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510(k) Summary for Dimension Vista® HbA1c Kit

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: K102045

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

Manufacturer: Siemens Healthcare Diagnostics Inc
Newark, Delaware 19714-6101

Contact Information: Siemens Healthcare Diagnostics Inc.
500 GBC Drive
P.O. Box 6101
Newark, Delaware 19714-6101
Attn: A. Kathleen Ennis
Tel: 302-631-9352
Fax: 302-631-6299

Preparation date: November 9, 2010

2. Device Name:

Dimension Vista® HbA1c Kit
Classification: Class II
Product Code: LCP
Panel: Hematology

3. Identification of the Legally Marketed Device:

Dimension Vista® HA1C Kit – K062128

4. Device Descriptions:

The Dimension Vista® HbA1c kit contains Flex® reagent cartridges and calibrator. Each cartridge contains reagents used to measure total hemoglobin and hemoglobin A1c. the reagents are liquid and ready to use on the instrument. The calibrator in the kit is a five level lyophilized product. Each level is hydrated with 2.0mL of reagent grade water. The lot matched reagents and calibrator product are for use on the Dimension Vista® Systems.

5. Device Intended Uses:

The HbA1c assay on the Dimension Vista® System is an *in vitro* diagnostic assay for the quantitative determination of hemoglobin A1c (HbA1c) in human anticoagulated whole blood. Measurements of hemoglobin A1c are effective in monitoring long term glucose control in individuals with diabetes mellitus.

6. Summary of the devices technological characteristics

The Dimension Vista® HbA1c kit has the same technological characteristics as the Dimension Vista® HA1C kit. A comparison of features is provided.

Feature	Predicate Device: Dimension Vista® HA1C kit (K062128)	New Device: Dimension Vista® HbA1c kit
Similarities		
Intended Use	Both kits are for *in vitro* diagnostic use for the quantitative measurement of hemoglobin A1c in human anticoagulated whole blood on the Dimension Vista® systems.	
Sample Type	Both devices are for use with human anticoagulated whole blood treated with EDTA.	
Technology	Both devices use turbidometric inhibition immunoassay (TINIA) for the HbA1c measurement and both devices use a modification of the alkaline hematin reaction for the total hemoglobin portion of the assay.	
Sample size	Both assays use 1 uL from the sample cup.	
Reagents	The methods use similar reagents.	
Calibrator	Both calibrator products are lyophilized human whole blood hemolysates.	
Instrument	Both methods are used with all models of the Dimension Vista® Systems.	
Differences		
Reporting Units	Reports in %HbA1c.	Reports in both %HbA1c and mmol/mol.
Analytical Measuring Range	1.0 – 30.0 g/dL Hb 0.2 – 2.9 g/dL HbA1c	3.5 – 16.0 % [15 – 151 mmol/mol] 5.0 – 25.0 g/dL [3.1 – 15.5 mmol/L] Hb 0.3 – 2.6 g/dL [0.2 – 1.6 mmol/L] HbA1c
Calibrator levels	Uses four calibrator levels plus saline.	Uses five calibrator levels.
Calibrator Traceability	Traceable to NGSP	Traceable to NGSP and IFCC

7. Method Comparison

A split sample method comparison was conducted using the new device, Dimension Vista ® HbA1c kit vs. the predicate, Dimension Vista®HA1C kit. one hundred and twenty- four (124) fresh, EDTA-treated whole blood samples with HbA1c values ranging 3.8 – 16.0 %HbA1c by the Dimension Vista®HA1C kit . The data was analyzed using Passing-Bablok regression analysis. The analysis is as follows:

	%HbA1c		mmol/mol HbA1c	
	Coefficient	**95% CI**	**Coefficient**	**95% CI**
Intercept	0.71	0.43 to 0.96	6.13	3.95 to 7.83
Slope	0.93	0.89 to 0.97	0.93	0.89 to 0.97
N = 124				

A split sample method comparison was also performed with the new device, Dimension Vista ® HbA1c kit and the Tosoh Ion Exchange HPLC analyzer using ninety- one (91) human whole blood samples preserved with EDTA. The HbA1c values from 4.6 to 9.6% HbA1c were used in a Bland-Altman bias analysis. The analysis is as follows:

Mean Bias = - 0.04 %HbA1c
SD = 0.26 %HbA1c
Upper 95% CI =0.47 %HbA1c
Lower 95% CI = -0.56%HbA1c
Tosoh Limits = ± 0.75 %HbA1c
Range of Values 4.6 – 9.6 %HbA1c
n = 91

8. Conclusion

Based on a review of the devices technological features and the method comparison study, the new Dimension Vista® HbA1c kit is substantially equivalent to the legally marketed device, Dimension Vista® HA1C kit.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Siemens Healthcare Diagnostics Inc.
c/o Ms. Anna-Marie K. Ennis
Regulatory Affairs Manager
500 GBC Drive, M/S 514
Newark, DE 19714-6101

Re: k102045
Trade/Device Name: Dimension VISTA HbA1c
Regulation Number: 21 CFR 864.7470
Regulation Name: Glycosylated Hemoglobin Assay.
Regulatory Class: Class II
Product Code: LCP, JIT
Dated: January 14, 2011
Received: January 18, 2011

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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 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 Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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/cdrh/industry/support/index.html.

Sincerely yours,

Courtney Harper, Ph.D.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): k102045

Device Name: Dimension Vista HbA1c

Indication For Use:

The HbA1c assay used on the Dimension Vista® system is an in vitro diagnostic assay for the quantitative determination of per cent Hemoglobin A1c in human anticoagulated whole blood. Measurements of hemoglobin A1c are effective in monitoring long term glucose control in individuals with diabetes mellitus.

HbA1c calibrator is intended for use in the calibration of the Hemoglobin A1c (HbA1c) method on the Dimension Vista® system.

Prescription Use x (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____ (21 CFR Part 801 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Carol C. Benson

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) k102045