

Genzyme Corporation
One Kendall Square
Cambridge, MA 02139

510(k) PREMARKET NOTIFICATION

June 16, 1997

K9 7/1/90
N-geneous™ HDL Cholesterol
Reagent Kit
March 28, 1997

ATTACHMENT 1

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

Trade or Proprietary Name: Genzyme 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 Genzyme N-geneous™ HDL Cholesterol Kit in the physician's office laboratory setting is substantially equivalent to the N-geneous™ HDL Cholesterol Kit when used in a clinical laboratory. The Genzyme N-geneous™ HDL Cholesterol Kit is an *in vitro* diagnostic product cleared (FDA Reference No. K962186) for use in the clinical laboratory for the quantitative determination of high density lipoprotein cholesterol in human serum or plasma. The present clinical laboratory setting is being expanded to include physician office laboratories.

In both user settings, the Genzyme N-geneous™ HDL Cholesterol Kit is a homogenous assay applicable to clinical chemistry analyzers that can accommodate two-reagent systems and does not require any off-line sample pretreatment or centrifugation steps.

The first reagent contains a mixture of polymers and polyanions that bind to the surface of low-density lipoproteins (LDL), very low-density lipoproteins (VLDL) and chylomicrons. These complexed lipoproteins are stabilized, even in the presence of detergent which is added as part of the second reagent, together with the remaining components of a cholesterol reagent. HDL particles, on the other hand, are not stabilized by the polymers and polyanions and become solubilized by the detergent. Consequently, only the HDL cholesterol is subject to cholesterol measurement.

In comparative performance studies, three physician office laboratories (POL) analyzed 40 serum samples using the N-geneous™ HDL Cholesterol Reagent Kit. Split samples from the same 40 specimens were also analyzed at Genzyme, which acted as the reference laboratory. The correlation coefficient between the reference testing site and the POL testing sites for this study were:

K971190

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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 Sodium Phosphotungstate MgCl₂ method (PTA) 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 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 a physician's office laboratory is substantially equivalent to performance of the N-geneous™ HDL Cholesterol Kit in a clinical laboratory setting. Furthermore, these data demonstrate that the performance of the N-geneous™ HDL Cholesterol Kit in a physician's office laboratory is substantially equivalent to the performance of the Sodium Phosphotungstate MgCl₂ method performed in their laboratory.

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: K971190
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.

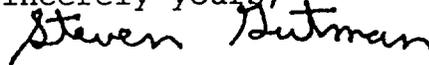
Page 2

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): New - Filed 3/28/97

Device Name: N-geneous HDL Cholesterol Kit and N-geneous HDL Cholesterol Calibrator

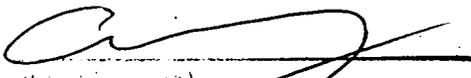
Indications For Use:

For the quantitative determination of high density lipoprotein (HDL) cholesterol in human serum or plasma.

For in vitro diagnostic use.

For the calibration of N-geneous HDL Cholesterol ass in serum or plasma.

For in vitro diagnostic use.


Division of Clinical Laboratory Devices
510(k) Number 97-1190

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)

Product Description
Submission Information
Administrative Information