

K073561

510 (k) Summary

This summary of 5109k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

FEB 26 2002

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:

Helen M. Lee
Dade Behring Inc.
P.O. Box 6101
Newark, DE 19714-6101
302.631.8706
302.631.6299 (fax)

Date of Preparation: November 28, 2007

2. Name of Products:

Dimension Vista® System IGG Flex® reagent cartridge
Dimension Vista® System Protein 1 Calibrator
Dimension Vista® System Protein 3 Control

3. Identification of the Legally marketed Device:

N Antisera to Human Immunoglobulins (IgG, IgA, and IgM) k042735
Dimension Vista® System Immunoglobulin G Flex® reagent cartridge
Dimension Vista® System Protein 1 Calibrator (k071980)
Dimension Vista® System Protein 3 Control (k072435)

4. Device Descriptions:

Dimension Vista® System Immunoglobulin G 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® System Protein 1 Calibrator

PROT1 CAL is a multi-analyte, liquid human serum based product containing:

α_1 -Acid Glycoprotein	Immunoglobulin G
α_1 -Antitrypsin	Immunoglobulin G Subclass 1
β_2 -Microglobulin	Immunoglobulin G Subclass 2
C3 Complement	Immunoglobulin G Subclass 3
C4 Complement	Immunoglobulin G Subclass 4
Ceruloplasmin	Immunoglobulin M
Haptoglobin	Prealbumin
Hemopexin	Retinol Binding Protein
Homocysteine	soluble Transferrin Receptor
Immunoglobulin A	Transferrin
Immunoglobulin E	

Dimension Vista® System Protein 3 Control

PROT3 CON is a multi-analyte, lyophilized, polygeline and rabbit albumin based product containing:

α_1 -Microglobulin
Immunoglobulin G
Albumin

5. Device Intended Uses:

Dimension Vista® Immunoglobulin G Flex® reagent cartridge

The IGG method is an *in vitro* diagnostic test for the quantitative measurement of immunoglobulin G in human serum, heparinized plasma and cerebrospinal fluid (CSF) on the Dimension Vista® System. Measurements of IgG aid in the diagnosis of abnormal protein metabolism and the body's lack of ability to resist infectious agents.

Dimension Vista® System Protein 1 Calibrator

PROT1 CAL is an *in vitro* diagnostic product for the calibration of the Dimension Vista® System for:

α_1 -Acid Glycoprotein (A1AG)	Immunoglobulin G (IGG) [serum/plasma] and Immunoglobulin G (IGG-C) [cerebrospinal fluid]
α_1 -Antitrypsin (A1AT)	Immunoglobulin G Subclass 1 (IGG1)
β_2 -Microglobulin (B2MIC)	Immunoglobulin G Subclass 2 (IGG2)
C3 Complement (C3)	Immunoglobulin G Subclass 3 (IGG3)
C4 Complement (C4)	Immunoglobulin G Subclass 4 (IGG4)

Ceruloplasmin (CER)
Haptoglobin (HAPT)
Hemopexin (HPX)
Homocysteine (HCYS)
Immunoglobulin A (IGA)
Immunoglobulin E (IGE)

Immunoglobulin M (IGM)
Prealbumin (PREALB)
Retinol Binding Protein (RBP)
soluble Transferrin Receptor (STFR)
Transferrin (TRF)

Dimension Vista® System Protein 3 Control

PROT3 CON is an assayed quality control for the assessment of precision and analytical bias on the Dimension Vista® System in quantitative determination of:

α_1 -Microglobulin (A1MIC)	Microalbumin (MALB)
Immunoglobulin G (IGG-C)*	specialty Albumin (sALB) *

* For cerebrospinal fluid (CSF)

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

The N Antisera to Human Immunoglobulins (IgG, IgA, and IgM) was determined to be substantially equivalent in 510(k) Premarket Notification k042735 and is the predicate for adding the CSF sample matrix to the Dimension Vista® IGG assay.

The current Dimension Vista® IGG Flex® reagent cartridge was originally determined to be substantially equivalent in 510(k) Premarket Notification k051087. The subsequent assay modifications are described in this submission. The changes include: adjustment of the measuring range; reagent stability (both on board and open well), as well as other minor changes to the IFU. The operating principle and reagent composition have not changed. For your convenience, the sections with changes have been underlined in the Draft Instructions for Use included in this submission.

