K081249

JUL 21 2008

510(k) Summary for

Dimension Vista® A2MAC Flex® reagent cartridge

Dimension Vista® Protein 1 Calibrator

Dimension Vista® Protein 1 Control L,M,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: K081249

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: Siemens Healthcare Diagnostics.

500 GBC Drive, M/S 514

Newark, Delaware 19702

Attn: Anna Marie Kathleen Ennis

Tel: 302-632-9352

Fax: 302-631-6299

Preparation date: April 28, 2008

2. Device Name:

Dimension Vista® A2MAC Flex® reagent cartridge

Dimension Vista® PROT 1 CAL

Dimension Vista® PROT 1 CON, L,M,H

Classification: Class II; Class II; Class I

Product Code: DEB, JIX, JJY

Panel: Immunology (82) and Clinical Chemistry (75)

3. Identification of the Legally Marketed Devices:

Dade Behring N Antisera to Human a_2- macroglobulin – K053073

N Protein Standard SL - K012470

N/T Protein Controls SL - K012468

4. Device Descriptions:

Dimension Vista® A2MAC 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: a_1-acid glycoprotein, a_1 -antitrypsin, a_2 -macroglobulin, b_2 -microglobulin, C3 complement, C4 complement,ceruloplasmin, haptoglobin, hemopexin, immunoglobulin A, immunoglobulin E,, immunoglobulin G, immunoglobulin G Subclass , immunoglobulin G subclass 2, immunoglobulin G subclass 3, immunoglobulin G subclass 4, immunoglobulin M, prealbumin, retinol binding protein, homocysteine, soluble transferrin receptor and transferrin.

Dimension Vista® Protein 1 Control L

Protein 1 Control L is a multi-analyte, low level liquid human serum based product containing :

a_1-acid glycoprotein, a_1-antitrypsin, a_2 -macroglobulin, C3 complement, C4 complement,ceruloplasmin, haptoglobin, hemopexin,immunoglobulin E, immunoglobulin A, immunoglobulin G, immunoglobulin G Subclass , immunoglobulin G subclass 2, immunoglobulin G subclass 3, immunoglobulin G subclass 4, immunoglobulin M, prealbumin, retinol binding protein,homocysteine, soluble transferrin receptor and transferrin

Dimension Vista® Protein 1 Control M and H

Protein 1 Control M and H are multi-analyte, mid and high level respectively, liquid human serum based products containing: a_1 -acid glycoprotein, a_1 -antitrypsin, a_2 -macroglobulin, b_2-microglobulin, C3 complement, C4 complement,ceruloplasmin, haptoglobin, hemopexin, immunoglobulin A, immunoglobulin E, immunoglobulin G, immunoglobulin G Subclass , immunoglobulin G subclass 2, immunoglobulin G subclass 3, immunoglobulin G subclass 4, immunoglobulin M, prealbumin, retinol binding protein,homocysteine, soluble transferrin receptor, and transferrin.

5. Device Intended Uses

Dimension Vista® A2MAC Flex® reagent cartridge:

The A2MAC method is an in vitro diagnostic test for the quantitative measurement of a_2-macroglobulin in human serum and plasma on the Dimension Vista® Systems. Measurements of a_2 -macroglobulin aid in the diagnosis of blood clotting or blood lysis disorders.

Dimension Vista® PROT 1 CAL:

PROT1 CAL is an in vitro diagnostic product for the calibration of the Dimension Vista® Systems for: a_1-Acid Glycoprotein (A1AG), a-Antitrypsin (A1AT), a_2–macroglobulin (A2MAC), b_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, IGG-C*), 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)

*For cerebrospinal fluid

Dimension Vista® Protein 1 Control L

PROT1 CON L is an assayed, low level, intralaboratory quality control for assessment of precision and analytical bias on the Dimension Vista® Systems in the quantitative determination of:

a_1-Acid Glycoprotein (A1AG), a_1-Antitrypsin (A1AT), a_2–macroglobulin (A2MAC), C3 Complement (C3), C4 Complement (C4), Ceruloplasmin (CER), Haptoglobin (HAPT), Hemopexin (HPX), Homocysteine (HCYS), Immunoglobulin A (IGA), Immunoglobulin E (IGE), Immunoglobulin G (IGG),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), specialty Albumin (sALB*), soluble Transferrin Receptor (STFR) and Transferrin (TRF).

