K072140

JUN 24 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 BIL; S-Test BUN; S-Test GLU Reagent cartridge (21 C.F.R. § 862.1110, Product code JFM; 21 C.F.R. § 862.1770, Product code CDQ; 21 C.F.R. § 862.1345, Product code CFR)
	Classification:	Class II
	Common/Classification Name:	Total bilirubin; blood urea nitrogen; glucose test systems
Predicate Devices:	Manufacturers for analyzer/reagent system predicates are: 1. <u>ACE plus ISE/ Clinical Chemistry System</u> ACE Total Bilirubin Reagent (K931786) ACE BUN Reagent (K931786) ACE GLU Reagent (K931786) 2. <u>Olympus AU640 Clinical Chemistry Analyzer</u> Total Bilirubin Reagent (K961274) BUN Reagent (K961274) GLU Reagent (K961274) 3. <u>Piccolo® xpress Chemistry Analyzer</u> Total Bilirubin Reagent (K942782) BUN Reagent (K942782) GLU Reagent (K942782)	
Device Description:	The S40 Clinical Analyzer is an automatic wet chemistry system intended for use in clinical laboratories or physician office laboratories that consists of a desktop analyzer, an operation screen that prompts the user for operation input and displays data, a unit cover, and disposable reagent cartridges. The desktop analyzer includes a single pipettor, an incubation rotor, and a multi-wavelength photometer. The analyzer can measure analytes in serum, heparin	

	plasma, whole blood, and urine. Once the sample is placed into the device, the analyzer pipettes the sample, pipettes the reagent, and mixes the sample and reagent together. After the sample and reagent react in the incubator bath, the analyzer measures the absorbance of the sample, and based on the absorbance, it calculates the concentration of analyte in the sample. The S-Test total bilirubin (BIL) reagent cartridge used with the S40 Clinical Analyzer is intended for quantitative *in vitro* diagnostic determination of total BIL by measuring bilirubin concentration in serum or heparin plasma based on an enzymatic photometric test measuring the formation of biliverdine from bilirubin. The S-Test blood urea nitrogen (BUN) reagent cartridge used with the S40 Clinical Analyzer is intended for quantitative *in vitro* diagnostic determination of BUN in serum or heparin plasma based on an enzymatic photometric test measuring the formation of NADP from NADPH. The S-Test glucose (GLU) reagent cartridge used with the S40 Clinical Analyzer is intended for quantitative *in vitro* diagnostic determination of GLU in serum or heparin plasma based on an enzymatic photometric test measuring the formation of NADPH from NADP.
Intended Use:	The S-Test Total Bilirubin Reagent is intended for the quantitative determination of bilirubin in serum or heparin plasma using the S40 Clinical Analyzer. Measurements of the levels of bilirubin, an organic compound formed during the normal and abnormal destruction of red blood cells, are used in the diagnosis and treatment of liver, hemolytic hematological, and metabolic disorders, including hepatitis and gall bladder block. This test is intended for use in clinical laboratories or physician office laboratories. For *in vitro* diagnostic use only. The S-Test Blood Urea Nitrogen Reagent is intended for the quantitative determination of urea nitrogen in serum or heparin plasma using the S40 Clinical Analyzer. Measurements of Urea Nitrogen are used in the diagnosis and treatment of certain renal and metabolic diseases. This test is intended for use in clinical laboratories or physician office laboratories. For *in vitro* diagnostic use only. The S-Test Glucose Reagent is intended for the quantitative determination of glucose in serum or heparin plasma using the S40 Clinical Analyzer. Glucose measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, neonatal hypoglycemia, idiopathic hypoglycemia, and pancreatic islet cell carcinoma. This test is intended for use in clinical laboratories or physician office laboratories. For *in vitro* diagnostic use only.

