510(k) SUMMARY

510(k) Owner:	Alfa Wassermann Diagnostic Technology, LLC 4 Henderson Drive West Caldwell, NJ 07006	SEP 1 8 2008
	Contact: Dennis Taschek Phone: 973-852-0177 Fax: 973-852-0237	K082226
Date Summary Prepared:	July 14, 2008	
Device:	Trade Names:	S-Test CK Reagent cartridge
	Classification:	Class II
	Common/Classification Name:	CK: Creatine phosphokinase/creatine kinase or isoenzymes test system (21 C.F.R. § 862.1215) Product Code JHS
Predicate Device:	Manufacturer for analyzer/reagent system predicate is: Alfa Wassermann ACE plus ISE/Clinical Chemistry System ACE Creatine Kinase Reagent (k931786)	
Device Description:	The S-Test Creatine Kinase (CK) reagent cartridge, used with the S40 Clinical Analyzer, is intended for quantitative *in vitro* diagnostic determination of CK activity in serum or heparin plasma based on a photometric test measuring the formation of NADPH, which absorbs strongly at 340 nm.	
Intended Use:	The S-Test Creatine Kinase Reagent is intended for the quantitative determination of Creatine Kinase activity in serum or heparin plasma using the S40 Clinical Analyzer. Measurements of creatine phosphokinase activity are used in the diagnosis and treatment of myocardial infarction and muscle diseases such as progressive, Duchenne-type muscular dystrophy. This test is intended for use in clinical laboratories or physician office laboratories. For *in vitro* diagnostic use only.	
Technological Characteristics:	The S-Test CK Reagent is contained in a bi-reagent cartridge. Reagent 1 contains: Hexokinase, glucose-6-phosphate dehydrogenase, adenosine-5'-diphosphoric acid, D-glucose, and nicotinamide adenine dinucleotide phosphate (oxidized form). Reagent 2 contains: Creatine phosphate.	

Performance Data:

Performance data on the S-Test CK reagent included precision, accuracy, and sensitivity data.

Precision: In testing at three CK levels for 22 days, the within-run CV ranged from 1.4 to 2.0%, and total CV ranged from 5.1 to 6.1%. In precision studies at three separate Physician Office Laboratory (POL) sites and in-house over five days, the within-run CVs ranged from 0.5 to 3.7% and total CVs ranged from 0.8 to 3.7%.

Accuracy: In a correlation study, 95 samples with CK values ranging from 32 to 1181 U/L were assayed on the S40 Clinical Analyzer using S-Test CK (y) and a comparative method (x). Least-squares regression analysis yielded a correlation coefficient of 0.998, a standard error estimate of 14.5, a confidence interval slope of 1.027 to 1.053, and a confidence interval intercept of -12.5 to -5.2. 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 1.00, standard error estimates of 5.0 to 8.5, confidence interval slopes of 1.006 to 1.059, and a confidence interval intercepts of -10.8 to -3.5.

Sensitivity: The detection limit was 24 U/L.

Conclusions:

Based on the foregoing data, the device is safe and effective. These data also indicate substantial equivalence to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Alfa Wassermann Diagnostic Technologies, Inc.
c/o Mr. Dennis Taschek
Vice President, Reagent and Instrument Technology
4 Henderson Drive
West Caldwell, NJ 07006

SEP 18 2008

Re: K082226
Trade/Device Name: S-Test CK Reagent Cartridge
Regulation Number: 21 CFR 862.1215
Regulation Name: Creatine phosphokinase/creatine kinase or isoenzymes test system
Regulatory Class: Class II
Product Code: JHS
Dated: August 14, 2008
Received: August 18, 2008

Dear Mr. Taschek:

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 information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0490. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 at http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Jean M. Cooper, M.S., D.V.M.

Jean M. Cooper, M.S., D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K082226

Device Name: S-Test Creatine Kinase (CK)

Indications for Use: The S-Test Creatine Kinase Reagent is intended for the quantitative determination of Creatine Kinase activity in serum or heparin plasma using the S40 Clinical Analyzer. Measurements of creatine phosphokinase activity are used in the diagnosis and treatment of myocardial infarction and muscle diseases such as progressive, Duchenne-type muscular dystrophy. This test is intended for use in clinical laboratories or physician office laboratories. For *in vitro* diagnostic use only.

Prescription Use ___X___ (Part 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 (ODE)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

CONFIDENTIAL

510(k) K082226