JUN 3 0 2005

510(k) SUMMARY
510(k) K050283

Submitter's Name and Address:
Stanbio Laboratory
1261 North Main Street
Boerne, Texas 78006

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Prepared By: Kirk Johnson
May 2, 2005

Product Name

Trade Name:	Creatinine LiquiColor®
Common Name:	Creatinine Test
Classification Name:	Enzymatic Method, Creatinine
Classification:	II
Product Code:	JFY

Substantial Equivalence of Device
This test is substantially equivalent to:

Product Name:	Creatinine Reagent
	510(k) K941837
	Roche Diagnostic

Description of Device
The Creatinine LiquiColor® test kit is comprised of two reagents, Reagent 1 (R1) and Reagent 2. To calibrate the test kit, a calibrator is used that has values determined by a similar method.

Intended Use of Device
The Stanbio Creatinine LiquiColor® test system is a device intended to measure creatinine levels in serum or urine. 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.

Comparison of Devices
The Stanbio methods employ absorbance change as a means for quantitative determination of creatinine concentration in serum or urine. The Stanbio method employs an enzymatic test method described below, whereas, the Roche method uses a kinetic modification of the Jaffe reaction.

Stanbio Method

1) Creatinine + H_2O $\xrightarrow{\text{Creatinine amidohydorolase}}$ Creatine

2) Creatine + H_2O $\xrightarrow{\text{Creatine amidinohydrolase}}$ Sarcosine + Urea

3) Sarcosine + H_2O + O_2 $\xrightarrow{\text{Sarcosine oxidase}}$ Glycine + HCHO + H_2O_2

4) $2H_2O_2$ + 4-aminoantipyrine + *ESPMT $\xrightarrow{\text{Peroxidase}}$ Quinoneimine Dye + 4 H_2O

*ESPMT: N-ethyl-N-sulfopropryl-m-toluidine

Roche Method

Creatinine + Picric Acid $\xrightarrow[\text{pH}]{\text{alkaline}}$ Red complex

The rate of formation of the red colored complex is measured at 500 nm and is proportional to the creatinine concentration in the sample.

Performance Data

Substantial equivalency was demonstrated by method comparison to the Roche Diagnostics Creatinine reagent.

Correlation

Correlation: Serum specimens (n = 30) were assayed by this method and by another commercial method.. Statistical analysis revealed a correlation coefficient (r) of 0.9991, with a regression equation of y = 1.4815x - 0.5831.

Correlation: Urine specimens (n = 37) were assayed by this method and by another commercial method.. Statistical analysis revealed a correlation coefficient (r) of 0.9854, with a regression equation of y = 1.0545x + 0.3607.

Precision:

Mean (mg/dL)	SD	CV%
In Series (Intra Assay)		
0.610	0.007	1.14
1.107	0.009	0.84
5.733	0.02	0.41

Day to Day (Inter Assay)		
0.629	0.008	1.98
1.134	0.011	0.98
5.814	0.022	0.38

Sensitivity: Based on an instrument resolution of A = 0.001, the method presented shows a sensitivity of 0.04 mg/dL.

Linearity: When performed as directed, it is linear to 200 mg/dL.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUN 3 0 2005

Mr. Kirk Johnson
QA/ Regulatory Affairs Manager
Stanbio Laboratory
1261 North Main St.
Boerne, TX 78006

Re: k050283
Trade/Device Name: Creatinine LiquiColor®
Regulation Number: 21 CFR 862.1225
Regulation Name: Creatinine test system
Regulatory Class: Class II
Product Code: JFY
Dated: May 2, 2005
Received: May 5, 2005

Dear Mr. Johnson:

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) 276-0484. 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Carol C. Benson

Carol C. Benson, M.A.
Acting 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): K050283

Device Name: Creatinine LiquiColor®

Indications For Use:

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Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

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