K073161

JUL 28 2008

510 (k) Summary

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.

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
Siemens Healthcare Diagnostics Inc.
500 GBC Drive, M/S 514
Newark, DE 19714-6101
302.631.8706
302.631.6299 (fax)

Date of Preparation: July 17, 2008

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:

Beckman Coulter IMMAGE® Immunochemistry System Urine Immunoglobulin G (k951635)
N Antisera to Human Immunoglobulins (IgG, IgA, and IgM) (k042735)
Dimension Vista® System Protein 1 Calibrator (k073561)
Dimension Vista® System Protein 3 Control (k073561)

4. Device Descriptions:

Dimension Vista® System Immunoglobulin G Flex® reagent cartridge
Proteins contained in human body fluids from 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, cerebrospinal fluid (CSF) and urine 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]
	Immunoglobulin G (IGG-C) [cerebrospinal fluid]
	Immunoglobulin G (IGG-U) [urine]
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)
Ceruloplasmin (CER)
Haptoglobin (HAPT)
Hemopexin (HPX)
Homocysteine (HCYS)
Immunoglobulin A (IGA)
Immunoglobulin E (IGE)
Immunoglobulin G Subclass 4 (IGG4)
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)
Immunoglobulin G (IGG-C)*
Immunoglobulin G (IGG-U) **
Microalbumin (MALB)
specialty Albumin (sALB) *

* For cerebrospinal fluid (CSF)
** For urine

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

The Beckman Coulter IMMAGE® Immunochemistry System Urine Immunoglobulin G was determined to be substantially equivalent in 510(k) Premarket Notification k951635 and is the predicate for adding the urine sample matrix to the previously cleared Dimension Vista® IGG assay.

The N Antisera to Human Immunoglobulins (IgG, IgA, and IgM) on the BN Systems was determined to be substantially equivalent in 510(k) Premarket Notification k042735 and is the predicate for the addition of a pre-reaction step to the previously cleared IGG-C (CSF). The operating principle and reagent composition have not changed. For your convenience, the sections with changes have been highlighted in the Draft Instructions for Use included in this submission.

Dimension Vista® Protein 1 Calibrator, modified to include IGG-U (IGG in urine), is substantially equivalent in intended use to the current Dimension Vista® Protein 1 Calibrator (k073561). 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-U (IGG in urine), is substantially equivalent in Intended Use to the current Dimension Vista® System Protein 3 Control (K073561). 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 Beckman Coulter IMMAGE® Immunochemistry System Urine Immunoglobulin G for urine sample matrix and the predicate N Antisera to Human Immunoglobulins (IgG IgA, and IgM) on the BN ProSpec® System for the addition of a pre-reaction step to the Dimension Vista® IGG-C assay.

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 information above.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Siemens Healthcare Diagnostics, Inc.
c/o Ms. Helen M. Lee
Regulatory Affairs and Compliance Manager
500 GBC Drive, MS 514
Newark, DE 19714-6101

JUL 2 8 2008

Re: k081161
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 and E immunological test system
Regulatory Class: Class II
Product Code: CFN, JIX, JJY
Dated: July 2, 2008
Received: July 3, 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 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 advice for your device on our labeling regulation (21 CFR Part 801), 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" (21CFR 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,

Maria M. Chan

Maria M. Chan, Ph.D.
Acting Division 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): K081161

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)*, Immunoglobulin G (IGG-U)** and Microalbumin (MALB).

* For Cerebrospinal fluid (CSF)
** For urine

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) K081161

Indications for Use Statement

510(k) Number (if known): K081161

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)
- α_1-Antitrypsin (A1AT)
- β_2-Microglobulin (B2MIC)
- C3 Complement (C3)
- C4 Complement (C4)
- Ceruloplasmin (CER)
- Haptoglobin (HAPT)
- Hemopexin (HPX)
- Homocysteine (HCYS)
- Immunoglobulin A (IGA)
- Immunoglobulin E (IGE)
- Immunoglobulin G (IGG) [serum/plasma], Immunoglobulin G (IGG-C) [cerebrospinal fluid] and Immunoglobulin G (IGG-U) [urine]
- Immunoglobulin G Subclass 1 (IGG1)
- Immunoglobulin G Subclass 2 (IGG2)
- Immunoglobulin G Subclass 3 (IGG3)
- Immunoglobulin G Subclass 4 (IGG4)
- Immunoglobulin M (IGM)
- Prealbumin (PREALB)
- Retinol Binding Protein (RBP)
- soluble Transferrin Receptor (STFR)
- Transferrin (TRF)

Prescription Use ___X___ (Per 21 CFR 801 Subpart D)

Over-The-Counter-Use _____ (21 CFR 801)

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Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K081161

Indications for Use Statement

510(k) Number (if known): K081161

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, cerebrospinal fluid (CSF) and urine 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)

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

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K081161