*For serum and plasma

Dimension Vista® Protein 1 Control M and H

PROT1 CON M and PROT1 CON H are assayed, mid-level and high level, intralaboratory quality controls for assessment of precision and analytical bias on the Dimension Vista® System in the quantitative determination of: a_2-Acid Glycoprotein (A1AG), a_1 -Antitrypsin (A1AT), a_2–Macroglobulin (A2MAC), b_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),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), specialty Albumin (sALB) and Transferrin (TRF).

*For serum and plasma

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

The Dimension Vista® A2MAC Flex® reagent cartridge, Dimension Vista® PROT 1 CAL and Dimension Vista® PROT 1 CON L, M, H are substantially equivalent to the Dade Behring N Antisera to Human a_2 –macroglobulin assay (K053073), N/T Protein Standard SL (K012470) and N Protein Controls SL (K012468). The Dimension Vista® A2MAC assay, like Dade Behring N Antisera to Human a_2–macroglobulin assay is an in vitro diagnostic test for the quantitative measurement of a_2 –macroglobulin in human serum and plasma.

7. Device Performance Characteristics:

The Dimension Vista® A2MAC assay was compared to the Dade Behring N Antisera to Human a_2 –macroglobulin assay on the BN ProSpec® System by evaluating serum and plasma samples with concentrations ranging from 28 – 637 mg/dL. Regression analysis of these results yielded the following equation.

Method Comparison Study

The Dimension Vista® A2MAC assay was compared to the N Antisera to Human a_2–macroglobulin on the BN ProSpec® System by evaluating serum and plasma samples with concentrations ranging from 28 - 637 mg/dL (0.28 - 6.37 g/L). Regression analysis of these results yielded the following equation:

Comparative Method	Slope	Intercept mg/dL [g/L]	Correlation Coefficient	n
α_2-macroglobulin on the BN ProSpec® System	1.042	+6.3 [+0.063]	0.993	143

8. Conclusion:

These studies demonstrate correlation and equivalent performance between the Dade Behring N Antisera to Human a_2–Macroglobulin assay and the Dimension Vista® A2MAC assay.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUL 21 2008

Siemens Healthcare Diagnostics
c/o Ms. Anna Marie K. Ennis
Sr. regulatory Affairs and Compliance Specialist
500 GBC Drive
M/S 514
Newark, DE 19714-6101

Re: k081249
Trade/Device Name: Dimension Vista® A2MAC 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 866.5620
Regulation Name: Alpha-2-macroglobulin antigen, antiserum, control
Regulatory Class: Class II
Product Code: DEB, JIX, JJY
Dated: May 1, 2008
Received: May 2, 2008

Dear Ms. Ennis:

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 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" (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,

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

510(k) Number (if known): K081249

Device Name: **Dimension Vista® A2MAC Flex® reagent cartridge**

Indications For Use:

Dimension Vista® A2MAC Flex® reagent cartridge:
The A2MAC method is an *in vitro* diagnostic test for the quantitative measurement of α_2-macroglobulin in human serum and plasma on the Dimension Vista® System. Measurements of α_2-macroglobulin aid in the diagnosis of blood clotting or blood lysis disorders.

Prescription Use __X__ (Per 21 CFR 801 Subpart D) AND/OR Over-The-Counter-Use____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and

510(k) K081249

Indications for Use

510(k) Number (if known): K081249

Device Name: **Dimension Vista® PROT 1 CAL**

Indications For Use:

Dimension Vista® PROT 1 CAL:

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)
α_2-Macroglobulin (A2MAC)
β_2-Microglobulin (B2MIC)
C3 Complement (C3)
C4 Complement (C4)
Ceruloplasmin (CER)
Haptoglobin (HAPT)
Hemopexin (HPX)
Homocysteine (HCYS)
Immunoglobulin A (IGA)
* For cerebrospinal fluid (CSF)

