ATTACHMENT 1

510(k) Summary Of Safety and Effectiveness Information Upon Which An Equivalence Determination Could be Made

Trade or Proprietary Name:	Genzyme Liquid N-geneous™ HDL Cholesterol Kit
Common or Usual Name:	Homogeneous assay for high density lipoprotein cholesterol
Classification Name:	High density lipoprotein cholesterol test
Manufacturer:	Genzyme Diagnostics One Kendall Square Cambridge, MA 02139-1562

Contact Person: Nancy E. Isaac, Associate Director, Regulatory Affairs (617) 374-7431 or Beth A. Crowley, Regulatory Associate (617) 252-7669.

The use of the Liquid Genzyme N-geneous™ HDL Cholesterol Kit in clinical and physician's office laboratory settings is substantially equivalent to the Sodium Phosphotungstate $MgCl_2$ (PTA) method.

The Genzyme Liquid N-geneous™ HDL Cholesterol Kit is a two-reagent homogeneous method for the direct quantitative determination of high density lipoprotein cholesterol (HDL-C) in human serum and plasma.

In both user settings, the principle of the test is based upon a unique detergent which selectively solubilizes only the HDL. This unique detergent also strongly inhibits the reaction of the enzymes with cholesterol contained in the low density lipoprotein (LDL), very low density lipoprotein (VLDL) and chylomicron particles. Consequently, only the cholesterol in the resultant micell complexes of the detergent and lipids is subject to the enzyme reactions, leading to the selective determination of HDL cholesterol.

Comparative performance studies were conducted using the Liquid N-geneous™ HDL Cholesterol Kit and two reference methods: Sodium Phosphotungstate $MgCl_2$ and the Center for Disease Control (CDC) designated comparison method (DCM). When samples contained triglyceride levels >200 mg/dL, the HDL reference method (ultracentrifugation, chemical precipitation and Abell-Kendall) was performed. Based on the Lipid Research Clinics (LRC) population studies, patient serum samples with HDL values between 27-91 mg/dL (5th and 95th percentile, respectively) were used for these comparative studies.

Ninety two serum samples, with HDL values between 25 and 91 mg/dL, were tested at Genzyme Corporation using the Liquid N-geneous™ HDL and the PTA precipitation methods. Of these 92 samples, 54 were tested with the CDC Designated Comparison Method for samples with triglyceride levels <200 mg/dL and the HDL reference method (ultracentrifugation, precipitation and Abell-Kendall) for samples with triglyceride levels >200 mg/dL.

Liquid N-geneous™ HDL	vs. Phosphotungstate (n = 92)	vs. CDC Method (n = 54)
Slope	0.960	1.056
Intercept (mg/dL)	3.97	-0.736
Correlation Coefficient (r)	0.991	0.992
Mean (mg/dL)	Ng: 51.3 PTA: 49.3	Ng: 54.3 CDC: 52.0
Standard Deviation (mg/dL)	Ng: 13.7 PTA: 14.1	Ng: 12.2 CDC: 11.5
Mean Difference (mg/dL)	2.0	2.2
Mean Percent Difference	4.7%	4.1%

Precision studies were conducted using the Liquid N-geneous™ HDL Cholesterol Test Kit. Both within-run and between-run studies were performed using frozen serum pools at three target levels of HDL cholesterol as determined by the National Cholesterol Education Program (NCEP): <35 mg/dL (low); 35-60 mg/dL (mid); and >60 mg/dL (high).

Within-Run	Low (<35 mg/dL)	Mid (35-60 mg/dL)	High (>60 mg/dL)
n	20	20	20
Sample Range (mg/dL)	22.6 - 23.5	55.1 - 56.7	84.3 - 85.0
Mean (mg/dL)	22.9	55.8	84.7
SD (mg/dL)	0.23	0.44	0.24
%CV	0.99	0.79	0.28

Between-Run	Low (<35 mg/dL)	Mid (35-60 mg/dL)	High (>60 mg/dL)
n	40	40	40
Sample Range (mg/dL)	22.6 - 24.1	54.5 - 57.1	83.7 - 87.8
Mean (mg/dL)	23.4	55.7	85.6
SD (mg/dL)	0.35	0.73	1.00
%CV	1.49	1.31	1.17

In separate comparative performance studies, three physician office laboratories (POL) analyzed separate sets of 40 serum samples using the lyophilized format of Genzyme's N-geneous™ HDL Cholesterol Reagent Kit. Split samples from the same 40 specimens were also analyzed at

K971162

Genzyme, which acted as the reference laboratory. The correlation coefficient between the reference testing site and the POL testing sites for this study were:

Parameter	Site #1	Site #2	Site #3
Slope	1.11	1.12	0.93
Intercept (mg/dL)	-1.44	-5.90	1.25
Correlation Coefficient (r)	0.97	0.99	0.99

In the same study, the three POL sites compared their Genzyme N-geneous™ HDL Cholesterol Reagent Kit results to their respective current HDL methods for each of these 40 patient samples. The correlation coefficient for these comparisons were:

Parameter	Site #1	Site #2	Site #3
Slope	0.88	1.05	0.77
Intercept (mg/dL)	2.90	-1.32	11.1
Correlation Coefficient (r)	0.97	0.99	0.98

Precision studies were conducted using the lyophilized N-geneous™ HDL Cholesterol Test Kit. Both within-run and between-run studies were performed using frozen serum pools at three target levels of HDL cholesterol as determined by the National Cholesterol Education Program (NCEP): <35 mg/dL (low); 35-60 mg/dL (mid); and >60 mg/dL (high). It was determined that each POL site achieved the NCEP goals of CVs ≤6% at ≥42 mg/dL, and ≤2.5 mg/dL SD at <42 mg/dL, when using the Genzyme N-geneous™ HDL Cholesterol Kit.

These data demonstrate that the performance of the N-geneous™ HDL Cholesterol Kit in both the clinical and physician office laboratories is substantially equivalent to the performance of the Sodium Phosphotungstate $MgCl_2$ and CDC Designated Comparison Methods.

In lieu of a 510(k) statement under 513(i) of the Act, this information is provided as a 510(k) summary for disclosure to any other persons/companies without the specific written authorization from Genzyme Corporation.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUN 16 1997

Nancy E. Isaac
Associate Director, Regulatory Affairs
Genzyme Corporation
One Kendall Square
Cambridge, Massachusetts 02139

Re: K971162
Liquid N-geneous™ HDL Cholesterol Kit/Cholesterol Calibrator
Regulatory Class: I & II
Product Code: LBS, JIS
Dated: March 28, 1997
Received: March 31, 1997

Dear Ms. Isaac:

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 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.

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

0(k) Number (if known): K971162

vice Name: Liquid N-geneous HDL Cholesterol Kit and N-geneous HDL Cholesterol Calibrator

ications For Use:

or the quantitative determination of high-density lipoprotein Cholesterol (HDL-C) n human serum and plasma.

or in vitro diagnostic use.

or the calibration of the Liquid N-geneous HDL Cholesterol assay.

or in vitro diagnostic use.

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K971162

LEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF EEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

escription Use ✓ OR Over-The-Counter Use ___
er 21 CFR 801.109)

(Optional Format 1-2-96)