

AUG 3 1998

K981303

510(k) Summary

Submitter's Name/Address

Abbott Laboratories
1920 Hurd Drive
Irving, Texas 75038

Contact Person

Mark Littlefield
Section Manager MS 1-8
ADD Regulatory Affairs
(972) 518-7861
Fax (972) 753-3367

Date of Preparation of this Summary:

April 9, 1998

Device Trade or Proprietary Name:

Direct LDL

Device Common/Usual Name or Classification Name: LDL

Classification Number/Class:

75JGJ/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:

K981303

Test Description:

LDL is an *in vitro* diagnostic assay for the quantitative determination of low-density lipoprotein cholesterol (LDL) in human serum or plasma. The detergent solubilizes only the non-LDL lipoprotein particles. The cholesterol released is consumed by cholesterol esterase and cholesterol oxidase in a non-color forming reaction. Another detergent solubilizes the remaining LDL particles and a chromogenic coupler allows for color formation. The enzyme reaction with LDL cholesterol in the presence of the coupler produces color which is proportional to the amount of LDL cholesterol present in the sample.

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Substantial Equivalence:

The LDL assay is substantially equivalent to the Roche Cobas Mira Automated Chemistry assay.

Similarities:

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

Differences:

- There is a difference between the assay range.
- There is a difference between the assay principles.
- There is a difference between reagent handling in that LDL is a two-reagent kit and the Roche® Cobas Mira® Plus Automated Chemistry System LDL Cholesterol (Direct) assay is single-reagent kit.

Intended Use:

The LDL assay is used in the quantitation of low-density lipoprotein cholesterol levels in serum or plasma.

Performance Characteristics:

Comparative performance studies were conducted using the ALCYON™ Analyzer. The LDL assay method comparison yielded acceptable correlation with the Roche Cobas Mira Plus Automated Chemistry System LDL assay for serum. The correlation coefficient = 0.9546, slope = 0.984, and Y-intercept = 7.466 mg/dL. Precision studies were conducted using the LDL assay. Within-run, between-run, and between-day studies were performed using two levels of control material. The total %CV for Level 1/Panel 141 control is 3.3% and Level 2/Panel 142 is 4.0%. The LDL assay is linear up to 600 mg/dL. The limit of quantitation (sensitivity) of the LDL assay is 1 mg/dL. These data demonstrate that the performance of the LDL assay is

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substantially equivalent to the performance of the Roche Cobas Mira Plus Automated Chemistry System LDL assay for serum.

Conclusion:

The LDL assay is substantially equivalent to the Roche Cobas Mira Plus Automated Chemistry System LDL assay as demonstrated by results obtained in the studies.



Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

AUG 3 1998

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

Re: K981303
LDL
Regulatory Class: I
Product Code: MRR
Dated: July 2, 1998
Received: July 6, 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 (Pre-market 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 pre-market 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.

Page 2

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): K981303

Device Name: LDL

Indications For Use:

The LDL assay is used for the quantitation of low-density lipoprotein cholesterol levels in human serum or plasma. LDL measurements are used in the diagnosis and treatment of the pathogenesis of arteriosclerosis and coronary artery disease.

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

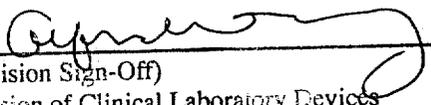
_____ Concurrency of CDRH, Office of Device Evaluation (ODE) _____

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)



Division Sign-Off
Division of Clinical Laboratory Devices
510(k) Number K981303