

JUN 25 1998

K98 1476

Section II
510(k) Summary

510(k) Summary

Submitter's Name/Address

Abbott Laboratories
1920 Hurd Drive
Irving, Texas 75038

Contact Person

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

Date of Preparation of this Summary:

April 23, 1998

Device Trade or Proprietary Name:

Chol

Device Common/Usual Name or Classification Name:

Cholesterol

Classification Number/Class:

75CHH/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:

Cholesterol is an *in vitro* diagnostic assay for the quantitative determination of cholesterol in human serum or plasma. The Cholesterol assay is a clinical chemistry assay in which cholesterol esters are enzymatically hydrolysed by cholesterol esterase to cholesterol and free fatty acids. Free cholesterol, including that originally present, is then oxidized by cholesterol oxidase to cholest-4-en-3-one and hydrogen peroxide. The hydrogen peroxide combines with Hydroxybenzoic Acid and 4-aminoantipyrine to form a chromophore (quinoneimine dye) which can be measured.

Substantial Equivalence:

The Cholesterol assay is substantially equivalent to the following device:

- Roche® Cobas Mira® Plus Automated Chemistry System Cholesterol assay (K896239)

These assays yield similar Performance Characteristics.

Similarities to Roche:

- Both assays are *in vitro* clinical chemistry methods.
- Both assays can be used for the quantitative determination of cholesterol.
- Both assays yield similar clinical results.
- Both assays have the same assay range.

Differences to Roche:

- There is a minor difference in the analysis medium.

Intended Use:

The Cholesterol assay is used for the quantitation of cholesterol in human serum or plasma.

Performance Characteristics:

Comparative performance studies were conducted using the ALCYON™ Analyzer. The Cholesterol assay method comparison yielded acceptable correlation with the Roche Cobas Mira Plus Automated Chemistry System Cholesterol assay. The correlation coefficient = 0.9887, slope = 0.916, and Y-intercept = 0.206 mg/dL. The ALCYON Cholesterol reagent was validated against the Abell-Kendall reference method in a CDC-Certified Cholesterol Reference Method Network Laboratory (CRMLN). A copy of the CRMLN Certificate of Traceability is included in Section III.F. Precision studies were conducted using the Cholesterol 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 control is 2.2% and Level 2/Panel 112 is 2.7%. The Cholesterol assay is linear up to 530 mg/dL.

The limit of quantitation (sensitivity) of the Cholesterol assay is 0.970 mg/dL. These data demonstrate that the performance of the Cholesterol assay is substantially equivalent to the performance of the Roche Cobas Mira Plus Automated Chemistry System Cholesterol assay.

Conclusion:

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



Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUN 25 1998

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

Re: K981476
Cholesterol
Regulatory Class: I
Product Code: CHH
Dated: April 23, 1998
Received: April 24, 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.

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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/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: Cholesterol

Indications For Use:

Cholesterol

The Cholesterol assay is used for the quantitation of cholesterol in human serum or plasma. Cholesterol measurements are used in the diagnosis and treatment of disorders involving excess cholesterol in the blood and lipid and lipoprotein metabolism disorders.

Carol C. Benson for Alfred Montgomery
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K981476

(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)

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