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

FEB 15 2007

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: K063425

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

Manufacturer:
Dade Behring Marburg GmbH
Emil-von-Behring Str. 76
35041 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: November 9, 2006

2. Device Name:
Dimension Vista™ IGE 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: DGC; JIX; JJY
Panel: Immunology (82) and Clinical Chemistry (75)

3. Identification of the Legally Marketed Device:

Dade Behring N Latex IgE mono– K991787
Dade Behring N Protein Standard SL – K012470
Dade Behring N/T Protein Control SL – K012468

4. Device Description:

Dimension Vista™ IGE Flex® reagent cartridge
Proteins contained in human body fluids form immune complexes in an immunochemical reaction with specific antibodies. These complexes scatter a beam of light passed through the sample. The intensity of the scattered light is proportional to the concentration of the respective protein in the sample. 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 complement, C4 complement, immunoglobulin A (IGA), immunoglobulin E (IGE), immunoglobulin G (IGG), immunoglobulin M (IGM) and prealbumin (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 complement, C4 complement, immunoglobulin A (IGA), immunoglobulin E (IGE), immunoglobulin G (IGG), immunoglobulin M (IGM) and prealbumin (PREALB).

5. Device Intended Use:

Dimension Vista™ IGE Flex® reagent cartridge:
The IGE method is an *in vitro* diagnostic test for the quantitative determination of Immunoglobulin E in human serum, heparinized plasma or EDTA plasma on the Dimension Vista® System. Measurements of IGE aid in the diagnosis of IgE mediated allergic disorders in conjunction with other clinical findings.

Dimension Vista™ Protein 1 Calibrator:
PROT1 CAL is an *in vitro* diagnostic product for the calibration of the C3 complement (C3), C4 complement (C4), Immunoglobulin A (IGA), Immunoglobulin E (IGE), Immunoglobulin G (IGG), Immunoglobulin M (IGM) and Prealbumin (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), immunoglobulin A (IGA), immunoglobulin E (IGE), immunoglobulin G (IGG), immunoglobulin M (IGM) and prealbumin (PREALB) on the Dimension Vista® System.

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

The Dimension Vista™ IGE assay, like the Dade Behring N Latex IgE mono assay is an *in vitro* diagnostic test for the quantitative measurement of Immunoglobulin E in human serum and plasma.

7. Device Performance Characteristics:

The Dimension Vista™ IGE assay was compared to the Dade Behring N Latex IgE mono assay on the BN ProSpec® System by evaluating serum and plasma samples with concentrations ranging from 18.2 IU/mL to 1126.5 IU/mL. Regression analysis of these results yielded the following equation.

Table 3
Method Comparison Study

Comparative Method	n	Slope	Intercept	Correlation Coefficient
N Latex IgE mono on the BN ProSpec®	120	1.041	0.151	0.999

8. Conclusion:

These studies demonstrate correlation and equivalent performance between the Dade Behring N Latex IgE mono assay and the Dimension Vista™ IGE assay.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Dade Behring Inc.
c/o Ms. Kathleen Dray-Lyons
Regulatory Affairs and Compliance Manager
Glasgow Site
P.O. Box 6101
Newark, DE 19714-6101

FEB 15 2007

Re: k063425
Trade/Device Name: Dimension Vista™ IgE 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
Regulation Number: 21 CFR 866.5510
Regulation Name: Immunoglobulin A, G, M, D and E Immunological Test System
Regulatory Class: Class II
Product Code: DGC, JIX, JJY
Dated: January 10, 2007
Received: January 11, 2007

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 the Code of Federal Regulations, Title 21, Parts 800 to 898. 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 Part 801); 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) 276-0450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Robert L. Becker, Jr., M.D., Ph.D.
Director
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications Statement

K063425

Device Name: **Dimension Vista™ IGE 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:

Dimension Vista™ IGE Flex® reagent cartridge:
The IGE method is an *in vitro* diagnostic test for the quantitative determination of Immunoglobulin E in human serum, heparinized plasma or EDTA plasma on the Dimension Vista® System. Measurements of IGE aid in the diagnosis of IgE mediated allergic disorders in conjunction with other clinical findings.

Dimension Vista™ Protein 1 Calibrator
PROT1 CAL is an *in vitro* diagnostic product for the calibration of the C3 Complement (C3), C4 Complement (C4), Immunoglobulin A (IGA), Immunoglobulin E (IGE), Immunoglobulin G (IGG), Immunoglobulin M (IGM), and Prealbumin (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), immunoglobulin A (IGA), immunoglobulin E (IGE), immunoglobulin G (IGG), immunoglobulin M (IGM), and prealbumin (PREALB) on the Dimension Vista® System.

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)

Maria M Chan
Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K063425