

JAN 26 1999

510(k) Summary

Submitter's Name/Address

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1920 Hurd Drive
Irving, Texas 75038

Contact Person

Linda Morris
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Regulatory Affairs
(972) 518-6711
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Date of Preparation of this Summary: September 17, 1998

Device Trade or Proprietary Name: ApoB

Device Common/Usual Name or Classification Name: Apolipoprotein B

Classification Number/Class: 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: K 983281.

Test Description:

Apolipoprotein B is an *in vitro* diagnostic assay for the quantitative determination of apolipoprotein B in human serum or plasma. Antibodies to apolipoprotein B combine with apolipoprotein B in the sample to form insoluble immune complexes. The immune complexes cause an increase in light scattering (turbidity). The resulting increase in sample turbidity, measured at 604 nm, is directly proportional to the concentration of apolipoprotein B in the sample.

Substantial Equivalence:

The Apolipoprotein B assay is substantially equivalent to the K-ASSAY® Apo B (K964296/S022) on the Hitachi® 717 Analyzer.

Both assays yield similar Performance Characteristics.

Similarities:

- Both assays are *in vitro* immunoassay methods.
- Both assays can be used for the quantitative determination of apolipoprotein B.
- Both assays yield similar clinical results.
- Both assays are based on the formation of immune complexes.

Differences:

- There is a difference between the assay range.

Intended Use:

The Apolipoprotein B assay is used for the quantitation of apolipoprotein B in human serum or plasma.

Performance Characteristics:

Comparative performance studies were conducted using the AEROSET™ System. The Apolipoprotein B assay method comparison yielded acceptable correlation with the K-ASSAY Apo B on the Hitachi 717 Analyzer. The correlation coefficient = 0.9793, slope = 1.064, and Y-intercept = -2.920 mg/dL. Precision studies were conducted using the Apolipoprotein B assay. Within-run, between-run, and between-day studies were performed using two levels of control material. The total %CV for Level 1/Panel 401 is 2.5% and Level 2/Panel 402 is 1.8%. The Apolipoprotein B assay range is 1.55 to 285.31 mg/dL. The limit of quantitation (sensitivity) for the Apolipoprotein B assay is 1.55 mg/dL. These data demonstrate that the performance of the Apolipoprotein B assay is substantially equivalent to the performance of the K-ASSAY Apo B on the Hitachi 717 Analyzer.

Conclusion:

The Apolipoprotein B assay is substantially equivalent to the K-ASSAY Apo B on the Hitachi 717 Analyzer as demonstrated by results obtained in the studies.



JAN 26 1999

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

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

Re: K983281
Trade Name: Apolipoprotein B
Regulatory Class: II
Product Code: DFC
Dated: December 3, 1998
Received: December 4, 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 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.

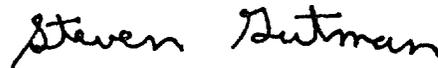
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Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

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,

A handwritten signature in black ink that reads "Steven Gutman". The signature is written in a cursive style with a large initial 'S' and 'G'.

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): K983281

Device Name: Apolipoprotein B

Indications For Use:

The Apolipoprotein B assay is used for the quantitation of apolipoprotein B in human serum or plasma. Apolipoprotein B measurements are useful in the diagnosis of premature coronary artery disease, hyper-b-lipoproteinemia, and hypo-b-lipoproteinemia.

(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)



(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K983281