K062024

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 2 8 2006

Date of Preparation: July 17, 2006

Name of Products:
Dimension Vista™ Digitoxin (DGTX) Flex® reagent cartridge
Dimension Vista™ Digoxin (DIG) Flex® reagent cartridge
Dimension Vista™ Gentamicin (GENT) Flex® reagent cartridge
Dimension Vista™ N-acetylprocainamide (NAPA) Flex® reagent cartridge
Dimension Vista™ Phenytoin (PTN) Flex® reagent cartridge
Dimension Vista™ Theophylline (THEO) Flex® reagent cartridge

FDA Classification Name:

Classification Name:	Common/Usual Name:
862.3300 Enzyme Immunoassay, Digitoxin	Digitoxin test system
862.3320 Enzyme Immunoassay, Digoxin	Digoxin test system
862.3450 Enzyme Immunoassay, Gentamicin	Gentamicin test system
862.3320 Enzyme Immunoassay, N-Acetylprocainamide	N-Acetylprocainamide test system
862.3350 Enzyme Immunoassay, Diphenylhydantoin	Diphenylhydantoin (phenytoin) test system
862.3880 Enzyme Immunoassay, Theophylline	Theophylline 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™ DGTX Flex® reagent cartridge	Dimension® DGTX Flex® reagent cartridge	K990251	II	862.3300	LFM
Dimension Vista™ DIG Flex® reagent cartridge	Dimension® DGNA Flex® reagent cartridge	K946153	II	862.3320	KXT
Dimension Vista™ GENT Flex® reagent cartridge	Dimension® GENT Flex® reagent cartridge	K962819	II	862.3450	LCD
Dimension Vista™ NAPA Flex® reagent cartridge	Dimension® NAPA Flex® reagent cartridge	K032564	II	862.3320	LAN

New Product	Predicate	Predicate 510(k) #	Device class	Regulation	Product Code
Dimension Vista™ PTN Flex® reagent cartridge	Dimension® PTN Flex® reagent cartridge	K911056	II	862.3350	DIP
Dimension Vista™ THEO Flex® reagent cartridge	Dimension® THEO Flex® reagent cartridge	K862955	II	862.3880	KLS

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:
Digitoxin
The DGTX method is an *in vitro* diagnostic test for the quantitative measurement of digitoxin in serum and plasma on the Dimension Vista™ System. Measurements of digitoxin are used in the diagnosis and treatment of digitoxin overdose and in monitoring levels of digitoxin to ensure appropriate therapy.

Digoxin
The DIG method is an *in vitro* diagnostic test for the quantitative measurement of digoxin in serum and plasma on the Dimension Vista™ System. Measurements of digoxin are used in the diagnosis and treatment of digoxin overdose and in monitoring levels of digoxin to ensure appropriate therapy.

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

N-acetylprocainamide
The NAPA method is an *in vitro* diagnostic test for the quantitative measurement of N-acetylprocainamide in serum and plasma on the Dimension Vista™ System. N-acetylprocainamide measurements may be used in therapeutic drug monitoring to maintain adequate procainamide therapy.

Phenytoin
The PTN method is an *in vitro* diagnostic test for the quantitative measurement of phenytoin, (dilantin, diphenylhydantoin), an anti-epileptic drug, in human serum and plasma on the Dimension Vista™ System. Phenytoin measurements may be used in the diagnosis and treatment of phenytoin overdose and in monitoring levels of phenytoin to ensure appropriate therapy.

Theophylline
The THEO method is an *in vitro* diagnostic test for the quantitative measurement of theophylline 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 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 DGTX, DIG, GENT, NAPA, PTN, and THEO 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
July 17, 2006

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUL 28 2006

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

Re: k062024
Trade/Device Name: Dimension Vista™ Digitoxin (DGTX) Flex® reagent cartridge
Dimension Vista™ Digoxin (DIG) Flex® reagent cartridge
Dimension Vista™ Gentamicin (GENT) Flex® reagent cartridge
Dimension Vista™ N-acetylprocainamide (NAPA)
Flex® reagent cartridge
Dimension Vista™ Phenytoin (PTN) Flex® reagent cartridge
Dimension Vista™ Theophylline (THEO) Flex® reagent cartridge
Regulation Number: 21 CFR§862.3300
Regulation Name: Digitoxin test system
Regulatory Class: Class II
Product Code: LFM, KXT, LCD, LAN, DIP, KLS
Dated: July 17, 2006
Received: July 18, 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.

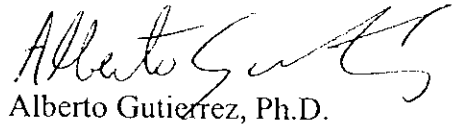
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish 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):

Device Name: Dimension Vista™ Digitoxin (DGTX) Flex® reagent cartridge

Indications For Use:

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

Prescription Use ___X____ 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)

K062024

Indications for Use

510(k) Number (if known):

Device Name: Dimension Vista™ Digoxin (DIG) Flex® reagent cartridge

Indications For Use:

The Dimension Vista™ Digoxin (DIG) Flex® reagent cartridge is a device intended to measure digoxin, a cardiovascular drug, in serum and plasma. Measurements of digoxin are used in the diagnosis and treatment of digoxin overdose and in monitoring levels of digoxin 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)

Indications for Use

510(k) Number (if known):

Device Name: Dimension Vista™ Gentamicin (GENT) Flex® reagent cartridge

Indications For Use:

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

Prescription Use ____X___ 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)

Indications for Use

510(k) Number (if known):

Device Name: Dimension Vista™ N-acetylprocainamide (NAPA) Flex® reagent cartridge

Indications For Use:

The Dimension Vista™ N-acetylprocainamide (NAPA) Flex® reagent cartridge is a device intended to measure N-acetylprocainamide in human serum and plasma. Measurements obtained by this device maybe used in therapeutic drug monitoring to maintain adequate procainamide therapy.

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)

Indications for Use

510(k) Number (if known):

Device Name: Dimension Vista™ Phenytoin (PTN) Flex® reagent cartridge

Indications For Use:

The Dimension Vista™ Phenytoin (PTN) Flex® reagent cartridge is a device intended to measure diphenylhydantoin (phenytoin), an antiepileptic drug, in serum and plasma. Measurements obtained by this device are used in the diagnosis and treatment of diphenylhydantoin (phenytoin) overdose and in monitoring levels of diphenylhydantoin (phenytoin) 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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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Indications for Use

510(k) Number (if known):

Device Name: Dimension Vista™ Theophylline (THEO) Flex® reagent cartridge

Indications For Use:

The Dimension Vista™ Theophylline (THEO) Flex® reagent cartridge is a device intended to measure theophylline (a drug used for stimulation of the muscles in the cardiovascular, respiratory, and central nervous systems), in serum and plasma. Measurements obtained by this device are used in the diagnosis and treatment of theophylline overdose or in monitoring levels of theophylline 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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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)