Wako

Wako Diagnostics
1600 Bellwood Road, Richmond, VA 23237 U.S.A.

APR 11 2003

K030320

510(k) Summary of Safety and Effectiveness

Diabetic nephropathy, which is accompanied by irreversible kidney damage and persistent proteinuria, is a major cause of death in persons with insulin-dependent diabetes mellitus and a main reason to initiate hemodialysis. Therefore, detection of kidney (glomerular) damage that is minimal and reversible is important. Micro-albuminuria is a condition characterized by increased urinary excretion of albumin in the absence of overt nephropathy. It has been reported in several studies to predict development of diabetic nephropathy and its mortality risk in both diabetes mellitus of insulin-dependent and non-insulin-dependent.
Because micro-albuminuria may be reversible if diabetes is well controlled, its early detection may be very beneficial in treatment programs for diabetes.

Principle of the method
When a sample is mixed with Buffer and Antibody, albumin in the sample combines specificaaly with anti-human albumin antibody (goat) in the Antibody to yeild an insoluble aggregate that causes increases turbidity in the solution. The degree of the turbidity of solution can be measured optically and is proportional to the concentration of albumin in the patient's sample.

Precision studies indicate acceptable values can be obtained on a day to day basis. The minimum detectable level of this method is estamiated to be 0.33 µg/dL. In comparison studies against the predicate, Wako Micro Albumin B assay, a correlation coefficient of 0.9984 and a regression equation of $y = 1.0179x - 0.9619$ was obtained.

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References:

Burtis, C.A. and Ashwood, E.R., Ed.: Tietz Textbook of Clinical Chemistry, 2nd Ed., Sanuders, Philadelphia, 1994.
Lothar Thomas, M.D., Ed.: Clinical Laboratory Diagnostics
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Tonya Mallory, Executive Manager
April 7, 2003
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DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

APR 11 2003

Ms. Lori Creasy
Regulatory Affairs Specialist
Wako Diagnostics
1600 Bellwood Road
Richmond, VA 23237

Re: k030320
Trade/Device Name: Wako Autokit Micro Albumin
Regulation Number: 21 CFR 862.1645
Regulation Name: Urinary protein or albumin (nonquantitative) test system
Regulatory Class: Class II
Product Code: JIS; JIQ; JJX
Dated: January 29, 2003
Received: January 30, 2003

Dear Ms. Creasy:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 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 information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer 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
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

K030320

Indications for Use:

A urinary protein or albumin (nonquantitative) test system is a device intended to identify proteins or albumin in urine. Idetnification of urinary protein or albumin (nonquantitative) is used in the diagnosis and treatment of disease conditions such as renal or heart diseases or thyroid disorders, which are characterized by proteinuria or albuminuria.

Proprietary Name: Wako Autokit Micro Albumin

Established Registration Number: 1627434

Premarket Notification 510 (k) Number:_____

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use_____
(Optional Format 1-2-96)

Jean Cooper

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K030320