

JUN - 8 1998

K981216

510(k) Summary

Submitter's Name/Address

Abbott Laboratories
1920 Hurd Drive
Irving, Texas 75038

Contact Person

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ADD Regulatory Affairs
(972) 518-7861
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Date of Preparation of this Summary:

April 2, 1998

Device Trade or Proprietary Name:

Amy

Device Common/Usual Name or Classification Name:

Amylase

Classification Number/Class:

75JFJ/Class II

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: _____.

Test Description:

Amylase is an *in vitro* diagnostic assay for the quantitative determination of amylase in serum, plasma, or urine. The Amylase assay is a clinical chemistry assay. The amylase in the sample hydrolyzes the 2-chloro-4-nitrophenyl- α -D-maltotrioxide (CNPG3) to release 2-chloro-4-nitrophenol (CPNP) and form 2-chloro-4-nitrophenyl- α -D-maltoside (CNPG2), maltotriose (G3), and glucose (G). The rate of formation of the 2-chloro-4-nitrophenol is measured as an increase in the absorbance at 405 nm and is directly proportional to the activity of amylase present in the sample.

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Substantial Equivalence:

The Amylase assay is substantially equivalent to the Roche® Cobas Mira® Plus Automated Chemistry System Amylase assay (K903309) for serum, plasma, or urine applications.

These assays yield similar Performance Characteristics.

Similarities to Roche:

- Both assays are *in vitro* clinical chemistry methods.
- Both assays can be used for the quantitative determination of amylase in serum or urine.
- Both assays yield similar clinical results.

Differences to Roche:

- The Roche Amylase assay on the Cobas Mira Plus Automated System is not intended for use with heparinized plasma.

Intended Use:

The amylase assay is used for the quantitation of amylase in human serum, plasma, or urine.

Performance Characteristics:

Comparative performance studies were conducted using the ALCYON™ Analyzer. The Amylase assay method comparison yielded acceptable correlation with the Roche Cobas Mira Plus Automated Chemistry System Amylase assay for the serum and urine applications. For serum applications, the correlation coefficient = 0.9791, slope = 1.126, and Y-intercept = -18.427 U/L. For urine applications, the correlation coefficient = 0.9702, slope = 0.977, and Y-intercept = 0.447 U/L. Precision studies were conducted using the Amylase assay. Within-run, between-run, and between-day studies were performed using two levels of control material. The total %CV for Level 1/Panel 111 is 3.3% and Level 2/Panel 112 is 3.7% for serum applications, and 10.6% for Level 1/Panel 131, and 4.4% for Level 2/Panel 132 for urine applications. The

Amylase assay is linear up to 2,500 U/L. The limit of quantitation (sensitivity) of the Amylase assay is 4.268 U/L. These data demonstrate that the performance of the Amylase assay is substantially equivalent to the performance of the Roche Cobas Mira Plus Automated Chemistry System Amylase assay for the serum and urine applications.

Conclusion:

The Amylase assay is substantially equivalent to the Roche Cobas Mira Plus Automated Chemistry System Amylase assay as demonstrated by results obtained in the studies.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

JUN 8 1998

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Mark Littlefield
Section Manager, Regulatory Affairs
Abbott Laboratories
1920 Hurd Drive
Irving, Texas 75038

Re: K981216
Amylase
Regulatory Class: II
Product Code: JFJ
Dated: April 2, 1998
Received: April 3, 1998

Dear Mr. Littlefield:

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 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.

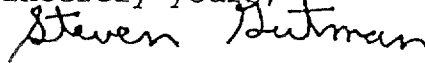
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Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

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

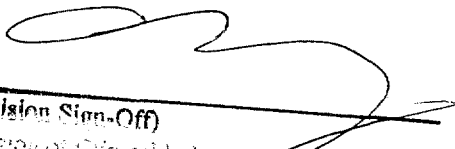
Enclosure

510(k) Number (if known): 12981216

Device Name: Amylase

Indications For Use:

The Amylase assay is used for the quantitation of amylase in serum, plasma, or urine. Amylase measurements are used primarily for the diagnosis and treatment of pancreatitis (inflammation of the pancreas).


(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) number 12981216

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

Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

0000006

510(k) Number (if known): 2981216

Device Name: Amylase

Indications For Use:

The Amylase assay is used for the quantitation of amylase in serum, plasma, or urine. Amylase measurements are used primarily for the diagnosis and treatment of pancreatitis (inflammation of the pancreas).


(Division Sign-Off)

Division of Clinical Laboratory Devices

510(k) number

2981216

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

Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

0000006