K080073

JUN 30 2008

510(k) SUMMARY

510(k) Owner:	Alfa Wassermann Diagnostic Technology, LLC 4 Henderson Drive West Caldwell, NJ 07006 Contact: Dennis Taschek Phone: 973-852-0177 Fax: 973-852-0237	
Date Summary Prepared:	June 19, 2008	
Device:	Trade Name:	S-Test CRE Reagent cartridge
	Common/Classification Names:	Creatinine test system (21 C.F.R. § 862.1225) Product Code JFY
	Classification:	Class II
Predicate Device:	Manufacturer for analyzer/reagent system predicate is: Alfa Wassermann ACE plus ISE/Clinical Chemistry System ACE Creatinine Reagent (K931786)	
Device Description:	The S-Test Creatinine (CRE) reagent cartridge, used with the S40 Clinical Analyzer, is intended for quantitative *in vitro* diagnostic determination of CRE in serum or heparin plasma based on a photometric test measuring the formation of a reddish-purple pigment in a coupled enzymatic reaction.	
Intended Use:	The S-Test Creatinine Reagent is intended for the quantitative determination of Creatinine concentration in serum or heparin plasma using the S40 Clinical Analyzer. Creatinine measurements are used in the diagnosis and treatment of renal diseases, in monitoring renal dialysis, and as a calculation basis for measuring other urine analytes. This test is intended for use in clinical laboratories or physician office laboratories. For *in vitro* diagnostic use only.	

Technological Characteristics:	The S-Test CRE Reagent is contained in a bi-reagent cartridge. Reagent 1 contains: Creatinine amidinohydrolase, sarcosine oxidase, N-ethyl-N-sulfobutyl-m-toluidine, catalase, and N-tris (hydroxymethyl) methyl-2-aminoethane sulfonic acid (TES) buffer. Reagent 2 contains: Creatinine amidohydrolase, 4-aminoantipyrine, peroxidase, and N-tris (hydroxymethyl) methyl-2-aminoethane sulfonic acid (TES) buffer.
Performance Data:	Performance data on the S-Test CRE Reagent included precision, accuracy, and sensitivity data. Precision: In testing at three CRE levels for 22 days, the within-run CV ranged from 1.3 to 9.6%, and total CV ranged from 4.3 to 17.2%. In precision studies at three separate Physician Office Laboratory (POL) sites and in-house over five days, the within-run CV ranged from 1.0 to 10.1% and total CV ranged from 1.3 to 10.8%. Accuracy: In the correlation study, 65 samples with CRE values ranging from 0.6 to 14.6 mg/dL were assayed on the S40 Clinical Analyzer using S-Test CRE (y) and a comparative method (x). Least-squares regression analysis yielded a correlation coefficient of 0.998, a standard error estimate of 0.16, a confidence interval slope of 1.002 to 1.031, and a confidence interval intercept of -0.20 to -0.10. In patient correlation studies at four separate POL sites using the S40 Clinical Analyzer and a comparative method, least-squares regression analysis yielded correlation coefficients ranged from 0.997 to 0.999, standard error estimates of 0.25 to 0.34, confidence interval slopes of 1.003 to 1.060 and a confidence interval intercepts of -0.38 to 0.10. Sensitivity: The detection limit was 0.3 mg/dL.
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 Technology, Inc.
c/o Mr. Dennis Tascheck
Vice President, Reagent & Instrument Technologies
4 Henderson Drive
West Caldwell, NJ 07006

JUN 3 0 2008

Re: k080073
Trade Name: S-Test Creatinine (CRE)
Regulation Number: 21 CFR 862.1225
Regulation Name: Creatinine
Regulatory Class: Class II
Product Codes: JFY
Dated: June 16, 2008
Received: June 17, 2008

Dear Mr. Tascheck:

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

Indication for Use

510(k) Number (if known): k080073

Device Name: S-Test Creatinine (CRE)

Indication For Use:

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

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

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