SEP 1 3 2002

510(k) Summary

Submitter's Name/Address
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Contact Person
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Date of Preparation of this Summary:	July 15, 2002
Device Trade or Proprietary Name:	Total Bilirubin
Device Common/Usual Name or Classification Name:	Total Bilirubin
Classification Number/Class:	CIG, Class II

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: k022339.

Test Description:

Total Bilirubin is an in vitro diagnostic assay for the quantitative determination of total bilirubin in human serum and plasma. Total (conjugated and unconjugated) bilirubin couples with the diazo reagent in the presence of a surfactant to form azobilirubin. The increase in absorbance at 548 nm due to azobilirubin formation is directly proportional to the total bilirubin concentration.

Substantial Equivalence:

The Total Bilirubin assay is substantially equivalent to the Roche Total Bilirubin assay (K910591) on the Hitachi® 717 Analyzer.

Both assays yield similar Performance Characteristics.

Similarities:

- Both assays are in vitro colorimetric assays.
- Both assays can be used for the quantitative determination of total bilirubin.
- Both assays yield similar clinical results.
- Both assays are based on a similar assay principle.
- Human serum and plasma are suitable specimens for both assays.
- Both assays have similar assay ranges.
- Both assays require a calibration with calibrators.

Differences:

- Suitable specimens for the Roche Total Bilirubin assay include neonatal specimens.

Intended Use:

The Total Bilirubin assay is used for the quantitation of total bilirubin in human serum and plasma.

Performance Characteristics:

Comparative performance studies were conducted using the AEROSET® System and ARCHITECT® c8000™ System. The Total Bilirubin assay method comparison yielded acceptable correlation with the Roche Total Bilirubin assay on the Hitachi 717 Analyzer. On the AEROSET System, the correlation coefficient = 0.999, slope = 0.93, and the Y-intercept = 0.16 mg/dL. On the ARCHITECT c8000 System, the correlation coefficient = 0.999, slope = 0.93, and the Y-intercept = 0.15 mg/dL. Precision studies were conducted using the Total Bilirubin assay. Within-run, between-run, and between-day studies were performed using four levels of control material. On the AEROSET System, the total %CV for Level 1 ranged from 2.5 to 4.6%, Level 2 ranged from 1.0 to 1.9%, Level 3 ranged from 0.9 to 1.3%, and Level 4 ranged from 0.9 to 1.2 %. On the ARCHITECT c8000 System, the total %CV for Level 1 ranged from 2.2 to 3.4%, Level 2 ranged from 1.1 to 1.2%, Level 3 ranged from 0.7 to 0.9%, and Level 4 ranged from 0.6 to 0.9%. The Total Bilirubin assay range is 0.1 to 35.7 mg/dL. The limit of quantitation (sensitivity) of the Total Bilirubin assay is 0.03 mg/dL on the AEROSET System and 0.08 mg/dL on the ARCHITECT c8000 System. These data demonstrate that the performance of the Total Bilirubin assay is substantially equivalent to the performance of the Roche Total Bilirubin assay on the Hitachi 717 Analyzer.

Conclusion:

The Total Bilirubin assay is substantially equivalent to the Roche Total Bilirubin assay on the Hitachi 717 Analyzer as demonstrated by results obtained in the studies.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

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SEP 13 2002

Re: k022339
Trade/Device Name: Total Bulirubin
Regulation Number: 21 CFR 862.1110
Regulation Name: Bilirubin test system
Regulatory Class: Class II
Product Code: CIG; JIT
Dated: July 15, 2002
Received: July 18, 2002

Dear Ms. Smith Waheed:

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 the Code of Federal Regulations, Title 21, Parts 800 to 898. 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 Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 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 advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained 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/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory-Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K022339

Device Name: Total Bilirubin

Indications For Use:

The Total Bilirubin assay is used for the quantitation of total bilirubin in human serum and plasma. Measurement of total 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 metabolic disorders, including hepatitis and gall bladder block.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use ____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Clinical Labora
510(k) Number K022339