K062236

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
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AUG 2 1 2006

Date of Preparation: August 1, 2006

Name of Products:
Dimension Vista™ Cyclosporine (CSA) Flex® reagent cartridge

FDA Classification Name:

Classification Name:	Common/Usual Name:
862.1235 Cyclosporine	Cyclosporine test system

Product code: MKW

Predicate Device:
Dimension® Cyclosporine (CSA) Flex® reagent cartridge (K023065)

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 (K051087). This Special 510(k) is submitted for a packaging modification to the Dimension® Cyclosporine (CSA) Flex® reagent cartridge (K023065), an *in-vitro* diagnostic device that has been cleared under the 510(k) process. The packaging change is to allow use on the Dimension Vista™ system.

The reagents contained in the Dimension Vista™ CSA Flex® reagent cartridges are the same as those contained in the CSA 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 device, nor does it alter the fundamental scientific technology of the device.

Intended Use:
The CSA method is an *in vitro* diagnostic test for the quantitative measurement of Cyclosporine A (CSA) in human whole blood on the Dimension Vista™ System.

Measurements of CSA are used as an aid in the management of heart, liver and kidney transplant patients.

Comparison to Predicate Device:
Both the Dimension Vista™ CSA Flex® reagent cartridges and the predicate Dimension® CSA 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™ CSA Flex® reagent cartridge	Dimension® CSA Flex® reagent cartridge K023065
Reagents	Prepackaged, 12-well plastic, Dade Behring Flex® reagent cartridges	Prepackaged, 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	The CSA Flex® reagent cartridge is an *in vitro* diagnostic test intended to quantitatively measure cyclosporine concentrations in human whole blood for the Dimension® clinical chemistry system. Measurements of CSA are used as an aid in the management of heart, liver, and kidney transplant patients.
Tablet Sizes	7/32"	7/32"
Total tests contained in each Flex® cartridge	20	20
Calibration	30 days	30 days
Sample Type	whole blood	whole blood
Reportable Range	25 - 500 ng/mL	25 - 500 ng/mL
Sample Size	1.9 µL	5 µL
Measurement	Bichromatic rate @ 577 & 700 nm	Bichromatic rate @ 577 & 700 nm

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

AUG 2 1 2006

Lorraine H Piestrak
Regulatory Affairs and Compliance Manager
Dade Behring Inc.
P.O. Box 6101, M/S 514
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Re: k062236
Trade/Device Name: Dimension Vista™ Cyclosporine (CSA) Flex® reagent cartridge
Regulation Number: 21 CFR 862.1235
Regulation Name: Cyclosporine test system
Regulatory Class: Class II
Product Code: MKW
Dated: August 1, 2006
Received: August 2, 2006

Dear:

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): K062236

Device Name: Dimension Vista™ Cyclosporine (CSA) Flex® reagent cartridge

Indications For Use:

The Dimension Vista™ Cyclosporine (CSA) Flex® reagent cartridge is an *in vitro* device intended to quantitatively determine cyclosporine concentrations in human whole blood. Measurements of CSA are used as an aid in the management of heart, liver, and kidney transplant patients receiving therapy with this drug.

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

510(k) K062236