SEP 11 2006

510(k) Summary for
Dimension Vista™ *Cardio*Phase® *hs*CRP Flex® reagent cartridge
Dimension Vista™ Protein 2 Calibrator
Dimension Vista™ high sensitivity CRP Control L and H

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: K061802

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

Manufacturer:
Dade Behring Marburg GmbH
Emil-von-Behring Str. 76
D-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: June 26, 2006

2. Device Name:
Dimension Vista™ *Cardio*Phase® *hs*CRP Flex® reagent cartridge (*hs*CRP)
Dimension Vista™ Protein 2 Calibrator
Dimension Vista™ high sensitivity CRP Control L
Dimension Vista™ high sensitivity CRP Control H

Classification: Class II; Class II; Class I
Product Code: NQD; JJY
Panel: Immunology (82) and Clinical Chemistry (75)

3. Identification of the Legally Marketed Device:

Dade Behring *Cardio*Phase® hsCRP - K033908
Dade Behring N Rheumatology Standard SL - K964527
Dade Behring N/T Rheumatology Control SL - K962373

4. Device Description:

Dimension Vista™ *Cardio*Phase® *hs*CRP Flex® reagent cartridge
Polystyrene particles coated with monoclonal antibodies specific to human CRP are aggregated when mixed with samples containing CRP. These aggregates 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 2 Calibrator
Protein 2 Calibrator is a liquid human serum based product containing C-reactive protein (CRP).

Dimension Vista™ high sensitivity CRP Control L and H
High sensitivity CRP Control L and H are liquid human serum based products containing C-reactive protein.

5. Device Intended Use:

Dimension Vista™ *Cardio*Phase® *hs*CRP Flex® reagent cartridge:
The Dimension Vista™ *Cardio*Phase® *hs*CRP method is an *in vitro* diagnostic test for the quantitative measurement of C-reactive protein (CRP) in human serum and plasma by means of particle enhanced immunonephelometry on the Dimension Vista™ System. High sensitivity CRP measurements may be used for evaluation of conditions thought to be associated with inflammation, in otherwise healthy individuals and as an independent risk marker for the identification and stratification of individuals at risk for future cardiovascular disease. Measurements of hsCRP, when used in conjunction with traditional clinical laboratory evaluation of acute coronary syndromes, may be useful as an independent marker of prognosis for recurrent events, in patients with stable coronary disease or acute coronary syndromes.

Dimension Vista™ Protein 2 Calibrator:
Protein 2 Calibrator is an *in vitro* diagnostic product for the calibration of the high sensitivity C-reactive protein (hsCRP) method on the Dimension Vista™ System.

Dimension Vista™ high sensitivity CRP Control L and H:
hsCRP Control L and H are for use as assayed intralaboratory quality controls for the assessment of precision and analytical bias in determination of C-reactive protein (CRP) on the Dimension Vista™ System.

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

The *Cardio*Phase® *hs*CRP Flex® reagent cartridge, Dimension Vista™ Protein 2 Calibrator and Dimension Vista™ high sensitivity CRP Control L and H are substantially equivalent to the Dade Behring *Cardio*Phase® hsCRP assay (K033908) assay, N Rheumatology Standard SL (K964527) and N/T Rheumatology Control SL (K962373), respectively. The Dimension Vista™ *Cardio*Phase® *hs*CRP assay, like the Dade Behring *Cardio*Phase® *hs*CRP assay is an *in vitro* diagnostic test for the quantitative measurement of C-reactive protein (CRP) in human serum and plasma by means of particle enhanced immunonephelometry.

7. Device Performance Characteristics:

The Dimension Vista™ *Cardio*Phase® *hs*CRP assay was compared to the Dade Behring *Cardio*Phase® *hs*CRP assay on the BN ProSpec® System by evaluating serum and plasma samples with concentrations ranging from 0.169 to 8.922 mg/L. Regression analyses of these results yielded the following equations:

Method Comparison Study

Dimension Vista™ *hs*CRP	n	Slope	Intercept	Correlation Coefficient
0.16 to 9.5 mg/L	133	1.044	+0.003	0.995
0.16 to 5.0 mg/L	104	1.079	-0.026	0.995

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

SEP 11 2006

Re: k061802
Trade/Device Name: Dimension Vista™ CardioPhase® reagent cartridge
Dimension Vista™ Protein 2 Calibrator
Dimension Vista™ high sensitivity CRP Control L
Dimension Vista™ high sensitivity CRP Control H
Regulation Number: 21 CFR 866.5270
Regulation Name: C-reactive protein immunological test system
Regulatory Class: Class II
Product Code: NQD, JIX, JJY
Dated: June 26, 2006
Received: June 27, 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.

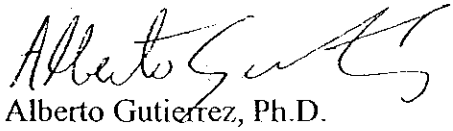
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish 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) 276-0484. 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 Statement

Device Name: **Dimension Vista™ *Cardio*Phase® *hs*CRP Flex® reagent cartridge**
Dimension Vista™ Protein 2 Calibrator
Dimension Vista™ high sensitivity CRP Control L
Dimension Vista™ high sensitivity CRP Control H

Indications for Use:

Dimension Vista™ *Cardio*Phase® hsCRP Flex® reagent cartridge:

The *Cardio*Phase® *hs*CRP method is an *in vitro* diagnostic test for the quantitative measurement of C-reactive protein (CRP) in human serum and plasma by means of particle enhanced immunonephelometry on the Dimension Vista™ System. High sensitivity CRP measurements may be used for evaluation of conditions thought to be associated with inflammation, in otherwise healthy individuals and as an independent risk marker for the identification and stratification of individuals at risk for future cardiovascular disease. Measurements of hsCRP, when used in conjunction with traditional clinical laboratory evaluation of acute coronary syndromes, may be useful as an independent marker of prognosis for recurrent events, in patients with stable coronary disease or acute coronary syndromes.

Dimension Vista™ Protein 2 Calibrator:

Protein 2 Calibrator is an *in vitro* diagnostic product for the calibration of the high sensitivity C-reactive protein (hsCRP) method on the Dimension Vista™ System.

Dimension Vista™ high sensitivity CRP Control L and Dimension Vista™ high sensitivity CRP Control H:

hsCRP Control L and H are for use as assayed intralaboratory quality controls for the assessment of precision and analytical bias in determination of C-reactive protein (CRP) 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)

Carol C Benson
Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

K061802