

JAN 13 1999

K984184

The logo consists of the word "Wako" in a white, sans-serif font, centered within a solid black rectangular box.

Wako Chemicals USA, Inc.
1600 Bellwood Road, Richmond, VA 23237 U.S.A.

510(k) Summary of Safety and Effectiveness

The Wako L-type Amylase test is an in vitro diagnostic assay for the quantitative determination of amylase activity in serum.

Amylase is one of the digesting enzymes secreted predominantly from pancreas and salivary gland, which hydrolyzes α -1,4-bonds of both straight-chain polysaccharides such as amylose and branched polysaccharides such as amylopectin. Determination of α -amylase activity is largely of use in the diagnosis of pancreatic diseases, but is also of value in detecting nonpancreatic disorders such as renal insufficiency, salivary gland lesions, macroamylasemia, and intra-abdominal diseases.¹ There are several methods used for the determination of α -amylase activity such as amyloclastic, saccharogenic, and defined-substrate methods.² The Wako L-type Amylase is a kinetic assay employing a defined-substrate, p-nitrophenylbenzy- α -maltopentaoside (BG5P), with glucoamylase and α -glucosidase as coupling enzymes.

When a sample is allowed to react with the BG5P, BG3 and p-nitrophenyl- α -maltoside (PNP-G2) are formed by the action of α -amylase in the sample. The PNP-G2 produced is hydrolyzed to p-nitrophenol by the reactions of glucoamylase and α -glucosidase. By measuring the increase in absorbance of p-nitrophenol at the optimum wavelength of 405 nm, α -amylase activity in the sample is determined. A benzyl group in the nonreducing end glucose residue of BG5P prevents the hydrolysis by the coupling enzymes and, thus, keeps a low blank absorbance. In this method, one unit of BG5P hydrolyzed by α -amylase converts to one p-nitrophenol molecule. Therefore, one unit of α -amylase can be defined stoichiometrically as the amount of enzyme that produces one micro mol. of p-nitrophenol per minute.^{3,4}

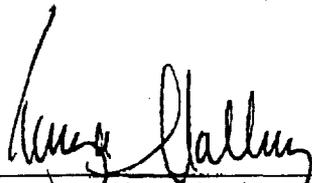
The safety and effectiveness of the Wako L-type Amylase assay is demonstrated by its substantial equivalency to the Sigma Amylase test.

Precision studies indicate acceptable values can be obtained on a day to day basis. The minimum detectable level of this method is estimated to be 1.0 IU/L. The Wako L-type Amylase assay had determined to be linear to 3000 IU/L.

510(k) Summary
Wako L-type Amylase
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References:

1. Berk, J.E. and Fridhandler, L.: Ann. Intern. Med., 26, 235-264 (1980).
2. Burtis, C.A. and Ashwood, E.R.: Tietz Textbook of Clinical Chemistry, 2nd ed., Saunders, Philadelphia, 1994.
3. Satomura, S., Sakata, Y., Omichi, K. and Ikenaka, T.: Clin. Chem. Acta, 174, 315-324 (1988).
4. Satomura, S., Iwata, T., Sakata, Y., Omichi, K. and Ikenaka, T.: Carbohydr. Res., 176, 107-115 (1988).



Tonya Mallory, Senior Manager, Diagnostics
January 12, 1999
Wako Chemicals USA, Inc.
1600 Bellwood Road
Richmond, VA 23237



JAN 13 1999

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ms. Tonya Mallory
Senior Manager, Diagnostics
Wako Chemicals USA, Inc.
1600 Bellwood Road
Richmond, Virginia 23237

Re: K984184
Trade Name: Wako L-type Amylase
Regulatory Class: II
Product Code: JFJ
Dated: November 16, 1998
Received: November 23, 1998

Dear Ms. Mallory:

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.

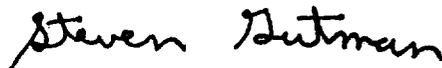
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Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

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/dsma/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): K9 841 84

DEVICE NAME: Wako L-type Amylase

INDICATIONS FOR USE:

Intended to measure the activity of the enzyme, amylase, in serum. ~~and tissue~~. Amylase measurements are used primarily for the diagnosis and treatment of pancreatitis.

Jean Coogan
(Division Chief-Off)
Division of Clinical Laboratory Devices
510(k) Number K984184

(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)