Dimension Vista® Protein 1 Calibrator, modified to include IGG-C (IGG in CSF), is substantially equivalent in intended use to the current Dimension Vista® Protein 1 Calibrator (k071980). The modified Dimension Vista® Protein 1 Calibrator, like the current product, is intended to be used for the calibration of human protein assays on the Dimension Vista® System.

Dimension Vista® System Protein 3 Control modified to include IGG-C (IGG in CSF), is substantially equivalent in Intended Use to the current Dimension Vista® System Protein 3 Control (K072435). The modified Dimension Vista® System Protein 3 Control like the current product is intended to be used as an assayed intralaboratory quality control on the Dimension Vista® System.

7. Conclusion:

The studies included in this submission demonstrate correlation to and equivalent performance between the predicate N Antisera to Human IGG for CSF sample matrix.

The modified Dimension Vista® System IGG assay, modified Dimension Vista® System Protein 1 Calibrator and modified Dimension Vista® System Protein 3 Control are substantially equivalent to the legally marketed devices based upon the demonstrated correlation and the information above.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

FEB 26 2008

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Dade Behring, Inc.
c/o Ms. Helen M. Lee
Regulatory Affairs and Compliance Manager
P.O. Box 6101, MS514
Newark, DE 19714-6101

Re: k073561

Trade/Device Name: Dimension Vista® System Immunoglobulin G Flex® Reagent
Cartridge
Dimension Vista® System Protein 1 Calibrator
Dimension Vista® System Protein 3 Control

Regulation Number: 21 CFR 866.5510

Regulation Name: Immunoglobulins A, G, M, D, E immunological test system

Regulatory Class: Class II

Product Code: CFN, JIX, JJY

Dated: February 18, 2008

Received: February 19, 2008

Dear Ms. Lee:

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.

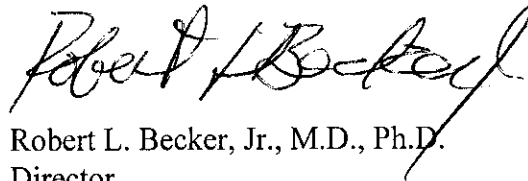
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

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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). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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,

A handwritten signature in black ink, appearing to read "Robert L. Becker, Jr.", with a stylized flourish at the end.

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 for Use Statement

510(k) Number (if known): K073561

Device Name:

Dimension Vista® System Immunoglobulin G Flex® Reagent cartridge

Indications for Use:

The IGG method is an *in vitro* diagnostic test for the quantitative measurement of immunoglobulin G in human serum, heparinized plasma and cerebrospinal fluid (CSF) on the Dimension Vista® System. Measurements of IgG aid in the diagnosis of abnormal protein metabolism and the body's lack of ability to resist infectious agents.

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) K073561

Indications for Use Statement

510(k) Number (if known): *K073561*

Device Name:

Dimension Vista® System Protein 1 Calibrator

Indications for Use:

PROT1 CAL is an *in vitro* diagnostic product for the calibration of the Dimension Vista® System for:

α_1 -Acid Glycoprotein (A1AG)

Immunoglobulin G (IGG) [serum/plasma]
and Immunoglobulin G (IGG-C)
[cerebrospinal fluid]

α_1 -Antitrypsin (A1AT)

Immunoglobulin G Subclass 1 (IGG1)

β_2 -Microglobulin (B2MIC)

Immunoglobulin G Subclass 2 (IGG2)

C3 Complement (C3)

Immunoglobulin G Subclass 3 (IGG3)

C4 Complement (C4)

Immunoglobulin G Subclass 4 (IGG4)

Ceruloplasmin (CER)

Immunoglobulin M (IGM)

Haptoglobin (HAPT)

Prealbumin (PREALB)

Hemopexin (HPX)

Retinol Binding Protein (RBP)

Homocysteine (HCYS)

soluble Transferrin Receptor (STFR)

Immunoglobulin A (IGA)

Transferrin (TRF)

Immunoglobulin E (IGE)

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

K073561

Indications for Use Statement

510(k) Number (if known): *K073561*

Device Name:

Dimension Vista® System Protein 3 Control

Indications for Use:

PROT3 CON is an assayed, low level intralaboratory quality control for assessment of precision and analytical bias on the Dimension Vista® System in the determination of α_1 -Microglobulin (A1MIC), specialty Albumin (sALB)*, Immunoglobulin G (IGG -C)* and Microalbumin (MALB).

* For Cerebrospinal fluid (CSF)

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)

Mona M Chan
Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) *K073561*