K102772
Dimension® MPAT
510 (k) Summary

OCT - 7 2011

This 510(k) summary is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

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Date of Preparation: October 6, 2011

Name of Product: 1. Dimension® Mycophenolic Acid Flex® Reagent Cartridge
2. Dimension® Mycophenolic Acid Calibrator

FDA Classification Name: 1. Immunoassay, Mycophenolic Acid (MPA)
2. Calibrator

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	510(k) number	Device Class	Regulation	Product Code
Dimension® MPAT Flex® Reagent Cartridge	Roche Total MPA assay for the COBAS INTEGRA system	K063520	II	21 CFR 862.3840	OAV
Dimension® MPAT Calibrator	Roche Total MPA Calibrators for the COBAS INTEGRA system	K063520	II	21 CFR 862.3200	DLJ

Device Description:

MPAT

The liquid reagents are configured in an eight well "Flex®"; the content of each Flex® well is described in the Instructions for Use.

The methodology for the Dimension® MPAT assay is based on a homogenous particle enhanced turbidimetric inhibition immunoassay (PETINIA) technique, which uses a latex particle-

mycophenolic acid conjugate (PR) and monoclonal mycophenolic acid specific antibody (Ab). Mycophenolic acid present in the sample competes with the mycophenolic acid on the particles for available antibody, thereby decreasing the rate of aggregation. Hence, the rate of aggregation is inversely proportional to the concentration of mycophenolic acid in the sample. The rate of aggregation is measured using bichromatic turbidimetric readings at 340 nm and 700 nm.

The concentration is determined by means of a mathematical function:

Mycophenolic acid + PR + Ab ———> *PR-Ab complex* (*scatters light at 340 nm*) + *mycophenolic acid-Ab*

To perform the MPAT assay, a sample cup containing the plasma or serum sample to be analyzed and a Dimension® MPAT reagent Flex® Reagent Cartridge are placed appropriately on the Dimension® analyzer.

Calibrator
The Dimension® MPAT Calibrator is used to calibrate the MPAT assay on the Dimension® system. The calibrator is a five level aqueous BSA matrix product containing Mycophenolic acid. The typical calibration levels for levels 1 through 5 respectively, are 0.0, 0.7, 2.3, 6.7 and 30.0 µg/mL. Level 1 is a zero level, and can be used to dilute samples that exceed 30 µg/mL.

Intended Use:

MPAT

The MPAT assay is an *in vitro* diagnostic test for the quantitative measurement of mycophenolic acid (MPA) in human serum and plasma on the Dimension® Clinical Chemistry System. Measurements of MPA are used as an aid in the management of mycophenolic acid therapy in renal, hepatic and cardiac transplant patients.

Calibrator
The MPAT calibrator is an *in vitro* diagnostic product for the calibration of the Mycophenolic Acid (MPAT) method on the Dimension® clinical chemistry system.

Comparison to Predicate Device:

Both the Dimension® Mycophenolic Acid Flex® Reagent Cartridge and the predicate Roche Total MPA assay for the COBAS INTEGRA system employ prepackaged reagents for use on automated clinical chemistry test systems. A comparison of the important similarities and differences of these methods is provided in the following table:

Feature	Dimension® Mycophenolic Acid Flex® Reagent Cartridge	Roche Total MPA assay for the COBAS INTEGRA system
Intended Use	*in vitro* diagnostic use; quantitative measurement of Mycophenolic Acid in human serum and plasma as an aid in the management of MPA therapy in renal, hepatic and cardiac transplant patients.	*in vitro* diagnostic use; quantitative measurement of Mycophenolic Acid in human serum or plasma as an aid in the management of MPA therapy in renal and cardiac transplant patients.
Sample Type	EDTA Plasma	Serum, EDTA Plasma
Assay Range	0.2 – 30.0 µg/mL [0.62 – 93.60 µmol/L]	0.4 - 15 µg/mL, extendable with post-dilution to 50 µg/mL
Technology	Homogenous particle enhanced turbidimetric inhibition immunoassay (PETINIA) technique with the MPA rate of aggregation inversely proportional to the MPA concentration in the sample.	Enzyme-mimicking assay with MPA concentration inversely proportional to the formation of NADH.
Detection	Bichromatic turbidimetric readings at 340 nm and 700 nm.	Spectrophotometric readings
Sample Size	5 µL	3 µL
Binding Protein	monoclonal mycophenolic acid specific antibody	N/A

Both the Dimension® Mycophenolic Acid Calibrator and the predicate Roche Total MPA Calibrators for the COBAS INTEGRA system have similar intended use. A comparison of the important similarities and differences is provided in the following table:

Feature	Dimension® Mycophenolic Acid Calibrator	Roche Total MPA Calibrators for the COBAS INTEGRA system
Intended Use	Calibrate MPAT on the Dimension® clinical chemistry system	Calibrate MPA on the COBAS INTEGRA system
Analytes	MPA	MPA
Matrix	Bovine Serum Albumin	Negative human serum
Traceable to:	Gravimetric preparation	Gravimetric preparation
Form	Liquid, stored at 2-8°C	Liquid
Volume	Vial containing Level 1 with 5.0 mL and Levels 2-5 have 2.0 mL per vial.	Levels A- F with 5.0 mL each and one vial of diluents (10.0 mL)
Levels	5 levels (0, 0.7, 2.3, 6.7, and 30.0 µg/mL)	6 levels (0, 1, 3, 5, 10, 15 µg/mL)

Comments on Substantial Equivalence:

Split sample comparison between the Dimension® Mycophenolic Acid Flex® Reagent Cartridge and HPLC/LC-MS assays gave the following correlation statistics, when tested with clinical samples from kidney, heart and liver transplant patients:

Dimension®	Reference Method	Slope	Intercept (µg/mL)	Correlation Coefficient (r)	n
MPAT	HPLC/ LC-MS	1.04	-0.02	0.98	109

Conclusion:

The Dimension® Mycophenolic Acid Flex® Reagent Cartridge with the associated Dimension® MPAT Calibrator are substantially equivalent in principle and performance to the Roche COBAS INTEGRA system based on the split sample comparison versus HPLC and HPLC/LC-MS reference methods discussed above.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Siemens Healthcare Diagnostics, Inc.
c/o Ms. Helen Lee
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Newark, DE 19714-6101

OCT - 7 2011

Re: k102772
Trade Name: Dimension®Mycophenolic Acid Flex® reagent cartridge
Dimension® Mycophenolic Acid Calibrator
Regulation Number: 21 CFR 862.3840
Regulation Name: Sirolimus test system
Regulatory Class: Class II
Product Code: OAV, DLJ
Dated: September 30, 2011
Received: October 4, 2011

Dear Ms. Lee:

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney H. Lias, 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 Form

510(k) Number (if known): k102772

Device Name: Dimension® Mycophenolic Acid Flex® reagent cartridge

Indications for Use:

The Dimension® Mycophenolic Acid Flex® reagent cartridge is an in vitro diagnostic test for the quantitative measurement of Mycophenolic acid (MPA) in human plasma on the Dimension® clinical chemistry system. Measurements of MPA are used as an aid in the management of mycophenolic acid therapy in renal, hepatic, and cardiac transplant patients.

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Ruth Chesler

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) k102772

Indications for Use Form

510(k) Number (if known): 102772

Device Name: Dimension® Mycophenolic Acid Calibrator

Indications for Use:

The Dimension® Mycophenolic Acid Calibrator is an in vitro diagnostic product for the calibration of the Mycophenolic Acid method on the Dimension® clinical chemistry system.

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

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

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