FEB 7 2006

K053576

## 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™ MYO reagent cartridge and
Dimension Vista™ MYO calibrator

**FDA Classification Name(s):** Myoglobin, Antigen, Antiserum, Control and associated calibrator

**FDA Guidance Documents:** Not applicable

**Predicate Device(s):** Dade Behring MYO immunoassay and Calibrator
(K984191/K984193)

**Device Description(s):**

Method
The MYO method is a homogenous sandwich chemiluminescent immunoassay based on Luminescent Oxygen Channeling Immunoassay (LOCI™) technology. LOCI™ reagents include two latex bead reagents and a biotinylated anti-myoglobin monoclonal antibody fragment. The first bead reagent (Sensibeads) is coated with streptavidin and contains photosensitizer dye. The second bead reagent (Chemibeads) is coated with a second anti-myoglobin monoclonal antibody and contains chemiluminescent dye. Sample is incubated with Chemibeads and biotinylated antibody to form a bead-myoglobin-biotinylated antibody sandwich. Sensibeads are added and bind to the biotin to form bead-pair immunocomplexes. Illumination of the complex by light at 680 nm generates singlet oxygen from Sensibeads which diffuses into Chemibeads, triggering a chemiluminescent reaction. The resulting signal is measured at 612 nm and is a direct function of the myoglobin concentration in the sample.

Calibrator
The Dade Behring MYO Calibrator is a three level (A, B, C), frozen liquid product containing purified human heart myoglobin in a 6% bovine albumin matrix with stabilizers and preservatives. The kit contains 3 vials of each level (A= 2.0 mL, B= 1.0 mL, C= 1.5 mL).

**Intended Use:**
Method
For the quantitative measurement of myoglobin in human serum and plasma on the Dimension Vista™ System as an aid in the rapid diagnosis of acute myocardial infarction.

Calibrator
For the calibration of the myoglobin (MYO) method on the Dimension Vista™ System.

**Comparison to Predicate Device:**

Method

A summary of the features of the Dade Behring Dimension Vista™ MYO reagent cartridge and the predicate Dade Behring Dimension® MYO reagent cartridge immunoassay (K984191/K984193) is provided in the following charts.

**Method:**

| Feature | Dimension® MYO | Dimension Vista™ MYO |
|---|---|---|
| Intended Use | For the *in vitro* quantitative determination of myoglobin in human serum and heparinized plasma as an aid in the diagnosis of myocardial infarction. | For the *in vitro* quantitative determination of myoglobin in human serum and heparinized plasma as an aid in the diagnosis of myocardial infarction. |
| Assay Type (detection) | photometric immunoassay | chemiluminescent immunoassay |
| Reportable Range | 1 to 1000 ng/mL | 0.5 - 1000 ng/mL |
| Antibody | Dade Behring mouse monoclonal | Dade Behring mouse monoclonal |
| Analytical Sensitivity | 1 ng/mL | 0.5 ng/mL |
| Analytical Specificity | There are no known cross reactive materials. | There are no known cross reactive materials. |
| Interferences | No significant interference from: bilirubin up to 60 mg/dL, hemoglobin up to 1000 mg/dL and triglycerides up to 1500 mg/dL | No significant interference from: bilirubin, conj. up to 60 mg/dL bilirubin, unconjugated up to 60 mg/dL, hemoglobin up to 1000 mg/dL and triglycerides up to 3000 mg/dL |
| Hook Effect | No high dose effect (up to 300,000 ng/mL) | No high dose effect (up to 300,000 ng/mL) |
| Calibration Interval | Calibration curve updated for each lot, using five levels and every 90 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 | 20 uL | 2 uL |

