MAY 2 8 1999

510(k) Summary

Submitter's Name/Address
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Contact Person
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Date of Preparation of this Summary: April 13, 1999

Device Trade or Proprietary Name: DBil

Device Common/Usual Name or Classification Name: Modification to Alcyon Direct Bilirubin

Classification Number/Class: 75CIG/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: K991175.

Test Description:

Direct Bilirubin is an *in vitro* diagnostic assay for the quantitative determination of direct bilirubin in human serum or plasma. The Direct Bilirubin assay is a clinical chemistry assay in which the conjugated bilirubin reacts with diazotised sulphanilic acid to produce an acid azobilirubin, the absorbance of which is proportional to the concentration of direct bilirubin in the sample and can be measured at 550 nm.

Substantial Equivalence:

The Direct Bilirubin assay is substantially equivalent to the Roche® Cobas Mira® Plus Automated Chemistry System Direct Bilirubin assay (K910593).

Both assays yield similar Performance Characteristics.

Similarities:

- Both assays are *in vitro* clinical chemistry methods.
- Both assays can be used for the quantitative determination of direct bilirubin.
- Both assays yield similar clinical results.

Differences:

- There is a minor difference between the assay range.

Intended Use:

The Direct Bilirubin assay is used for the quantitation of direct bilirubin in human serum or plasma.

Performance Characteristics:

Comparative performance studies were conducted using the ALCYON™ Analyzer. The Direct Bilirubin assay method comparison yielded acceptable correlation with the Roche Cobas Mira Plus Automated Chemistry System Direct Bilirubin assay, the correlation coefficient = 0.997, slope = 0.77, and Y-intercept = 0.08 mg/dL. The Direct Bilirubin assay method comparison yielded acceptable correlation with the Boehringer Mannheim Direct Bilirubin assay on the Hitachi 717 analyzer, the correlation coefficient = 0.996, slope = 1.08, and Y-intercept = -0.03 mg/dL. Precision studies were conducted using the Direct Bilirubin assay. Within-run, between-run, and between-day studies were performed using two levels of control material. The total %CV for Level 1/Panel 111 ranged from 5.9 to 10.4% and Level 2/Panel 112 ranged from 2.7 to 3.0%. The Direct Bilirubin assay is linear up to 10 mg/dL. The limit of quantitation (sensitivity) for the Direct Bilirubin assay is 0.1 mg/dL. These data demonstrate that the performance of the Direct Bilirubin assay is substantially equivalent to the performance of the Roche Cobas Mira Plus Automated Chemistry System Direct Bilirubin assay.

Conclusion:

The Direct Bilirubin assay is substantially equivalent to the Roche Cobas Mira Plus Automated Chemistry System Direct Bilirubin assay 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

MAY 28 1999

Mark Littlefield
Abbott Laboratories
ADD Regulatory Affairs
1920 Hurd Drive
Irving, TX 75038

Re: K991175
Trade Name: Abbott Alcyon Direct Bilirubin
Regulatory Class: II
Product Code: CIG
Dated: March 25, 1999
Received: March 29, 1999

Dear Mr. Littlefield:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

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"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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): K991175

Device Name: Modification to ALCYON Direct Bilirubin

Indications For Use:

The Direct Bilirubin assay is used for the quantitation of direct bilirubin in human serum or plasma. Measurements 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 metabolic disorders, including hepatitis and gall bladder block.

Jean Cooper

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K991175

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use \/ OR Over-The-Counter Use____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)