K063756

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.

MAR 1 9 2007

Submitter's Name: George M. Plummer
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P.O. Box 6101
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Date of Preparation: December 18, 2006

Name of Product(s): Dimension Vista™ CTNI Flex® reagent cartridge

FDA Classification Name(s): Immunoassay method, Troponin subunit (862.1215)

FDA Guidance Documents: None applicable

Predicate Device(s): Dade Behring Dimension® CTNI immunoassay (K0101313)

Device Description(s):
The CTNI method is a one-step sandwich chemiluminescent immunoassay based on LOCI™ technology. LOCI™ reagents include two synthetic bead reagents and a biotinylated anti-cardiac troponin I monoclonal antibody fragment. The first bead reagent (Sensibeads) is coated with streptavidin and contains photosensitive dye. The second bead reagent (Chemibeads) is coated with a second anti-cardiac troponin I monoclonal antibody and contains chemiluminescent dye. Sample is incubated with Chemibeads and biotinylated antibody to form a particle/cardiac troponin I/biotinylated antibody sandwich. Sensibeads then are added and bind to the biotin to form bead-aggregated immunocomplexes. Illumination of the complex by light at 680 nm generates singlet oxygen from Sensibeads, which diffuses into the Chemibeads and triggers a chemiluminescent reaction. The resulting chemiluminescent signal is measured at 612 nm and is a direct function of the cardiac troponin I concentration in the sample.

Intended Use:
The CTNI method is an *in vitro* diagnostic test for the quantitative measurement of cardiac troponin I in human serum and plasma on the Dimension Vista® System. Measurements of cardiac troponin I are used to aid in the diagnosis of acute myocardial infarction (AMI) and in the risk stratification of patients with acute coronary syndromes with respect to their relative risk of mortality.

Substantial Equivalence
A summary of the performance attributes of the Dade Behring Dimension Vista™ CTNI Flex® reagent cartridge and the predicate Dade Behring Dimension® CTNI reagent cartridge immunoassay (K0101313) is provided in the following chart.

Feature	Dimension® CTNI	Revised Dimension Vista™ CTNI
Intended Use	For the *in vitro* quantitative determination of cardiac troponin -I in human serum and heparinized plasma as an aid in the diagnosis of myocardial infarction and in the risk stratification of patients with acute coronary syndromes with respect to their relative risk of mortality.	For the *in vitro* quantitative determination of cardiac troponin -I in human serum and heparinized plasma as an aid in the diagnosis of myocardial infarction and in the risk stratification of patients with acute coronary syndromes with respect to their relative risk of mortality.
Assay Type	photometric immunoassay	chemiluminescent immunoassay
Reportable Range	0.04 to 40 ng/mL	0.015 to 40 ng/mL
Antibody	Dade Behring mouse monoclonal	Dade Behring mouse monoclonal
Analytical Sensitivity	0.04 ng/mL	0.015 ng/mL
Functional Sensitivity	Not specified	0.04 ng/mL
Analytical Specificity	Cross reactivity at 1000 ng/mL with skeletal muscle troponin-I, cardiac troponin –T and cardiac troponin-C is 0.04 ng/mL, 0.34 ng/mL and 0 ng/mL respectively.	Cross reactivity at 1000 ng/mL with skeletal muscle troponin-I, cardiac troponin –T and cardiac troponin-C is 0.14 ng/mL, 0.05 ng/mL and 0 ng/mL respectively.
Hook Effect	No high dose effect up to 1800 ng/mL	No high dose effect up to 1000 ng/mL
Calibration Interval	Calibration curve updated for each lot, using five levels and every 60 days, thereafter with the same reagent lot.	Calibration curve updated for each lot, using six levels every 30 days with the same reagent lot.
Sample Volume	50 uL	20 uL

Method performance Summary:

Analytical Results

Method Comparison

A split, serum patient sample method comparison demonstrated good agreement between the revised Dade Behring Dimension Vista™ CTNI method and the predicate Dade Behring Dimension® CTNI method.

Dimension® Sample Range	Dimension Vista® Sample Range	n	Slope	Intercept	Correlation Coefficient
0-35.34	0.13 – 38.85	91	0.99	-0.10	0.993

The model equation for the linear least squares regression statistics is: [results for revised Dimension Vista™ CTNI] = slope x [comparative method results] + intercept.

Serum versus Plasma Results

Comparison of sixty-three matched serum and lithium heparin plasma samples were tested with the revised Dimension Vista™ CTNI method. The following table summarizes the linear least squares regression from the study.

Plasma Sample Range	Serum Sample Range	n	Slope	Intercept	Correlation Coefficient
0.026-23.7	0.026-22.9	63	1.02	0.031	0.999

Lithium Heparin versus Sodium Heparin Results

Comparison of 50 matched lithium and sodium heparin plasma samples were tested with the revised Dimension Vista™ CTNI method. The following table summarizes the linear least squares regression results from the study.

Li Heparin Sample Range	Na Heparin Sample Range	n	Slope	Intercept	Correlation Coefficient
0.09 -39.85	0.1 – 38.2	50	0.99	-0.05	0.998

Reproducibility

Typical precision observed for the Dimension Vista™ CTNI method is summarized below:

		Repeatability		Within Lab	
Sample	**Mean (ng/mL)**	**SD (ng/mL)**	**%CV**	**SD (ng/mL)**	**%CV**
Serum Pool 1	0.073	0.003	3.8	0.005	7.36
Serum Pool 2	0.43	0.005	1.25	0.014	3.18
Serum Pool 3	22.5	0.237	1.05	0.499	2.22
Serum Pool 4	30.55	0.310	1.0	0.975	3.76
Biorad Cardiac Quality Control, Level 2	0.51	0.009	1.7	0.005	1.05

The reproducibility testing was conducted in accordance with the CLSI Approved Guideline for User Evaluation of Precision Performance of Clinical Chemistry Devices EP5-A2. For each test level, a single test from two independent cups was analyzed twice per day. The repeatability and within-lab standard deviations were calculated by the analysis of variance method.

Comments on Substantial Equivalence:

Both the predicate Dimension® CTNI reagent cartridge and the revised Dimension Vista™ CTNI immunoassays are intended for the quantitative determination of troponin I. Comparative data for human serum and heparinized plasma samples demonstrate good analytical and clinical agreement between the methods.

Conclusion:

The Dade Behring revised Dimension Vista™ CTNI and the predicate Dade Behring Dimension® CTNI immunoassays (K0101313) are substantially equivalent based on their intended use and performance characteristics as described above.

George M. Plummer
Regulatory Affairs and Compliance Manager
December 18, 2006

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Rockville MD 20850

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MAR 19 2007

Re: k063756
Trade/Device Name: Dimension VISTA™ CTNI Flex® reagent cartridge
Regulation Number: 21 CFR 862.1215
Regulation Name: Creatine phosphokinase/creatine kinase or isoenzymes test system.
Regulatory Class: Class II
Product Code: MMI
Dated: December 18, 2006
Received: December 19, 2006

Dear Mr. Plummer:

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) 276-0490. 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 (240) 276-3150 or at its Internet address at http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Jean M. Cooper, M.S., D.V.M.

Jean M. Cooper, M.S., D.V.M.
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 STATEMENT

510(k) Number (If Known): K063756

Device(s) Name(s):

Dimension Vista™ CTNI Flex® reagent cartridge

Indications for Use:

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Prescription Use ____X__ **and/or** **Over-the-counter Use** _____
(Part 21 CFR 801 Subpart D) **(21 CFR 801 Subpart C)**

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

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

Carol C Benson

...sion Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

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