**Calibrator:**

| Feature | Dimension® MYO | Dimension Vista™ MYO |
|---|---|---|
| Intended Use | MYO method calibration | MYO method calibration |
| Analyte | Human heart myoglobin | Human heart myoglobin |
| Matrix | Bovine serum albumin | Bovine serum albumin |
| Form | Liquid | Frozen liquid |
| Volume | 10 vials, 2 at each level, 1 mL each | 9 vials, 3 at each level, 2.0, 1.0, 1.5 mL for level A, B, C, respectively |
| Levels | 5 levels (0, 35, 100, 500, and 1060 ng/mL) | 3 levels provided (0, 125 and 1050 ng/mL); 3 additional levels made on-board (36.7, 367 and 733 ng/mL) |

Method performance Summary:

**Analytical Results**

Method Comparison

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

| Comparative Method | Slope | Intercept (ng/mL) | Correlation Coefficient | n |
|---|---|---|---|---|
| Dimension® MYO | 1.003 | 6.98 | 0.998 | 160 |

The model equation for linear regression statistics is: [results for Dimension Vista™ MYO] = slope x [comparative method results] + intercept. The range of MYO values in the correlation study was: 12 to 932 ng/mL.

Serum/Plasma Comparison

Serum and heparin plasma matched pairs were examined on the Dimension Vista™ system. Serum samples (n=37) ranging from 28 to 600 ng/mL when compared to lithium heparin samples gave a slope of 1.05, correlation coefficient of 1.0, and an intercept of -5.12 ng/mL using linear least squares regression statistics.

A separate study was conducted to evaluate the comparison of 115 lithium and sodium heparin samples ranging from 16 ng/mL to approximately 823 ng/mL. A linear least squares regression analysis comparing the lithium to sodium heparin samples gave a slope of 1.00, a correlation coefficient of 1.0, and an intercept of -0.54 ng/mL.

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

| | | Repeatability | | Within Lab | |
|---|---|---|---|---|---|
| **Sample** | **Mean (ng/mL)** | **SD (ng/mL)** | **%CV** | **SD (ng/mL)** | **%CV** |
| **Human Serum Pool** | | | | | |
| Pool 1 | 110.3 | 5.4 | 4.9 | 5.5 | 5.0 |
| Pool 2 | 501.5 | 17.3 | 3.4 | 18.7 | 3.7 |
| Pool 3 | 830.8 | 23.1 | 2.8 | 27.6 | 3.3 |
| **Biorad Liquichek™Cardiac Marker Control LT** | | | | | |
| Level 1 | 113.5 | 2.7 | 2.4 | 4.0 | 3.6 |

* Liquichek™ is a registered trademark of Biorad Laboratories, Irvine CA.

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

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

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

**Conclusion:**
The Dade Behring Dimension Vista™ MYO and the predicate Dade Behring Dimension® MYO immunoassays (K984191/K984193) 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

FEB 7 2006

Mr. George M. Plummer
Regulatory Affairs & Compliance Manager
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PO Box 6101
Newark, DE 19714-6101

Re: k053576
Trade/Device Name: Dimension Vista™ MYO reagent cartridge and
Dimension Vista™ MYO calibrator
Regulation Number: 21 CFR§ 866.5680
Regulation Name: Myoglobin immunological test system
Regulatory Class: Class II
Product Code: DDR, JIT
Dated: December 20, 2005
Received: December 23, 2005

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.

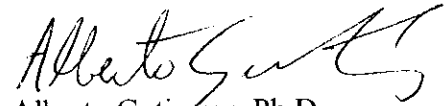
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish 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):** K053576

**Device(s) Name(s):**

Dimension Vista™ MYO reagent cartridge and
Dimension Vista™ MYO calibrator

**Indications for Use:**

Method
For the quantitative measurement of myoglobin in human serum and plasma on the Dimension Vista™ System as an aid in the rapid diagnosis of acute myocardial infarction.

Calibrator
For the calibration of the myoglobin (MYO) method on the Dimension Vista™ System.

**Prescription Use** ✓ **(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 IF NEEDED)**

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

Ann Chappie
Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K053576