used in the diagnosis and treatment of procainamide overdose and in monitoring levels of procainamide to ensure appropriate therapy.

Prescription Use  (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_ (21 CFR 801)

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*Carol C Benson*  
Signature

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## Indications for Use

510(k) Number (if known):

Device Name: Dimension Vista™ Salicylate (SAL) Flex® reagent cartridge

Indications For Use:

The Dimension Vista™ Salicylate (SAL) Flex® reagent cartridge is a device intended to measure salicylates, a class of analgesic, antipyretic and anti-inflammatory drugs that includes aspirin, in human serum. Measurements obtained by this device are used in the diagnosis and treatment of salicylate overdose and in monitoring salicylate levels to ensure appropriate therapy.

Prescription Use   X    
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801)

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*Carol C. Benson*  
Director

Office of In Vitro Diagnostic Device  
Evaluation and Safety

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## Indications for Use

510(k) Number (if known):

Device Name: Dimension Vista™ Thyroxine (T4) Flex® reagent cartridge

Indications For Use:

The Dimension Vista™ Thyroxine (T4) Flex® reagent cartridge is a device intended to measure total (free and protein bound) thyroxine (thyroid hormone) in serum and plasma. Measurements obtained by this device are used in the diagnosis and treatment of thyroid diseases.

Prescription Use  (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_ (21 CFR 801)

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*Carol Benson*  
\_\_\_\_\_  
For Signature

Office of In Vitro Diagnostic Devices  
Regulation and Safety

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## Indications for Use

510(k) Number (if known):

Device Name: Dimension Vista™ Tobramycin (TOBR) Flex® reagent cartridge

Indications For Use:

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

Prescription Use   X    
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801)

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*Carol C Benson*

Director

Office of In Vitro Diagnostic Devices  
and Biologics Safety

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## Indications for Use

510(k) Number (if known):

Device Name: Dimension Vista™ Triglyceride (TRIG) Flex® reagent cartridge

Indications For Use:

The Dimension Vista™ Triglyceride (TRIG) Flex® reagent cartridge is a device intended to measure triglyceride (neutral fat) in serum and plasma. Measurements obtained by this device are used in the diagnosis and treatment of patients with diabetes mellitus, nephrosis, liver obstruction, other diseases involving lipid metabolism, or various endocrine disorders.

Prescription Use  (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801)

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*Carol C. Benson*

Office of In Vitro Diagnostic Devices  
Regulation and Safety

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## Indications for Use

510(k) Number (if known):

Device Name: Dimension Vista™ Uric Acid (URCA) Flex® reagent cartridge

Indications For Use:

The Dimension Vista™ Uric Acid (URCA) Flex® reagent cartridge is a device intended to measure uric acid in serum, plasma, and urine. Measurements obtained by this device are used in the diagnosis and treatment of numerous renal and metabolic disorders, including renal failure, gout, leukemia, psoriasis, starvation or other wasting conditions, and of patients receiving cytotoxic drugs.

Prescription Use   X    
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801)

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*Carol C Benson*

Office of In Vitro Diagnostic Devices  
Center for Devices and Radiological Control

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## Indications for Use

510(k) Number (if known):

Device Name: Dimension Vista™ Valproic Acid (VALP) Flex® reagent cartridge

Indications For Use:

The Dimension Vista™ Valproic Acid (VALP) Flex® reagent cartridge is a device intended to measure valproic acid, an anti-convulsant drug in serum and plasma. Measurements obtained may be used in the diagnosis and treatment of valproic acid overdose and in monitoring levels of valproic acid to ensure appropriate therapy.

Prescription Use   X    
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801)

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*Carol C Benson*

\_\_\_\_\_  
Signature Sign-Off

Office of In Vitro Diagnostic Devices  
Regulation and Safety

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## Indications for Use

510(k) Number (if known):

Device Name: Dimension Vista™ Vancomycin (VANC) Flex® reagent cartridge

Indications For Use:

The Dimension Vista™ Vancomycin (VANC) Flex® reagent cartridge is a device intended to measure vancomycin, an antibiotic drug, in serum and plasma. Measurements obtained by this device are used in the diagnosis and treatment of vancomycin overdose and in monitoring the level of vancomycin to ensure appropriate therapy.

Prescription Use  (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801)

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*Carol Benson*  
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Signature

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