OCT 21 2009

510(k) Summary for
Dimension Vista® IGG Subclass 1 Assay
Dimension Vista® IGG Subclass 2 Assay
Dimension Vista® IGG Subclass 3 Assay
Dimension Vista® IGG Subclass 4 Assay

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: K092283

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

Manufacturer:
Siemens Healthcare Product GmbH
Emil von Behring Str. 76
Marburg, 35041 Germany

Contact Information:
Siemens Healthcare Diagnostics
P.O. Box 6101
Newark, Delaware 19714-6101
Attn: Kathleen Dray-Lyons
Tel: 781-826-4551
Fax: 781-826-2497

Preparation date: September 9, 2009

2. Device Name:
Dimension Vista® IGG1 Flex® reagent cartridge
Dimension Vista® IGG2 Flex® reagent cartridge
Dimension Vista® IGG3 Flex® reagent cartridge
Dimension Vista® IGG4 Flex® reagent cartridge

Classification: IGG (Gamma Chain Specific),Class II
Product Code: DFZ
Panel: Immunology (82)

3. Identification of the Legally Marketed Device:

Siemens N Antisera to Human IgG subclasses 1 and 2
Siemens N Latex IgG Subclasses 3 and 4

4. Device Description:

Dimension Vista® IGG 1-2 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® IGG 3-4 Flex® reagent cartridge
Antibodies as well as polystyrene particles coated with antibodies specific to human IGG3 or IGG4 are aggregated when mixed with samples containing IGG3 or IGG4. 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.

5. Device Intended Use:

Dimension Vista® IGG1 Flex® Reagent Cartridge:
The IGG1 method is an *in vitro* diagnostic test for the quantitative measurement of immunoglobulin G subclass 1 in human serum, heparinized plasma and EDTA plasma on the Dimension Vista® System. Measurements of immunoglobulin G subclass 1 aid in the diagnosis of plasma cell antibody forming abnormalities in conjunction with clinical and other laboratory findings.

Dimension Vista® IGG2 Flex® reagent cartridge:
The IGG2 method is an *in vitro* diagnostic test for the quantitative measurement of immunoglobulin G subclass 2 in human serum, heparinized plasma and EDTA plasma on the Dimension Vista® System. Measurements of immunoglobulin G subclass 2 aid in the diagnosis of plasma cell antibody forming abnormalities in conjunction with clinical and other laboratory findings.

Dimension Vista® IGG3 Flex® reagent cartridge:
The IGG3 method is an *in vitro* diagnostic test for the quantitative measurement of immunoglobulin G subclass 3 in human serum, heparinized plasma and EDTA plasma on the Dimension Vista® System. Measurements of immunoglobulin G subclass 3 aid in the diagnosis of plasma cell antibody forming abnormalities in conjunction with clinical and other laboratory findings.

Dimension Vista® IGG4 Flex® reagent cartridge:
The IGG4 method is an *in vitro* diagnostic test for the quantitative measurement of immunoglobulin G subclass 4 in human serum, heparinized plasma and EDTA plasma on the Dimension Vista® System. Measurements of immunoglobulin G subclass 4 aid in the diagnosis of plasma cell antibody forming abnormalities in conjunction with clinical and other laboratory findings.

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

The Dimension Vista® IGG1, 2, 3 and 4 reagent cartridges are substantially equivalent to the Siemens N Antisera to Human IgG Subclasses 1 and 2 assay and Siemens N Latex IgG3 and 4 respectively. The Dimension Vista® IGG1, 2, 3 and 4 assays, like the N Antisera to Human IgG Subclasses 1 and 2 and N Latex IGG 3 and 4 assays are an *in vitro* diagnostic reagents for the quantitative measurement of immunoglobulin G subclass 1-4 in human serum and plasma.

