510(k) Summary for Dimension Vista® HCYS Flex® reagent cartridge Dimension Vista® Protein 1 Calibrator Dimension Vista® Protein 1 Control L, M and H

DEC 2 8 2006

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.

The assigned 510(k) number is: K063206

1. Manufacturer's Name, Address, Telephone, and Contact Person, Date of Preparation:

Manufacturer:
Dade Behring Marburg GmbH
Emil-von-Behring Str. 76
35001 Marburg, Germany

Contact Information:
Dade Behring Inc.
P.O. Box 6101
Newark, Delaware 19714-6101
Attn: Kathleen Dray-Lyons
Tel: 781-826-4551
Fax: 781-826-2497

Preparation date: October 20, 2006

2. Device Name:
Dimension Vista® HCYS Flex® reagent cartridge
Dimension Vista® Protein 1 Calibrator
Dimension Vista® Protein 1 Control L
Dimension Vista® Protein 1 Control M
Dimension Vista® Protein 1 Control H

Classification: Class II; Class II; Class I
Product Code: LPS; JIX; JJY
Panel: Clinical Chemistry (75)

3. Identification of the Legally Marketed Device:

Dade Behring N Latex HCY – K052788
Dade Behring N Protein Standard SL – K012470
Dade Behring N/T Protein Control SL – K012468

4. Device Description:

Dimension Vista® HCYS Flex® reagent cartridge
Bound homocysteine in the sample is reduced to free homocysteine by the action of dithiothreitol, and then converted enzymatically to S-adenosyl-homocysteine (SAH). Conjugated S-adenosylcysteine (SAC), added at the onset of the reaction, competes with the SAH in the sample for bonding by anti-SAH antibodies bound to polystyrene particles. In the presence of SAH, there is either no aggregation or a weak aggregation of particles. In the absence of SAH in the sample, an aggregation of the polystyrene particles by the conjugated SAC occurs. The higher the SAH content of the reaction mixture, the smaller the scattered light signal. The result is evaluated by comparison with a standard of known concentration.

Dimension Vista® Protein 1 Calibrator
Protein 1 Calibrator is a multi-analyte, liquid, human serum based product containing C3, C4, Homocysteine (HCYS), Immunoglobulin A (IGA), Immunoglobulin G (IGG), Immunoglobulin M (IGM), and Prealbumin / Transthyretin (PREALB).

Dimension Vista® Protein 1 Control L, M and H
Protein 1 Control L, M and H are multi-analyte, liquid, human serum based products containing C3, C4, Homocysteine (HCYS), Immunoglobulin A (IGA), Immunoglobulin G (IGG), Immunoglobulin M (IGM), and Prealbumin / Transthyretin (PREALB).

5. Device Intended Use:

Dimension Vista® HCYS Flex® reagent cartridge:
The HCYS method is an *in vitro* diagnostic test for the quantitative determination of total homocysteine in human serum, heparinized and EDTA plasma on the Dimension Vista® System. Measurements of homocysteine aid in the diagnosis and treatment of patients suspected of having hyperhomocysteinemia and homocystinuria.

Dimension Vista® Protein 1 Calibrator:
PROT1 CAL is an *in vitro* diagnostic product for the calibration of the C3 complement (C3), C4 complement (C4), Homocysteine (HCYS), Immunoglobulin A (IGA), Immunoglobulin G (IGG), Immunoglobulin M (IGM) and Prealbumin / Transthyretin (PREALB) methods on the Dimension Vista® System.

Dimension Vista® Protein 1 Control L, M and H:
PROT1 CON L, M and H are assayed intralaboratory quality controls for assessment of precision and analytical bias in the determination of C3 Complement (C3), C4 Complement (C4), Homocysteine (HCYS), Immunoglobulin A (IGA), Immunoglobulin G (IGG), Immunoglobulin M (IGM) and Prealbumin / Transthyretin (PREALB) on the Dimension Vista®.

6. Medical device to which equivalence is claimed and comparison information:

The Dimension Vista® HCYS Flex® reagent cartridge, Dimension Vista® Protein 1 Calibrator and Dimension Vista® Protein 1 Control L, M and H are substantially equivalent to the Dade Behring N Latex HCY assay (K052788), N Protein Standard SL (K012470), and N/T Protein Control SL (K012468), respectively.

7. Device Performance Characteristics:

The Dimension Vista® HCYS assay was compared to the Dade Behring N Latex HCY assay on the BN ProSpec® System by evaluating serum and plasma samples with concentrations ranging from 3.43 to 56.52 µmol/L. Regression analysis of these results yielded the following equation:

Method Comparison Study

	n	Slope	Intercept	Correlation Coefficient
Dimension Vista® HCYS	215	1.056	0.239	0.995

8. Conclusion:

These studies demonstrate correlation and equivalent performance between the Dade Behring N Latex HCY assay and the Dimension Vista® HCYS assay.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ms. Kathleen Dray-Lyons
Dade Behring Inc.
Glasgow Site, P.O. Box 6101
Newark, DE 19714

DEC 2 8 2006

Re: k063206
Trade/Device Name: Dimension Vista Homocysteine Flex Reagent,
Dimension Vista Protein 1 Calibrator and Controls
Regulation Number: 21 CFR §862.1377, §862.1150, §862.1660
Regulation Name: Urinary homocystine (non-quantitative) test system, multi-analyte calibrators, and multi-analyte controls
Regulatory Class: Class II
Product Codes: LPS, JIX, JJY
Dated: October, 20, 2006
Received: October, 23, 2006

Dear Ms. Dray-Lyons:

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

K063206

Indications Statement

Device Name: **Dimension Vista® HCYS Flex® reagent cartridge**
Dimension Vista® Protein 1 Calibrator
Dimension Vista® Protein 1 Control L
Dimension Vista® Protein 1 Control M
Dimension Vista® Protein 1 Control H

Indications for Use:

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Dimension Vista® Protein 1 Control L, M and H
PROT1 CON L, M and H are assayed intralaboratory quality controls for assessment of precision and analytical bias in the determination of C3 Complement (C3), C4 Complement (C4), Homocysteine (HCYS), Immunoglobulin A (IGA), Immunoglobulin G (IGG), Immunoglobulin M (IGM) and Prealbumin / Transthyretin (PREALB) on the Dimension Vista®.

Prescription Use __X__ (Per 21 CFR 801 Subpart D)
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

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Office of In Vitro Diagnostic Device Evaluation and Safety

K063206