K033610

DEC - 5 2003

510(k) Summary - HDL-Cholesterol plus 2nd generation

Introduction	According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence
Submitter name, address, contact	Roche Diagnostics Corporation 9115 Hague Rd Indianapolis IN 46250 (317) 521-3831 Contact person: Sherri L. Coenen Date prepared: November 12, 2003
Device Name	Proprietary name: HDL-Cholesterol plus 2nd generation Common name: HDL-Cholesterol Assay Classification name: LDL and VLDL Precipitation, Cholesterol via Esterase-Oxidase, HDL
Device description	The HDL-Cholesterol plus 2nd Generation test principle uses magnesium sulfate and dextran sulfate to form water-soluble complexes with LDL, VLDL, and chylomicrons which are resistant to PEG-modified enzymes. The cholesterol concentration of HDL-cholesterol is determined enzymatically by cholesterol esterase and cholesterol oxidase coupled with PEG. The color intensity of the blue quinoneimine dye formed is directly proportional to the HDL-cholesterol concentration and is measured photometrically.
Intended use	HDL-C plus 2nd generation is an enzymatic in-vitro assay for the direct quantitative determination of high-density lipoprotein cholesterol (HDL-C) in human serum and plasma on automated clinical chemistry analyzers.
Predicate Device	We claim substantial equivalence to the currently marketed HDL Cholesterol plus Assay. (K000568).

510(k) Summary - HDL-Cholesterol plus 2nd generation,
continued

Reagent Summary

The following table describes the similarities and differences between the HDL-Cholesterol plus 2nd generation and the predicate device.

Topic	HDL-C plus (K000568)	HDL-Cholesterol plus 2nd generation (Modified Device)
Intended Use	For the direct quantitative determination of high-density lipoprotein cholesterol (HDL-cholesterol) in serum and plasma.	HDL-C plus 2nd generation is an enzymatic in-vitro assay for the direct quantitative determination of high-density lipoprotein cholesterol (HDL-C) in human serum and plasma on automated clinical chemistry analyzers.
Method	Homogeneous enzymatic colorimetric	Same
Sample type	Serum Li-, Na-Heparin plasma EDTA plasma	Serum Li-, Na-, NH_4- Heparin plasma EDTA plasma
Measuring range	3 – 120 mg/dl	Same
Expected values	National Cholesterol Education Program (NCEP) guidelines: < 35 mg/dL : low HDL Cholesterol (major risk factor for CHD) > 60 mg/dL High HDL Cholesterol (negative risk factor for CHD)	National Cholesterol Education Program (NCEP) guidelines: < 40 mg/dL : low HDL Cholesterol (major risk factor for CHD) ≥ 60 mg/dL High HDL Cholesterol (negative risk factor for CHD)
Formulation R1	Sulfated alpha-cyclodextrin, dextran sulfate, magnesium chloride, HSDA, ascorbate oxidase (Acremonium), peroxidase (horseradish), MOPS buffer, preservative	Dextran sulfate, magnesium sulfate heptahydrate, HSDA, ascorbate oxidase (Eupenicillium sp., recombinant), peroxidase (horseradish), MOPS buffer, preservative
Formulation R2	PEG cholesterol esterase (Pseudomonas), PEG cholesterol oxidase (Pseudomonas), peroxidase (horseradish), 4-aminophenazone, PIPES buffer, preservative	PEG cholesterol esterase (Pseudomonas), PEG cholesterol oxidase (Streptomyces sp., recombinant) peroxidase (horseradish), 4-amino-antipyrine, PIPES buffer, preservative

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC - 5 2003

Ms. Sherri L. Coenen
Regulatory Affairs Consultant
Roche Diagnostics Corporation
9115 Hague Road
P.O. Box 50457
Indianapolis, IN 46250-0457

Re: k033610
Trade/Device Name: HDL-Cholesterol plus 2nd generation
Regulation Number: 21 CFR 862.1475
Regulation Name: Lipoprotein test system
Regulatory Class: Class I
Product Code: LBS
Dated: November 12, 2003
Received: November 17, 2003

Dear Ms. Coenen:

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 (301) 594-3084. 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/dsma/dsmamain.html.

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): ~~N/A~~ K033610

Device Name: HDL-Cholesterol plus 2nd generation

Indications For Use:

HDL-C plus 2nd generation is an enzymatic in-vitro assay for the direct quantitative determination of high-density lipoprotein cholesterol (HDL-C) in human serum and plasma on automated clinical chemistry analyzers.

Lipoprotein measurements are used in the diagnosis and treatment of lipid disorders (such as diabetes mellitus), atherosclerosis, and various liver and renal diseases.

Carol C Benson/s/ Jean Cooper, DVM

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K033610

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X (Per 21 CFR 801.109) OR Over-The-Counter Use _____

(Optional Format 1-2-96)