



K973369

510(k) Summary

ROCHE UNIMATE HDL DIRECT REAGENT

In accordance with the Safe Medical Devices Act of 1990, a 510(k) summary is provided as outlined in 21 CFR 807.92.

I. Identification of 510(k) Sponsor:

Roche Diagnostic Systems, Inc.
 a subsidiary of Hoffmann-La Roche, Inc.
 Branchburg Township
 1080 U.S. Highway 202
 Somerville, New Jersey 08876-3771

510(k) Submission dated September 5, 1997

Contact: James W. Haynes
 Regulatory Affairs Associate
 Phone: (908) 253-7569
 Fax: (908) 253-7547

II. Device Name:

The device name, including both the trade/proprietary name and the classification name are provided in the table below.

Table 1

Proprietary Name	Classification Name	Product Code	Regulation Number
Roche UNIMATE HDL Direct reagent (with POL claim)	Cholesterol test system	CHH	862.1175

III. Identification of the legally marketed device to which the 510(k) sponsor claims equivalence:

The following table identifies the legally marketed device to which Roche Diagnostic Systems, Inc. claims equivalence.

Table 2

Proprietary Name	Predicate Product Name	K number	Date of substantial equivalence
Roche UNIMATE HDL Direct reagent (with POL claim)	Roche UNIMATE HDL Direct reagent	K971902	6/16/97

IV. Description of the Device/Statement of Intended Use:

The Roche UNIMATE HDL Direct reagent is an *in vitro* diagnostic test for the quantitative determination of High Density Lipoprotein Cholesterol (HDL CHOL) in serum. UNIMATE HDL Direct is intended for use in clinical and physician's office laboratories (POL) on COBAS MIRA systems. Determination of HDL cholesterol is useful for early detection of an increased risk of atherosclerosis.

Low HDL levels are recognized as a strong and common risk factor for atherosclerotic Coronary Artery Disease (CAD). Therefore, determination of HDL cholesterol is routinely offered as part of a lipid profile. Usually VLDL and LDL are selectively precipitated from serum or plasma samples followed by determination of cholesterol in the HDL - containing supernatant. These techniques require a centrifugation step to remove the precipitated lipoproteins and thus cannot be fully automated. UNIMATE HDL Direct, however, allows for the direct specific determination of HDL cholesterol in the presence of LDL, VLDL and chylomicrons without any sample pretreatment, therefore, lending itself to automated routine analysis.

The principle of the Roche UNIMATE HDL Direct reagent is based on the absorbance of synthetic polymers and polyanions to the surface of lipoproteins. LDL, VLDL, and chylomicrons are transformed into a detergent-resistant form, whereas HDL is not. Combined actions of polymers, polyanions and detergent solubilizes cholesterol from HDL, but not from LDL, VLDL, and chylomicrons. Solubilized cholesterol is oxidized by the sequential enzymatic action of cholesterol esterase and cholesterol oxidase. The H₂O₂ produced in this reaction is reacted with chromogens to form a colored dye. The increase in absorbance at 550 nm is directly proportional to the HDL cholesterol concentration of the sample.

V. Summary of the technological characteristics of the new device in comparison to those of the predicate.

The Roche UNIMATE HDL reagent was previously cleared on June 16, 1997 (K971902) for use in clinical laboratories. The proposed labeling for the Roche UNIMATE HDL reagent has been modified to include the use of this product in physician office laboratories.

In addition, Roche has documented traceability to the National Reference System for Cholesterol by performing a direct comparison with the cholesterol reference method using fresh human specimens that cover the National Cholesterol Education Program (NCEP) medical decision points.

VI. Brief discussion of the clinical and nonclinical tests relied on for a determination of substantial equivalence:

Comparative performance studies were performed at three different physician office laboratories (POLs) on a minimum of 50 split samples provided by each laboratory. Aliquots of each sample were also tested in-house at Roche Diagnostics Systems' (RDS) laboratory to establish a reference site for comparative purposes. The study utilized COBAS MIRA Systems in use at each of the POLs. The results obtained for each sample at each POL site were compared to results using the POL's usual method and to Roche UNIMATE HDL Direct reagent's results.

The sample results obtained at the POL user sites for the UNIMATE HDL Direct studies were compared to the RDS reference laboratory UNIMATE HDL Direct sample results and gave the following results:

Table 3

Parameter	Site #1	Site #2	Site #3
n =	50	59	65
Correlation	r = 0.990	r = 0.994	r = 0.991
Linear Regression	$y = 1.03x - 0.03$ mmol/L (-1.0 mg/dL)	$y = 1.06x - 0.07$ mmol/L (-2.5 mg/dL)	$y = 0.97X - 0.03$ mmol/L (-1.2 mg/dL)

The sample results obtained at the POL user sites for their usual methodologies were compared to the POL user sites UNIMATE HDL Direct sample results and gave the following correlations for each independent study:

Table 4

Parameter	Site #1	Site #2	Site #3
n =	50	59	65
Correlation	r = 0.965	r = 0.986	r = 0.944
Linear Regression	$y = 0.86x + 0.12$ mmol/L (4.7 mg/dL)	$y = 0.99x + 0.0$ mmol/L (0.0 mg/dL)	$y = 1.07x - 0.16$ mmol/L (-6.1 mg/dL)

Within-run testing of 20 replicates was performed on three serum pools and, on Roche N and Roche P controls. Total precision was determined by performing duplicate determinations twice a day over five days for a total of 20 determinations at each POL site. Each POL site achieved the NCEP goals of CVs $\leq 6\%$ at ≥ 42 mg/dL, and SDs of ≤ 2.50 mg/dL at < 42 mg/dL when using the UNIMATE HDL Direct reagent.



Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

NOV 21 1997

James W. Haynes
Regulatory Affairs Associate
Roche Diagnostics Systems
1080 U.S. Highway 202
Somerville, New Jersey 08876-3771

Re: K973369
Roche UNIMATE HDL Direct Reagent
Regulatory Class: II
Product Code: LBR, JIS
Dated: September 5, 1997
Received: September 8, 1997

Dear Mr. Haynes:

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.

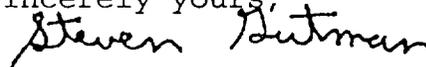
Page 2

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 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) _____

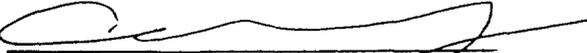
Device Name: Roche UNIMATE HDL Direct reagent

Indications for Use:

The Roche UNIMATE HDL Direct reagent is an *in vitro* diagnostic device intended for use in clinical and physician's office laboratories (POL) on COBAS MIRA systems for the quantitative determination of High Density Lipoprotein Cholesterol (HDL CHOL) in serum.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Clinical Laboratory Services

510(k) Number 2973369

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use
(Optional Format 1-2-96)