JUN 1 1 1998

K981580

510(k) Summary

Submitter's Name/Address
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Contact Person
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Date of Preparation of this Summary: May 1, 1998

Device Trade or Proprietary Name: HDL

Device Common/Usual Name or Classification Name: Direct HDL

Classification Number/Class: 75LBS /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: _____.

Test Description:

Direct HDL is an *in vitro* diagnostic assay for the quantitative determination of high-density lipoprotein cholesterol in serum or plasma. The Direct HDL assay is a two reagent format and depends on the properties of a unique detergent. This detergent solubilizes only the HDL lipoprotein particles, thus releasing the HDL cholesterol to react with cholesterol esterase and cholesterol oxidase, in the presence of chromogens to produce color. In addition to selectively disrupting the HDL lipoprotein particles, this unique detergent also inhibits the reaction of the cholesterol enzymes with LDL, VLDL, and chylomicron lipoproteins by adsorbing to their surfaces. A polyanion is contained in the first reagent to assist with complexing LDL, VLDL, and chylomicron lipoproteins, further enhancing the selectivity of the detergent and enzymes for HDL cholesterol.

Substantial Equivalence:

The Direct HDL assay is substantially equivalent to the Boehringer Mannheim® Direct HDL-Cholesterol assay (K963213) on the Hitachi® 717 Analyzer. 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 Direct HDL.
- Both assays yield similar clinical results.

Differences:

- There is a difference between the assay range.

Intended Use:

The Direct HDL assay is used for the quantitation of high-density lipoprotein cholesterol in serum or plasma.

Performance Characteristics:

Comparative performance studies were conducted using the AEROSET™ System. The Direct HDL assay method comparison yielded acceptable correlation with the Boehringer Mannheim Direct HDL-Cholesterol assay on the Hitachi 717 Analyzer. The correlation coefficient = 0.9883, slope =1.041, and Y-intercept =0.118 mg/dL. Precision studies were conducted using the Direct HDL assay. Within-run, between-run, and between-day studies were performed using two levels of control material. The total %CV for Level 1/Panel 109 is 5.3% and Level 2/Panel 110 is 3.3%. The Direct HDL assay is linear up to 309.6 mg/dL. The limit of quantititation (sensitivity) of the Direct HDL assay is 1.2 mg/dL. These data demonstrate that the performance of the Direct HDL assay is substantially equivalent to the performance of the Boehringer Mannheim Direct HDL-Cholesterol assay on the Hitachi 717 Analyzer.

Conclusion:

The Direct HDL assay is substantially equivalent to the Boehringer Mannheim Direct HDL-Cholesterol 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

JUN 11 1998

Mark Littlefield
Section Manager, Regulatory Affairs
Abbott Laboratories
1920 Hurd Drive
Irving, Texas 75038

Re: K981580
Direct HDL
Regulatory Class: I
Product Code: LBS
Dated: May 1, 1998
Received: May 4, 1998

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 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): _____

Device Name: Direct HDL

Indications For Use:

The Direct HDL assay is used for the quantitation of high-density lipoprotein cholesterol levels in human serum or plasma. Low Direct HDL measurements are used in the diagnosis and treatment of coronary artery disease.

(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
510(k) Number k984580