K053577

APR 14 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:	George M. Plummer Dade Behring Inc. P.O. Box 6101 Newark, DE 19714-6101
Date of Preparation:	December 20, 2005
Name of Product(s):	Dimension Vista™ CTNI Flex® reagent cartridge Dimension Vista™ CTNI Calibrator Dimension Vista™ CTNI SDIL Sample Diluent
FDA Classification Name(s):	Immunoassay method, Troponin subunit (862.1215), secondary calibrator (862.1150) both Class II
FDA Guidance Documents:	None applicable
Predicate Device(s):	Dade Behring CTNI immunoassay and Calibrator (K010313/K010314)

Device Description(s):

Method

The CTNI method is a one-step sandwich chemiluminescent immunoassay based on Luminescent Oxygen Channeling Immunoassay (LOCI™) technology. LOCI™ reagents include two latex 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.

Calibrator

The Dade Behring CTNI Calibrator is a three level frozen liquid product (levels A, B, C) containing human troponin complex in a human serum matrix with stabilizers and preservative. The kit contains 3 vials of each level (A= 2.0 mL, B= 1.0 mL, C= 1.5 mL).

Sample Diluent

The Dimension Vista™ CTNI SDIL Sample Diluent is a single level liquid product containing a human serum matrix with stabilizers and preservative. The kit contains 6 vials with 2.5 mL in each vial.

Intended Use:

Method

The CTNI method is an *in vitro* diagnostic test for the quantitative measurement of cardiac troponin I in human serum 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.

Calibrator:

The CTNI CAL is an *in vitro* diagnostic product for the calibration of cardiac Troponin-I (CTNI) on the Dimension Vista™ system.

Diluent:

For use on the Dimension Vista™ System to dilute samples with elevated CTNI results.

Substantial Equivalence

Method

A summary of the features of the Dade Behring Dimension Vista™ CTNI Flex® reagent cartridge and the predicate Dade Behring Dimension® CTNI reagent cartridge immunoassay (K010313/K010314) is provided in the following charts.

Method:

Feature	Dimension® CTNI	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.	The CTNI method is an *in vitro* diagnostic test for the quantitative measurement of cardiac troponin I in human serum 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.
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 0.12 ng/mL, 0.06 ng/mL and 0 ng/mL respectively.
Interferences	No significant interference from: bilirubin up to 20 mg/dL, hemoglobin up to 1000 mg/dL and triglycerides up to 3000 mg/dL	No significant interference from: bilirubin, conjugated up to 40 mg/dL bilirubin, unconjugated up to 40 mg/dL, hemoglobin up to 500 mg/dL and triglycerides up to 3000 mg/dL
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

Calibrator:

Feature	Dimension® CTNI	Dimension Vista™ CTNI
Intended Use	CTNI method calibration	CTNI method calibration
Analyte	Human troponin complex	Human troponin complex
Matrix	Human serum	Human serum
Form	Liquid, frozen	Liquid, frozen
Volume	10 vials, 2 at each level, 2 mL each	6 vials, 2 at each level, Level A = 2.0 mL Level B = 1.0 mL and Level C = 1.5 mL
Levels	5 levels (0, 2, 10, 25, and 45 ng/mL)	3 levels provided (0, 0.5 and 41 ng/mL); three additional levels made on-board

Method performance Summary:

Analytical Results

Method Comparison

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

Comparative Method	Slope	Intercept (ng/mL)	Correlation Coefficient	n
Dimension® CTNI	1.015	-0.003	0.993	197

The model equation for the linear least squares regression statistics is: [results for Dimension Vista™ CTNI] = slope x [comparative method results] + intercept. The range of CTNI values in the correlation study was: 0 to 35.72 ng/mL.

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, Level 1	0.123	0.005	4.21	0.007	5.77
Serum Pool, Level 2	0.55	0.012	2.28	0.016	2.93
Serum Pool, Level 3	24.51	1.012	4.13	1.167	4.60
Serum Pool, Level 32	31.41	0.95	3.0	1.18	3.76

The reproducibility testing was conducted in accordance with the CLSI/NCCLS 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 within-run and total standard deviations were calculated by the analysis of variance method.

Calibrator
The Dimension Vista™ CTNI Calibrator is similar to other calibrator products associated with their assays, such as the Dimension® CTNI Calibrator.

Sample Diluent
The Dimension Vista™ CTNI SDIL Sample Diluent is similar to other diluent products associated with their assays.

Comments on Substantial Equivalence:
Both the Dimension Vista™ CTNI reagent cartridge and the Dimension® CTNI immunoassays are intended for the quantitative determination of troponin I. Comparative data for human serum samples demonstrate good analytical and clinical agreement between the methods.

Conclusion:
The Dade Behring Dimension Vista™ CTNI and the predicate Dade Behring Dimension® CTNI immunoassays (K010313/K010314) are substantially equivalent based on their intended use and performance characteristics as described above. The calibrator products are also equivalent in their design and intended use with their respective assay systems.

George M. Plummer
Regulatory Affairs and Compliance Manager
December 20, 2005

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

APR 14 2006

Mr. George M. Plummer
Regulatory Affairs and Compliance Manager
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Glasgow Business Community
Bldg. 500 Mail Box 514
PO Box 6101
Newark, DE 19714-6101

Re: k053577
Trade/Device Name: Dimension Vista™ CTNI Flex® reagent cartridge
Dimension Vista™ CTNI Calibrator
Dimension Vista™ CTNI SDIL Sample Diluent
Regulation Number: 21 CFR§862.1215
Regulation Name: Creatine phosphokinase/creatine kinase or isoenzymes test system
Regulatory Class: Class II
Product Code: MMI and JIT
Dated: February 24, 2006
Received: February 27, 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) 276-0484. 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 STATEMENT

510(k) Number (If Known): K053577

Device(s) Name(s):

Dimension Vista™ CTNI Flex® reagent cartridge
Dimension Vista™ CTNI Calibrator
Dimension Vista™ CTNI SDIL Sample Diluent

Indications for Use:

Method:
The CTNI method is an *in vitro* diagnostic test for the quantitative measurement of cardiac troponin I in human serum 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.

Calibrator:
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Diluent:
For use on the Dimension Vista™ System to dilute samples with elevated CTNI results.

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)

Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

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