Immunoglobulin E (IGE)
Immunoglobulin G (IGG, IGG-C*)
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) AND/OR Over-The-Counter-Use____ (21 CFR 801 Subpart C)

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510(k) K081249

Indications for Use

510(k) Number (if known): K081249

Device Name: **Dimension Vista® PROT 1 CON L**

Indications For Use:

PROT1 CON L is an assayed, low-level, intralaboratory quality control for the assessment of precision and analytical bias on the Dimension Vista® System in the quantitative determination of:

α1-Acid Glycoprotein (A1AG)
α1-Antitrypsin (A1AT)
α_2-Macroglobulin (A2MAC)
C3 Complement (C3)
C4 Complement (C4)
Ceruloplasmin (CER)
Haptoglobin (HAPT)
Hemopexin (HPX)
Homocysteine (HCYS)
Immunoglobulin A (IGA)
Immunoglobulin E (IGE)
Immunoglobulin G (IGG)
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)
specialty Albumin (sALB*)
Transferrin (TRF)

* For serum and plasma

Prescription Use ___X___ (Per 21 CFR 801 Subpart D) AND/OR Over-The-Counter-Use____ (21 CFR 801 Subpart C)

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510(k) K081249

Indications for Use

510(k) Number (if known): K081249

Device Name: **Dimension Vista® PROT 1 CON M**

Indications For Use:

PROT1 CON M is an assayed, mid-level, intralaboratory quality control for the assessment of precision and analytical bias on the Dimension Vista® System in the quantitative determination of:

α_1-Acid Glycoprotein (A1AG)	Immunoglobulin G (IGG)
α_1-Antitrypsin (A1AT)	Immunoglobulin G Subclass 1 (IGG1)
α_2-Macroglobulin (A2MAC)	Immunoglobulin G Subclass 2 (IGG2)
β_2-Microglobulin (B2MIC)	Immunoglobulin G Subclass 3 (IGG3)
C3 Complement (C3)	Immunoglobulin G Subclass 4 (IGG4)
C4 Complement (C4)	Immunoglobulin M (IGM)
Ceruloplasmin (CER)	Prealbumin (PREALB)
Haptoglobin (HAPT)	Retinol binding Protein (RBP)
Hemopexin (HPX)	soluble Transferrin Receptor (STFR)
Homocysteine (HCYS)	specialty Albumin (sALB*)
Immunoglobulin A (IGA)	Transferrin (TRF)
Immunoglobulin E (IGE)	

* For serum and plasma

Prescription Use __X__ (Per 21 CFR 801 Subpart D) AND/OR Over-The-Counter-Use____ (21 CFR 801 Subpart C)

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510(k) K081249

Indications for Use

510(k) Number (if known): K081249

Device Name: **Dimension Vista® PROT 1 CON H**

Indications For Use:

PROT1 CON H is an assayed, high-level, intralaboratory quality control for the assessment of precision and analytical bias on the Dimension Vista® System in the quantitative determination of:

α_1-Acid Glycoprotein (A1AG)	Immunoglobulin G (IGG)
α_1-Antitrypsin (A1AT)	Immunoglobulin G Subclass 1 (IGG1)
α_2-Macroglobulin (A2MAC)	Immunoglobulin G Subclass 2 (IGG2)
β_2-Microglobulin (B2MIC)	Immunoglobulin G Subclass 3 (IGG3)
C3 Complement (C3)	Immunoglobulin G Subclass 4 (IGG4)
C4 Complement (C4)	Immunoglobulin M (IGM)
Ceruloplasmin (CER)	Prealbumin (PREALB)
Haptoglobin (HAPT)	Retinol binding Protein (RBP)
Hemopexin (HPX)	soluble Transferrin Receptor (STFR)
Homocysteine (HCYS)	specialty Albumin (sALB*)
Immunoglobulin A (IGA)	Transferrin (TRF)
Immunoglobulin E (IGE)	

* For serum and plasma

Prescription Use __X__ (Per 21 CFR 801 Subpart D) AND/OR Over-The-Counter-Use____ (21 CFR 801 Subpart C)

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