OCT 18 1999

K992766

510(k) PREMARKET NOTIFICATION

Genzyme Corporation
One Kendall Square
Cambridge, MA 02139

N-geneous® LDL-ST Cholesterol Reagent, Controls and Calibrator
August 16, 1999

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

Trade or Proprietary Name:	Genzyme N-geneous® LDL-ST Cholesterol Reagent Genzyme N-geneous® LDL-ST 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:	Robert Yocher, Vice President, Regulatory Affairs (617) 374-7275 Barbara Pizza, Manager, Regulatory Affairs (617) 252-7953.

The use of the Genzyme N-geneous® LDL-ST Cholesterol Reagents in the clinical laboratory setting is substantially equivalent to the N-geneous® LDL Cholesterol Reagents and the ß-Quantification methods.

The Genzyme N-geneous® LDL-ST 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. This method is applicable to Olympus two-reagent Chemistry Analyzers and does not require any off-line pretreatment or centrifugation steps.

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-ST Cholesterol Reagents and two reference methods: N-geneous® LDL Cholesterol Reagent and ß-Quantification.

Seventy-seven serum samples, with LDL values between 54.5 and 222.1 mg/dL, were tested at Genzyme Corporation using the N-geneous® LDL-ST on the Olympus AU600 Analyzer and the N-geneous® LDL methods. Of these 77 samples, 62 had sufficient volume to run ß-Quantification method.

N-geneous® LDL-ST on the Olympus AU600	**vs. ß-Quantification** (n = 62)	**vs. N-geneous® LDL on Hitachi 911** (n = 77)
Slope	1.08	1.02
Intercept (mg/dL)	-8.7	-1.7
Correlation Coefficient (r)	0.969	0.990
Mean (mg/dL)	LDL-ST: 119.6 β-Q: 119.0	LDL-ST: 121.6 LDL: 121.3
Standard Deviation (mg/dL)	LDL-ST: 28.9 β-Q: 26.0	LDL-ST: 30.7 LDL: 29.9
Mean Difference (mg/dL)	0.6	0.3
Mean Percent Difference (%)	-0.1	0.1

β-Q = ß-Quantification

Precision studies were conducted using the N-geneous® LDL-ST Cholesterol Reagents on the Olympus Analyzers. Both within-run and between-run studies were performed using Genzyme Desirable and Risk controls:

Within-Run Precision	**Low** (<130 mg/dL)	**High** (≥160 mg/dL)
n	20	20
Sample Range (mg/dL)	92.0 – 97.0	229.6 – 237.3
Mean (mg/dL)	93.8	233.5
SD (mg/dL)	1.3	1.9
%CV	1.4	0.8

Between run	**Low** (<130 mg/dL)	**High** (≥160 mg/dL)
n	20	20
Sample Range (mg/dL)	83 - 90	178 – 195
Mean (mg/dL)	86.9	188.4
SD (mg/dL)	1.8	5.0
%CV	2.1	2.7

These data demonstrate that the performance of the N-geneous® LDL-ST Cholesterol Reagents in the clinical laboratory is substantially equivalent to the performance of the N-geneous® LDL Cholesterol Reagent and the ß-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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

OCT 18 1999

Ms. Barbara Pizza
Manager, Regulatory Affairs
Genzyme Corporation
One Kendall Square
Cambridge, Massachusetts 02139-1562

Re: K992766
Trade Name: N-geneous® LDL-ST Cholesterol Reagent
Regulatory Class: I reserved Product Code: MRR
N-geneous® LDL-ST Cholesterol Calibrator
Regulatory Class: II Product Code: JIS
Genzyme LDL Cholesterol Control Set
Regulatory Class: I reserved Product Code: JJX
Dated: August 16, 1999
Received: August 17, 1999

Dear Ms. Pizza:

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 legally marketed predicate 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.

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/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

3.0 INTENDED USE

510(k) Number (if known): K993766

Device Name: N-geneous® LDL-ST Cholesterol Reagent

N-geneous® LDL-ST Cholesterol Calibrator

Genzyme LDL Cholesterol Control Set

Indications for Use:

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

Calibrator:
For the calibration of the N-geneous® LDL-ST Cholesterol assay in serum or plasma.

Controls:
To monitor the performance of the Genzyme Direct LDL Cholesterol, N-geneous® LDL Cholesterol and N-geneous® LDL-ST Cholesterol Reagents.

Joan Cofer
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K993764

Rx V

37C