K983134

SEP 23 1998

510(k) Summary

Submitter's Name/Address
Abbott Laboratories
1920 Hurd Drive
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Contact Person
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Regulatory Affairs
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Date of Preparation of this Summary: September 4, 1998

Device Trade or Proprietary Name: NBil

Device Common/Usual Name or Classification Name: Neonatal Bilirubin

Classification Number/Class: Class I

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: K983134

Test Description:

Neonatal Bilirubin is an *in vitro* diagnostic assay for the quantitative determination of bilirubin in human neonate serum or plasma. The Neonatal Bilirubin assay is a clinical chemistry assay which uses a differential wavelength method. The absorbance of bilirubin, measured at 444 and 548 nm, is directly proportional to the bilirubin concentration in serum or plasma. Measurement at a secondary wavelength (548 nm) is used to correct for any hemoglobin present in the sample.

Substantial Equivalence:

The Neonatal Bilirubin assay is substantially equivalent to the A-GENT® Neonatal Bilirubin assay (K880743) on the ABBOTT SPECTRUM® Series II™ System.

These assays yield similar Performance Characteristics.

Similarities:

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

Differences:

- There is a minor difference in the assay range.

Intended Use:

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

Performance Characteristics:

Comparative performance studies were conducted using the AEROSET™ System. The Neonatal Bilirubin assay method comparison yielded acceptable correlation with the A-GENT Neonatal Bilirubin assay on the ABBOTT SPECTRUM Series II System. The correlation coefficient = 0.9995, slope = 0.941, and the Y-intercept = 0.275 mg/dL. Precision studies were conducted using the Neonatal 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 120 is 3.3% and Level 2/Panel 121 is 3.5%. The Neonatal Bilirubin assay is linear up to 51.11 mg/dL. The limit of quantitation (sensitivity) of the Neonatal Bilirubin assay is 0.04 mg/dL. These data demonstrate that the performance of the Neonatal Bilirubin assay is substantially equivalent to the performance of the A-GENT Neonatal Bilirubin assay on the ABBOTT SPECTRUM Series II System.

Conclusion:

The Neonatal Bilirubin assay is substantially equivalent to the A-GENT Neonatal Bilirubin assay on the ABBOTT SPECTRUM Series II System 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

SEP 23 1998

Linda Morris
Senior Regulatory Specialist
Abbott Laboratories
1920 Hurd Drive
Irving, Texas 75038

Re: K983134
Neonatal Bilirubin
Regulatory Class: I
Product Code: MQM
Dated: September 4, 1998
Received: September 8, 1998

Dear Ms. Morris:

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 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/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): K983134

Device Name: Neonatal Bilirubin

Indications For Use:

The Neonatal Bilirubin assay is used for the quantitation of bilirubin in human neonate serum or plasma. Measurements of bilirubin (total and unbound) in newborn infants are used to aid in indicating the risk of bilirubin encephalopathy (kernicterus).

K983134

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K983134

(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)