

K911573

510(k) PREMARKET NOTIFICATION

Genzyme Corporation  
One Kendall Square  
Cambridge, MA 02139

N-geneous™ LDL Cholesterol  
Reagent and Calibrator  
April 29, 1997

June 18, 1997

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

**Trade or Proprietary Name:** Genzyme N-geneous™ LDL Cholesterol Reagent  
Genzyme N-geneous™ LDL Cholesterol Calibrator  
Genzyme LDL Control Set

**Common or Usual Name:** Homogeneous assay for low density lipoprotein cholesterol

**Classification Name:** Low density lipoprotein cholesterol test  
Calibrator, Primary  
Low density lipoprotein control

**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 Affairs Associate (617) 252-7669.

The use of the Genzyme N-geneous™ LDL Cholesterol Reagents in the clinical laboratory setting is substantially equivalent to the Direct LDL Cholesterol Immunoseparation Reagent and the  $\beta$ -Quantification methods.

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

The principle of the test is based upon a unique detergent which selectively solubilizes only the non-LDL lipoproteins, allowing them to be removed by cholesterol enzymes prior to the LDL cholesterol reaction. The LDL particles remain intact. The hydrogen peroxide produced by the reaction of the enzymes with the released cholesterol is consumed by a peroxidase reaction with 4-aminoantipyrine, yielding a colorless product. A second detergent, capable of releasing LDL cholesterol molecules, is added. The enzyme reaction with LDL cholesterol in the presence of the coupler produces color which is proportional to the amount of LDL cholesterol in the sample.

Comparative performance studies were conducted using the N-geneous™ LDL Cholesterol Reagents and two reference methods: Direct LDL Cholesterol Immunoseparation Reagent and  $\beta$ -Quantification.

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Ninety-two serum samples, with LDL values between 68.1 and 214.5 mg/dL, were tested at Genzyme Corporation using the N-geneous™ LDL and the Direct LDL methods. Of these 92 samples, 54 were tested with the β-Quantification reference method.

N-geneous™ LDL	vs. β-Quantification (n = 54)	vs. Direct LDL (n = 92)
Slope	0.96	0.94
Intercept	3.02	4.46
Correlation Coefficient (r)	0.96	0.97
Mean (mg/dL)	Ng: 122.5 βQ: 125.1	Ng: 120.0 Dir: 122.8
Standard Deviation (mg/dL)	Ng: 30.7 βQ: 30.9	Ng: 30.5 Dir: 31.6
Mean Difference	-2.62	-2.81
Mean Percent Difference	-1.9%	-2.0%

Precision studies were conducted using the N-geneous™ LDL Cholesterol Reagents. Both within-run and between-run studies were performed using frozen serum pools at three target levels of LDL cholesterol as determined by the National Cholesterol Education Program (NCEP): <130 mg/dL (low); 130-159 mg/dL (mid); and ≥160 mg/dL (high).

Within-Run	Low (<130 mg/dL)	Mid (130-159 mg/dL)	High (≥160 mg/dL)
n	20	20	20
Sample Range (mg/dL)	97.1 - 99.6	144.9 - 148.7	207.0 - 211.5
Mean (mg/dL)	98.1	146.5	209.8
SD (mg/dL)	0.72	0.96	1.31
%CV	0.73%	0.66%	0.62%

Between-Run	Low (<130 mg/dL)	Mid (130-159 mg/dL)	High (≥160 mg/dL)
n	40	40	40
Sample Range (mg/dL)	93.0 - 101.9	137.5 - 148.6	199.3 - 213.9
Mean (mg/dL)	98.1	142.7	207.3
SD (mg/dL)	2.2	2.8	3.6
%CV	2.27%	1.95%	1.73%

These data demonstrate that the performance of the N-geneous™ LDL Cholesterol Reagents in the clinical laboratory is substantially equivalent to the performance of the Direct LDL Cholesterol Immunoseparation Reagent and the β-Quantification 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.*



Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

JUN 18 1997

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

Re: K971573  
N-geneous™ LDL Cholesterol Reagent/Cholesterol Calibrator  
Genzyme LDL Cholesterol Control Set  
Regulatory Class: I & II  
Product Code: LBR, JIS, JIX  
Dated: April 29, 1997  
Received: April 30, 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.

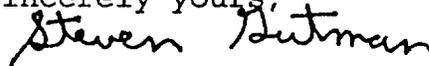
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Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

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



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2098 Gaither Road  
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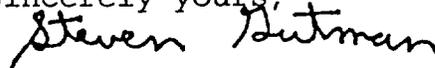
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Sincerely yours,



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

Genzyme Corporation  
One Kendall Square  
Cambridge, MA 02139-1562  
Telephone (617) 252-7500

510(k) Number (if known): \_\_\_\_\_

Device Name: N-geneous™ LDL Cholesterol Reagent  
N-geneous™ LDL Cholesterol Calibrator  
Genzyme LDL Cholesterol Control Set

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FDA/CDRH/ODE/DMC

**Indications For Use:**

Reagents:

For the direct, quantitative determination of low-density lipoprotein cholesterol (LDL-C) in human serum or plasma.

Calibrators:

For the calibration of the N-geneous™ LDL Cholesterol assay in serum or plasma.

Controls:

To monitor the performance of Genzyme LDL Cholesterol Reagents.

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

*Andrew...*  
(Division Sign-Off)  
Division of Clinical Laboratory Devices  
510(k) Number K 971537

Prescription Use   
(Per 21 CFR 801.109)

OR

Over-The-Counter Use \_\_\_\_\_

(Optional Format 1-2-96)

SK-19