AUG - 8 2001

510(k) Summary K012286

Introduction

According to the requirements established in the Food and Drug Administration's guidance document entitled "The New 510(k) Paradigm: Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications", 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 Road
Indianapolis, IN 46250
(317) 521 - 3831

Contact Person: Sherri L. Coenen

Date Prepared: July 17, 2001

Device Name

Proprietary name: HDL-Cholesterol plus 2nd Generation

Common name: HDL-Cholesterol

Classification name: Lipoprotein test system

Predicate Device

We claim substantial equivalence to the currently marketed Roche/Hitachi HDL-Cholesterol plus 2nd generation assay (K963213).

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. It is determined by measuring the increase in absorbance at 583 nm.

510(k) Summary, Continued

Intended use	The cassette COBAS Integra HDL-Cholesterol plus 2nd Generation contains an in vitro diagnostic reagent system intended for use on COBAS Integra systems for the quantitative determination of HDL-cholesterol concentration in serum and plasma.
Indications for Use	A lipoprotein test system is a device intended to measure lipoprotein in serum and plasma. Lipoprotein measurements are used in the diagnosis and treatment of lipid disorders (such as diabetes mellitus), atherosclerosis, and various liver and renal diseases.
Substantial Equivalence	The proposed device is the HDL-Cholesterol plus 2nd generation reagent packaged for and applied to the COBAS Integra family of analyzers. The COBAS Integra family application described in this submission is, in our opinion, substantially equivalent to the predicate device.
Comparison to predicate device	The COBAS Integra application of the HDL-cholesterol plus 2nd generation assays has the same intended use and indication for use, the same scientific principle, the same formulation and similar application parameters as the predicate device, the HDL-Cholesterol plus 2nd generation assay as applied to the Roche/Hitachi family of analyzers.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

AUG - 8 2001

Ms. Sherri L. Coenen
Regulatory Submissions, Centralized Diagnostics
Roche Diagnostics Corporation
9115 Hague Road
PO Box 50457
Indianapolis, IN 46250-0457

Re: 510(k) Number: K012286
Trade/Device Name: HDL-Cholesterol plus 2nd Generation
Regulation Number: 862.1475
Regulatory Class: I, reserved
Product Code: LBS
Dated: July 17, 2001
Received: July 20, 2001

Dear Ms. Coenen:

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 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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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.

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" (21CFR 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/dsma/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

Indications for Use Statement

510(k) Number (if known): N/A K012286

Device Name: HDL-Cholesterol plus 2nd Generation

Indications For Use:

The cassette COBAS Integra HDL-Cholesterol plus 2nd Generation (HDL-C) contains an in vitro diagnostic reagent system intended for use on COBAS Integra systems for the quantitative determination of HDL-cholesterol concentration in serum and plasma.

A lipoprotein test system is a device intended to measure lipoprotein in serum and plasma. Lipoprotein measurements are used in the diagnosis and treatment of lipid disorders (such as diabetes mellitus), atherosclerosis, and various liver and renal diseases.

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

(Optional Format 1-2-96)

Kesia Alexander for Jean Cooper
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K012286