

DEC 16 1999

K993468

**Wako**

Wako Chemicals USA, Inc.

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### 510(K) Summary of Safety and Effectiveness

The Wako L-Type GOT.J2 test is an in vitro assay for the quantitative determination of glutamic-oxaloacetic transaminase (GOT) activity in serum.

#### **Summary:**

Glutamic-oxaloacetic transaminase (GOT), an enzyme that catalyzes transamination of L-aspartate and  $\alpha$ -ketoglutarate to glutamate and oxaloacetate, is abundantly distributed in the cardiac muscle, liver, brain and other organs. GOT measurements are used in the diagnosis and treatment of certain types of liver and heart diseases. A commonly used method of GOT assay is the UV kinetic method. The Wako L-Type GOT.J2 is a reagent kit for GOT assay. <sup>1</sup>

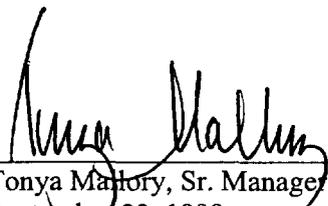
#### **Principle:**

When a sample is mixed with substrate-enzyme and  $\alpha$ -KG, glutamate and oxaloacetate are formed from L-aspartate and  $\alpha$ -ketoglutarate in a reaction catalyzed by GOT in the sample. The oxaloacetate thus produced is converted to malate by malate dehydrogenase (MDH) and at the same time, NADH is oxidized to NAD. By measuring the decrease in absorbance at 340 nm due to the oxidation of NADH, GOT activity in the sample is determined.

The safety and effectiveness of the Wako Wako L-Type GOT.J2 Test is demonstrated by its substantial equivalency to the Wako UA 30R GOT product. Both test systems are used to measure to measure GOT in the serum. In comparison studies against the predicate assay, a correlation coefficient of 0.9996 and a regression equation of  $y = 1.055x + 2.38$  was obtained. Precision studies indicate acceptable values can be obtained on a day to day basis. The minimum detectable level of this method is 4 IU/L.

#### **References:**

1. Burtis, C.A. and Ashwood, E.R., Ed.: Tietz Textbook of Clinical Chemistry, 2<sup>nd</sup> Ed., Saunders, Philadelphia, 1994.
2. DG Klinische Chemie Mitteilungen 26 (1995) Heft 5.



Tonya Maffery, Sr. Manager Wako Diagnostics  
September 22, 1999  
1600 Bellwood Road  
Richmond, VA 23237



DEPARTMENT OF HEALTH & HUMAN SERVICES

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Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

DEC 16 1999

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

Re: K993468  
Trade Name: Wako L-Type GOT Test  
Regulatory Class: II  
Product Code: CIT  
Dated: September 23, 1999  
Received: October 13, 1999

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.

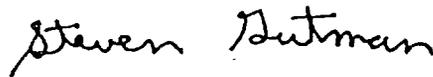
Page 2

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

Page 1 of 1

510(k) Number (if known): K993468

Device Name: Wako L-Type GOT Test

**Indications For Use:**

AST/GOT measurements are used in the diagnosis and treatment of certain types of liver and heart disease.

Jean Cooper  
(Division Sign-Off)  
Division of Clinical Laboratory Devices  
510(k) Number K993468

(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)