K091711

510(k) SUMMARY DEC 11 2009

510(k) Owner:	Alfa Wassermann Diagnostic Technologies, LLC 4 Henderson Drive West Caldwell, NJ 07006 Contact: Hyman Katz, Ph.D. Phone: 973-852-0158 Fax: 973-852-0237	
Date Summary Prepared:	June 8, 2009 (updated November 6, 2009)	
Device:	Trade Name: Classification: Common/Classification Name:	S-Test HbA1c Reagent cartridge Class II Assay, Glycosylated Hemoglobin (21 C.F.R. § 864.7470), Product code LCP
Predicate Devices:	Manufacturer for analyzer/reagent system predicate: Siemens Medical Solutions Diagnostics, DCA Vantage (K071466) and DCA 2000+ Analyzer (K951361), Test system for Hemoglobin A1c	
Device Description:	The S-Test Hemoglobin A1c (HbA1c) reagent cartridges, used with the S40 Clinical Analyzer, are intended for quantitative *in vitro* diagnostic determination of %HbA1c concentration in EDTA whole blood. This method is based on a colorimetric assay for total hemoglobin and an enzymatic assay for HbA1c.	
Intended Use:	The S-Test Hemoglobin A1c Reagent is intended for the quantitative determination of percent Hemoglobin A1c concentration in EDTA whole blood using the S40 Clinical Analyzer. Measurement of glycosylated hemoglobin is used for monitoring the long-term glycemic control of individuals with diabetes. This test is intended for use in clinical laboratories or physician office laboratories. For *in vitro* diagnostic use only.	
Technological Characteristics:	The S-Test HbA1c Reagent is contained in two bi-reagent cartridges. Cartridge 1, Reagent 1 contains Protease and ProClin 300; Reagent 2 contains N-ethylmaleimide and ProClin 300. Cartridge 2, Reagent 1 contains N-(carboxymethyl aminocarbonyl)-4,4'-bis(dimethylamino) diphenylamine sodium salt (20 μmol/L), surfactant, ProClin 300, and sodium azide (0.001%); Reagent 2 contains surfactant, fructosyl peptide oxidase, and peroxidase.	

Performance Data:	Performance data on S-Test HbA1c reagent included precision and accuracy data. Precision: In testing at three HbA1c levels for 20 days, the within-run CV ranged from 0.9 to 1.1% and total CV ranged from 1.2 to 1.5%. In precision studies at three separate Physician Office Laboratory (POL) sites over five days, the within-run CV ranged from 0.5 to 1.8% and total CV ranged from 0.7 to 3.2%. Accuracy: In a correlation study, 110 EDTA whole blood samples with HbA1c values ranging from 4.0 to 13.4% were assayed on the S40 Clinical Analyzer using S-Test HbA1c (y) and a comparative method (x). Least-squares regression analysis yielded a correlation coefficient of 0.982, a standard error estimate of 0.39, a confidence interval slope of 0.988 to 1.062, and a confidence interval intercept of -0.48 to 0.02. In patient correlation studies at three separate POL sites using the S40 Clinical Analyzer and a comparative method, least-squares regression analysis yielded correlation coefficients of 0.988 to 0.996, standard error estimates of 0.18 to 0.31, confidence interval slopes of 0.957 to 1.065, and confidence interval intercepts of -0.64 to 0.16.
Conclusions:	Based on the foregoing data, the device is safe and effective. These data also indicate substantial equivalence to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center – WO66-0609
Silver Spring, MD 20993-0002

Alfa Wassermann Diag. Technologies, LLC
c/o Dr. Hyman Katz
Vice President, Quality Assurance
& Regulatory Affairs
4 Henderson Drive
West Caldwell, NJ 07006

DEC 11 2009

Re: k091711
Trade Name: S-Test % Hemoglobin A1c (HbA1c)
Regulation Number: 21 CFR §864.7470
Regulation Name: Glycosylated hemoglobin assay
Regulatory Class: Class II
Product Codes: LCP
Dated: November 24, 2009
Received: November 25, 2009

Dear Dr. Katz:

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); 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 Part 801), 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 postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. 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) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney C. 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): K091711

Device Name: S-Test % Hemoglobin A1c (HbA1c)

Indication For Use: The S-Test Hemoglobin A1c Reagent is intended for the quantitative determination of percent Hemoglobin A1c concentration in EDTA whole blood using the S40 Clinical Analyzer. Measurement of glycosylated hemoglobin is used for monitoring the long-term glycemic control of individuals with diabetes. This test is intended for use in clinical laboratories or physician office laboratories. For *in vitro* diagnostic use only.

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) K091711