JAN 20 1999

K984122

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

510(k) Summary of Safety and Effectiveness

The Wako L-type UIBC test is an in vitro diagnostic assay for the quantitative determination of iron in serum.

Approximately two thirds of iron in the body is in hemoglobin of red blood corpuscles (RBCs) and the rest is in liver, spleen, bone marrow and other tissues as stored in iron. Numerous cellular enzymes and coenzymes require iron, such as peroxidases and cytochromes. Transport of iron from one organ to another is accomplished by serum iron, bound to transferrin. Serum transferrin has considerable reserve iron binding capacity, which is called the serum unsataturated iron binding capacity (UIBC), because normally about one third of the iron binding sites of transferrin are occupied by iron. Measurement of serum iron concentration, UIBC and total iron binding capacity (TIBC) are is largely of use in the diagnosis of iron deficiency anemia, hemochromatosis, chronic inflammatory disorders and malignancies. There are several methods used for the measurement of UIBC and TIBC.[1,2] The Wako L-type UIBC is a method utilizing bathophenanthroline as a chromogen.

When a sample is mixed with the Buffer containing a known excess amount of iron, unsaturated transferrin in serum quantitatively associates with iron in the Buffer and is converted to a saturated state. The portion of iron which remains unassociated is assayed through color development with ascorbic acid and bathophenanthroline disulfonic acid disdoium salt. The unsaturated transferrin concentration in the sample can be determiend by calculating the decrement of iron in the Buffer.

The safety and effectiveness of the Wako L-type UIBC assay is demonstrated by its substantial equivalency to the Wako UIBC manual 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 1.8 mg/dL. The Wako L-type UIBC assay has determined to be linear to 600 µg/dL.

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

References:

1. Burtis, C.A. and Ashwood, E.R.: Tietz Textbook of Clinical Chemistry, 2nd ed., Saunders, Philadelphia, 1994.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JAN 20 1999

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

Re: K984122
Trade Name: Wako L-type UIBC and Wako UIBC Calibrator
Regulatory Class: I Product Code: JQF
II JIS
Dated: November 16, 1998
Received: November 18, 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.

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 Gutman

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): K98 4122

DEVICE NAME: Wako L-type UIBC, Wako UIBC Calibrator

INDICATIONS FOR USE:

Iron-binding capacity measurements are used in the diagnosis and treatment of anemia.

Jean Cooper

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K984122

(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)