JUN 3 0 2005

510(k) SUMMARY
K050266

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

Phone: (830) 249-0772
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Prepared By: Kirk Johnson
May 2, 2005

Product Name
Trade Name: Direct Bilirubin LiquiColor®; Total Bilirubin LiquiColor®
Common Name: Direct Bilirubin Test; Total Bilirubin Test
Classification Name: Enzymatic Method, Bilirubin
Classification: II
Product Code: JFM

Substantial Equivalence of Device
This test is substantially equivalent to:
Product Name: Direct Bilirubin; Roche, 510(k) K910593
Total Bilirubin: Roche, 510(k) K910591

Description of Device
The Direct Bilirubin 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.

The Total Bilirubin 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 Direct Bilirubin LiquiColor® and Total Bilirubin LiquiColor® test systems are devices intended to measure the levels of bilirubin (direct and total) in serum and plasma. Measurements of the levels of bilirubin, an organic compound formed during the normal and abnormal destruction of red blood cells, is used in the diagnosis and treatment of liver, hemolytic, hematological, and

Comparison of Devices
Both methods employ absorbance change as a means for quantitative determination of direct and total bilirubin concentration in serum and plasma. The Stanbio method employs DCA (2,4-Dichloraniline), whereas, the Roche is a diazo-colorimetry method. The change in absorbance correlates with concentration of direct and total bilirubin.

Performance Data
Substantial equivalency was demonstrated by method comparison by performing correlation studies, linearity, precision studies (intra and inter), interference studies, and sensitivity.

Direct Bilirubin LiquiColor®

Precision: (performed according to NCCLS EP-5A)
Intra-assay Precision n = 20

Sample Number	Mean mg/dL	SD mg/dL	CV %
1	0.36	0.01	3.12
2	0.76	0.01	1.46
3	2.07	0.03	1.30

Inter-assay Precision n = 20

Sample Number	Mean mg/dL	SD mg/dL	CV %
1	0.35	0.01	3.34
2	0.75	0.01	1.00
3	2.13	0.02	0.71

Correlation: Determination of bilirubin by the procedure described (y) and by a another commercially available test (x) using 85 samples gave the following results: y = 0.9394x - 0.06 mg/dL; r = 0.995.

Sensitivity: The procedure showed a sensitivity of 0.1 mg/dL per 0.001 absorbance units.

Linearity: (Performed according to NCCLS EP6-P) Linear from 0.1 to 10 mg/dL.

Comparison of Plasma vs. Serum: Determination of Direct Bilirubin by the procedure described by y (serum) and by x (plasma) using 22 samples gave the following results: y = 1.0118x – 0.0078; r = 0.9999.

Total Bilirubin LiquiColor®

Precision: (performed according to NCCLS EP-5A)

Intra-assay Precision n = 20

Sample Number	Mean mg/dL	SD mg/dL	CV %
1	0.89	0.03	3.05
2	1.02	0.02	2.32
3	4.83	0.05	0.95

Inter-assay Precision n = 20

Sample Number	Mean mg/dL	SD mg/dL	CV %
1	0.87	0.02	2.74
2	1.15	0.04	3.49
3	4.65	0.13	2.86

Correlation: Determination of bilirubin by the procedure described (y) and by a another commercially available test (x) using 247 samples gave the following results: y = 1.0108x - 0.0145 mg/dL; r = 0.999.

Sensitivity: The procedure showed a sensitivity of 0.07 mg/dL per 0.001 absorbance units.

Linearity: (Performed according to NCCLS EP6-P) Linear from 0.07 to 30 mg/dL.

Comparison of Plasma vs. Serum: Determination of Direct Bilirubin by the procedure described by y (serum) and by x (plasma) using 19 samples gave the following results: y = 1.02x – 0.006; r = 0.9995.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

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

Re: k050266
Trade/Device Name: Direct Bilirubin LiquiColor® and Total Bilirubin LiquiColor
Regulation Number: 21 CFR 862.1110
Regulation Name: Bilirubin (total or direct) test system
Regulatory Class: Class II
Product Code: JFM
Dated: May 2, 2005
Received: May 4, 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): K050266

Device Name: Direct Bilirubin LiquiColor® and Total Bilirubin 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

510(k) K050266/S1