AUG 25 2005

510(k) Summary

Submitter's Name/Address
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Contact Person
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Date of Preparation of this Summary:	July 12, 2005
Device Trade or Proprietary Name:	Ultra HDL
Device Common/Usual Name or Classification Name:	Ultra HDL
Classification Number/Class:	LBS/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: K051962

Test Description:

The Ultra HDL assay is a homogeneous method for directly measuring HDL cholesterol concentrations in serum or plasma without the need for any off-line pretreatment or centrifugation steps.

The method uses a two-reagent format and depends on the properties of a unique detergent. This method is based on accelerating the reaction of cholesterol oxidase (CO) with non-HDL unesterified cholesterol and dissolving HDL cholesterol selectively using a specific detergent. In the first reagent, non-HDL unesterified cholesterol is subject to an enzyme reaction and the peroxide generated is consumed by a peroxidase reaction with DSBmT yielding a colorless product. The second reagent consists of a detergent (capable of solubilizing HDL cholesterol), cholesterol esterase (CE), and chromagenic coupler to develop color for the quantitative determination of HDL cholesterol.

Substantial Equivalence:

The Ultra HDL assay is substantially equivalent to the Genzyme N-geneous Ultra HDL Cholesterol assay (K021316) on the Hitachi® 717 Analyzer. These assays yield similar Performance Characteristics.

Similarities:

- Both assays use the same in vitro clinical chemistry methodology.
- Both assays can be used for the quantitative determination of HDL.
- Both assays yield similar clinical results.

Differences:

None

Intended Use:

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

Performance Characteristics:

Comparative performance studies were conducted using the AEROSET® System and ARCHITECT® c8000® System. The Ultra HDL assay method comparison yielded acceptable correlation with the Genzyme N-geneous Ultra HDL Cholesterol assay on the Hitachi 717 Analyzer. The AEROSET System showed a correlation coefficient of 0.999, slope of 0.97, and Y-intercept of 0.46 mg/dL when compared to the Hitachi 717 Analyzer. The ARCHITECT c8000 System showed a correlation coefficient of 0.999, slope of 0.97, and Y-intercept of 0.91 mg/dL when compared to the Hitachi 717 Analyzer. The Ultra HDL assay method comparison yielded acceptable correlation between the AEROSET System and ARCHITECT c8000 System. The ARCHITECT c8000 System showed a correlation coefficient of 0.999, slope of 1.00, and Y-intercept of 0.61 mg/dL when compared to the AEROSET System. Precision studies were

conducted using the Ultra HDL assay. On the AEROSET System, the total %CV for Level 1 is 5.5%, and Level 2 is 1.4%. On the ARCHITECT c8000 System, the total %CV for Level 1 is 3.3%, and Level 2 is 1.4%. The Ultra HDL assay is linear from 5 to 180 mg/dL. The limit of quantitation (sensitivity) of the Ultra HDL assay is 5 mg/dL. These data demonstrate that the performance of the Ultra HDL assay is substantially equivalent to the performance of the Genzyme N-geneous Ultra HDL Cholesterol assay on the Hitachi 717 Analyzer.

Conclusion:

The Ultra HDL assay is substantially equivalent to Genzyme N-geneous Ultra HDL Cholesterol assay on the Hitachi 717 Analyzer as demonstrated by results obtained in the studies.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

AUG 25 2005

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

Re: k051962
Trade/Device Name: Ultra HDL
Regulation Number: 21 CFR § 862.1475
Regulation Name: Lipoprotein test system
Regulatory Class: I
Product Code: LBS
Dated: July 12, 2005
Received: July 19, 2005

Dear Ms. Morris:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 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 information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Carol C. Benson

Carol C. Benson, M.A.
Acting Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K051962

Device Name: Ultra HDL

Indications For Use:

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

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k)

Prescription Use X AND/OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostics Devices (OIVD)