OCT 4 1999

K993132

Genzyme Corporation
One Kendall Square
Cambridge, MA 02139

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

Trade or Proprietary Name:	Genzyme Direct Amylase Verifier
Common or Usual Name:	Calibrator for the Genzyme Direct Amylase assay
Classification Name:	Calibrator, Secondary
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 Genzyme Direct Amylase Verifier is intended to be used as a companion product with the Genzyme Direct Amylase reagent manufactured by Genzyme but sold separately. The product is buffer formulated with human amylase and preservative. The Verifier values are in the clinically relevant range of 200 U/L to 275 U/L. The Direct Amylase Verifier is for use during initiation or validation of Genzyme Direct Amylase reagent on a clinical chemistry analyzer to confirm the analyzer has the correct enzyme factor. It is possible this Verifier would need to be used again if significant maintenance was performed on the analyzer and this is addressed in the Direct Amylase Verifier product labeling.

The Genzyme Direct Amylase Verifier used with the Genzyme Direct Amylase reagent on other analyzers performs substantially equivalent to the Genzyme Direct Amylase Reagent on the Roche Cobas FARA Analyzer as demonstrated by results obtained in Genzyme's testing.

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 4 1999

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

Re: K993132
Trade Name: Genzyme Direct Amylase Verifier
Regulatory Class: II
Product Code: JIT
Dated: September 15, 1999
Received: September 20, 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): K993132

Device Name: Direct Amylase Verifier

Indications for Use:

For determination of the instrument specific Direct Amylase reagent factor for analyzers using Genzyme Direct Amylase Reagent.

Jean Cooper
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K993132

(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)