APR 3 2000

K993925

Wako Chemicals USA, Inc.
1600 Bellwood Road, Richmond, VA 23237 U.S.A.
Telephone (804) 271-7677 Telex 293208 WAKO UR(RCA) Facsimile (804) 271-7791

510(K) Summary of Safety and Effectiveness

The Wako L-Type UN test is an in vitro assay for the quantitative determination of urea nitrogen in serum and plasma.

Summary:

In humans, urea is the major nitrogen-containing metabolic product of protein catabolism. The determination of serum urea nitrogen is one of the most widely used tests for the evaluation of kidney function. The test is frequently requested along with the serum creatinine test since simultaneous determination of these two compounds appears to aid in the differentiate diagnosis of prerenal, renal and postrenal azotemia. The procedures for the quantitation of urea nitrogen employ either a direct determination of the urea or an indirect determination of the ammonia released by the enzymatic action of urease on urea.
The Wako L-Type UN is a method based on enzymatic assay utilizing urease and glutamate dehydrogenase. [1,2]

Principle:

Urea in a specimen is decomposed to produce ammonia and carbon dioxide catalyzed by urease. In the presence of α-Ketoglutarate and NADH, this ammonia causes the oxidation of an equal amount of NADH to NAD in a reaction catalyzed by glutamate dehydrogenase (GLDH). The decrease in absorbance of NADH at 340nm is directly proportional to the amount of urea in the sample.

The safety and effectiveness of the Wako L-Type UN test is demonstrated by its substantial equivalency to product. Both test systems are used to measure urea in serum. In comparison studies against the predicate assay, a correlation coefficient of and a regression equation of y = x + was obtained. Precision studies indicate acceptable values can be obtained on a day to day basis. The minimum detectable level of this method is 0.6 mg/dL.

References:

1. Burtis, C.A. and Ashwood, E.R., Ed.: Tietz Textbook of Clinical Chemistry, 2nd Ed., Saunders, Philadelphia, 1994.
2. Kaltwasser, H. and Schlegel, H.G.: Anal. Biochem., 16,132-138 (1966)
3. DG Klinische Chemie Mitteilungen 26 (1995) Heft 5.

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 3 2000

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

Re: K993925
Trade Name: Wako L-Type Urea N
Regulatory Class: II
Product Code: CDQ
Dated: February 15, 2000
Received: February 18, 2000

Dear Ms. Mallory:

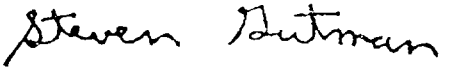
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 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.

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" (21CFR 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): K993925

Device Name: Wako L-Type Urea N

Indications For Use:

Measurements obtained by this device are used in the diagnosis and treatment of certain renal and metabolic diseases.

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K993925

(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)