7. Device Performance Characteristics:

The Dimension Vista® IGG 1 and 2 assays were compared to N Antiserum to Human IgG Subclasses 1 and 2 on the BN ProSpec® System. Regression analysis of these results yielded the following equations:

Method Comparison Study

	n	Slope	Intercept g/L	Correlation Coefficient
Dimension Vista® IGG1	129	1.002	-0.165	0.994

Dimension Vista® IGG2	147	1.000	-0.020	0.994

The Dimension Vista® IGG 3 and 4 assays were compared to N N Latex IgG3 and IgG4 on the BN ProSpec® System. Regression analysis of these results yielded the following equations:

Method Comparison Study

	n	Slope	Intercept g/L	Correlation Coefficient
Dimension Vista® IGG3	142	1.047	-0.002	0.993
Dimension Vista® IGG4	150	1.020	-0.009	0.996

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

OCT 2 1 2009

Siemens Healthcare Diagnostics
c/o Ms. Kathleen Ann Dray-Lyons
Manager, Regulatory Affairs
500 GBC Drive
PO Box 6101
Newark, DE 19714

Re: k092283
Trade/Device Name: Dimension Vista® IgG Subclass 1 Flex® reagent cartridge
Dimension Vista® IgG Subclass 2 Flex® reagent cartridge
Dimension Vista® IgG Subclass 3 Flex® reagent cartridge
Dimension Vista® IgG Subclass 4 Flex® reagent cartridge
Regulation Number: 21 CFR §866.5510
Regulation Name: Immunoglobulins A, G, M, D, and E Immunological Test System
Regulatory Class: Class II
Product Code: DFZ
Dated: July 27, 2009
Received: July 29, 2009

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 class II (Special Controls), 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 Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Maria M. Chan, 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

510(k)Number: *K092283*

Device Name: Dimension Vista® Immunoglobulin G Subclass 1 Flex® reagent cartridge

Indications for Use: The IgG1 method is an *in vitro* diagnostic test for the quantitative measurement of immunoglobulin G subclass 1 in human serum, heparinized plasma and EDTA plasma on the Dimension Vista® System. Measurements of immunoglobulin G subclass 1 aid in the diagnosis of plasma cell antibody forming abnormalities in conjunction with clinical and other laboratory findings.

Prescription use___X_____ AND/OR Over-the-counter use_____

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of in vitro Diagnostic devices (OIVD)

Reena Philip

Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safet

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Indications for Use

510(k)Number: *K092283*

Device Name: Dimension Vista® Immunoglobulin G Subclass 2 Flex® reagent cartridge

Indications for Use: The IgG2 method is an *in vitro* diagnostic test for the quantitative measurement of immunoglobulin G subclass 2 in human serum, heparinized plasma and EDTA plasma on the Dimension Vista® System. Measurements of immunoglobulin G subclass 2 aid in the diagnosis of plasma cell antibody forming abnormalities in conjunction with clinical and other laboratory findings.

Prescription use X AND/OR Over-the-counter use_____

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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Reena Philip

Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

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Indications for Use

510(k)Number: *K092283*

Device Name: Dimension Vista® Immunoglobulin G Subclass 3 Flex® reagent cartridge

Indications for Use: The IgG3 method is an *in vitro* diagnostic test for the quantitative measurement of immunoglobulin G subclass 3 in human serum, heparinized plasma and EDTA plasma on the Dimension Vista® System. Measurements of immunoglobulin G subclass 3 aid in the diagnosis of plasma cell antibody forming abnormalities in conjunction with clinical and other laboratory findings.

Prescription use___X_____ AND/OR Over-the-counter use_____

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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Reena Philip

Division Sign-Off

Office of in Vitro Diagnostic
Device Evaluation and Safety

510(k) K092283

Indications for Use

510(k)Number: ***K092283***

Device Name: Dimension Vista® Immunoglobulin G Subclass 4 Flex® reagent cartridge

Indications for Use: The IgG4 method is an *in vitro* diagnostic test for the quantitative measurement of immunoglobulin G subclass 4 in human serum, heparinized plasma and EDTA plasma on the Dimension Vista® System. Measurements of immunoglobulin G subclass 4 aid in the diagnosis of plasma cell antibody forming abnormalities in conjunction with clinical and other laboratory findings.

Prescription use___X_____ AND/OR Over-the-counter use_____

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of in vitro Diagnostic devices (OIVD)

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Office of In Vitro Diagnostics
Device Evaluation and Safety

510(k) K092283