Technological Characteristics:	The S-Test BIL is a bi-reagent cartridge. Reagent 1 and Reagent 2 both contain bilirubin oxidase (BOD) (2000-6000 U/L) and buffer. The S-Test BUN is a bi-reagent cartridge. Reagent 1 contains: nicotinamide adenine dinucleotide phosphate (NADPH, reduced form), carbonate buffer (pH 10), and Good's buffer (pH 6.0). Reagent 2 contains: urease (derived from sword bean), glutamate dehydrogenase (GLDH) (derived from yeast), and N,N-bis (2-hydroxyethyl) glycine (BICINE) buffer (pH 8.2). The S-Test GLU is a bi-reagent cartridge. Reagent 1 contains: hexokinase (HK) (derived from yeast), glucose-6-phosphate dehydrogenase (G-6-PDH, derived from bacillus), nicotinamide adenine dinucleotide phosphate (NADP, oxidized type), and magnesium acetate 2-amino-2-hydroxymethyl-1,3-propanediol buffer (pH 9.0). Reagent 2 contains: adenosine triphosphate disodium salt (ATP), and 2-amino-2-hydroxymethyl 1,3-propanediol buffer (pH 9.0).
Performance Data:	Performance data on the S-Test BIL, S-Test BUN, and S-Test GLU included precision, accuracy, and sensitivity data. **S-Test BIL** Precision: In testing conducted at three BIL levels for 22 days, the within-run CV ranged from 0.9 to 10.7%, and total CV ranged from 5.2 to 13.3%. In precision studies at three separate Physician Office Laboratory (POL) sites and in-house over five days, the within-run CV ranged from 0.0 to 10.4% and the total CV ranged from 0.0 to 10.4%. Accuracy: In the correlation study, 91 samples with BIL values ranging from 0.2 to 23.9 mg/dL were assayed on the S40 Clinical Analyzer using S-Test BIL reagent and a comparison method. Least-squares regression analysis yielded a correlation coefficient of 0.996, a standard error estimate of 0.5, a confidence interval slope of 0.963 to 1.125, and a confidence interval intercept of 0.00 to 0.15. 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 ranged from 0.997 to 0.998, standard error estimates of 0.48 to 0.53, confidence interval slopes of 0.926 to 0.981, and confidence interval intercepts of 0.02 to 0.30. Sensitivity: The detection limit was 0.2 mg/dL. **S-Test BUN** Precision: In testing at three BUN levels for 22 days, the within-run CV ranged from 1.2 to 2.3%, and total CV ranged from 6.2 to 6.6%. In precision studies at three separate POL sites and in-house over five days, the within-run CV ranged from 0.7 to 2.5% and total CV ranged from 0.9 to 2.5%. Accuracy: In the correlation study, 94 samples with BUN values ranging from 6 to 70 mg/dL were assayed on the S40 Clinical Analyzer using S-Test BUN

	reagent and a comparison method. Least-squares regression analysis yielded a correlation coefficient of 0.997, a standard error estimate of 0.9, a confidence interval slope of 0.979 to 1.040, and a confidence interval intercept of 0.34 to 1.47. 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 0.996 to 0.997, standard error estimates of 1.11 to 1.83, confidence interval slopes of 0.922 to 1.012, and confidence interval intercepts of -2.11 to 1.30. Sensitivity: The detection limit was 4.9 mg/dL. **S-Test GLU** Precision: In testing conducted at three GLU levels for 22 days, the within-run CV ranged from 1.4 to 1.8%, and the total CV ranged from 5.8 to 6.6%. In precision studies at three separate POL sites and in-house over five days, the within-run CV ranged from 1.1 to 2.9%, and the total CV ranged from 1.3 to 3.4%. Accuracy: In the correlation study, 97 samples with GLU values ranging from 26 to 454 mg/dL were assayed on the S40 Clinical Analyzer using S-Test GLU and on a comparison method. Least-squares regression analysis yielded a correlation coefficient of 0.996, a standard error estimate of 7.4, a confidence interval slope of 0.994 to 1.073, and a confidence interval intercept of -10.3 to -1.87. 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 ranging from 0.989 to 0.998, standard error estimates of 7.7 to 16.0, confidence interval slopes of 1.044 to 1.133, and confidence interval intercept of -17.5 to -2.6. Sensitivity: The detection limit was 18 mg/dL.
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

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 24 2008

Re: k072140
Trade Name: S-Test Glucose (GLU), S-Test Total Bilirubin (BIL), S-Test Blood Urea Nitrogen (BUN)
Regulation Number: 21 CFR 862.1770
Regulation Name: Urea Nitrogen Test System.
Regulatory Class: Class II
Product Codes: CDN, JFM, CFR, JJE
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): k072140

Device Name: S40 Clinical Analyzer

Indication For Use:

The S40 Clinical Analyzer is an automatic wet chemistry system intended for use in clinical laboratories or physician office laboratories that consists of a desktop analyzer, an operation screen that prompts the user for operation input and displays data, a unit cover, and disposable reagent cartridges. The desktop analyzer includes a single pipettor, an incubation rotor, and a multi-wavelength photometer.

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

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

K072140

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

510(k) K072140

Indication for Use

510(k) Number (if known): k072140

Device Name: S-Test Glucose (GLU)

Indication For Use:

The S-Test Glucose Reagent is intended for the quantitative determination of glucose in serum or heparin plasma using the S40 Clinical Analyzer. Glucose measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, neonatal hypoglycemia, idiopathic hypoglycemia, and pancreatic islet cell carcinoma. 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)

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Evaluation and Safety

510(k) k072140

Indication for Use

510(k) Number (if known): k072140

Device Name: S-Test Total Bilirubin (BIL)

Indication For Use:

The S-Test Total Bilirubin Reagent is intended for the quantitative determination of bilirubin in serum or heparin plasma using the S40 Clinical Analyzer. Measurements of the levels of bilirubin, an organic compound formed during the normal and abnormal destruction of red blood cells, are used in the diagnosis and treatment of liver, hemolytic hematological, and metabolic disorders, including hepatitis and gall bladder block. 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)

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510(k) K072140

Indication for Use

510(k) Number (if known): k072140

Device Name: S-Test Blood Urea Nitrogen (BUN)

Indication For Use:

The S-Test Blood Urea Nitrogen Reagent is intended for the quantitative determination of urea nitrogen in serum or heparin plasma using the S40 Clinical Analyzer. Measurements of Urea Nitrogen are used in the diagnosis and treatment of certain renal and metabolic diseases. 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)

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