

3/9/99

K981446

**510(k) Summary of Safety and Effectiveness**

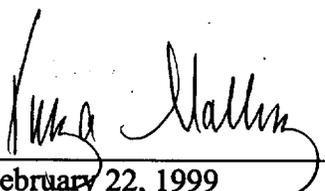
The Wako Autokit Lp(a) test is an in vitro diagnostic assay for the quantitative determination of lipoprotein (a) in serum or plasma to aid, in conjunction with other lipoprotein tests, with the risk assessment of coronary artery disease (CAD).

Components of Lp(a) have similarities to both LDL and plasminogen, suggesting that Lp(a) may represent a bridge between the fields of atherosclerosis and thrombosis. Numerous studies suggested an association of plasma Lp(a) concentrations with atherosclerotic vascular disease. There are numerous techniques for measuring Lp(a) such as radial immunodiffusion(RID), radio immunoassay (RIA), enzyme-linked immunoassay (ELISA), nephelometric immunoassay (NIA), and turbidimetric immunoassay (TIA). The Wako Lp(a) test kit is based on the TIA methodology.

When a sample is mixed with the Buffer and the Antibody, Lp(a) in the sample combines specifically with anti-human lipoprotein (a) antibodies in the reagent to yield an insoluble aggregate that causes turbidity. The degree of turbidity can be measured optically and is proportional to the amount of Lp(a) in the sample.

The safety and effectiveness of the Wako Autokit Lp(a) assay is demonstrated by its substantial equivalency to the Apo-tek Lp(a) assay and Sigma's LDL, in its ability to determine cardiac risk. All of these systems are used to assess the risk of coronary artery disease (CAD).

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 0.3 mg/dL. The Wako Autokit Lp(a) assay had determined to be linear to 100 mg/dL.



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February 22, 1999  
Tonya Mallory  
Wako Chemicals USA, Inc.  
1600 Bellwood Road  
Richmond, VA 23237



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

MAR - 9 1999

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

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

Re: K981446  
Trade Name: Wako Autokit Lp(a)  
Regulatory Class: II  
Product Code: DFC  
Dated: January 7, 1999  
Received: January 11, 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.

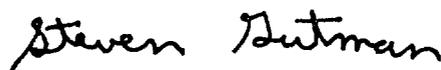
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Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

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

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**Wako Autokit Lp(a)**  
**510(k) Number K981446**

Jean Coogan  
(Division Sign-Off)  
Division of Clinical Laboratory Devices  
510(k) Number K981446

**Indications for Use:**

The Wako Lp(a) assay is an in vitro turbidimetric immunoassay for the quantitative determination of lipoprotein(a) in serum or plasma to aid in the risk assessment of coronary heart disease (CAD).

Tonya Mallory  
Tonya Mallory  
Wako Diagnostics

February 19, 1999

Prescription Use ✓