Wako

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

NOV 1 2 1999

K993162

510(k) Summary of Safety and Effectiveness

The Wako Transferrin test is an in vitro diagnostic assay for the quantitative determination of transferrin in serum.

Summary:
Transferrin is the major iron-carrying protein in blood plasma. It is mainly synthesized in the liver. It is a glycoprotein, which has a molecular weight of 80kDa. The molecule is divided in two domains, each conatining one metal-binding site. Iron is the most important metal bound by transferrin in vivo. Clinical evaluation of transferrin levels is useful for the the differential diagnosis of anemia and for monitoring its treatment. Assay methods for measuring transferrin have been developed, such as immunochemical methods, nephelometry, radial immunodiffusion(RID), turbidimetric immunoassay. Wako transferrin test utilizes turbidimetric immunoassay[1].

Principle:
When the sample is mixed with Buffer and Antiserum, transferrin in the sample combines specifically with anti-human transferrin antibodies in the Antiserum to yield an insoluable aggregate that causes increased turbidity. The degree of turbidity cab be measured optically and is proportional to the amount of transferrin in the sample.

The safety and effectiveness of the Wako Transferrin assay is demonstrated by its substantial equivalency to the Beckman Transferrin product. Both test systems are used to measure transferrin in serum. In comparison studies against the predicate assay, a correlation coefficient of 0.988 and a regression equation of $y = 0.975x + 0.41$ was obtained. Precision studies indicate acceptable values can be obtained on a day to day basis. The minimum detectable level of this method is 4.7 mg/dL.

References

1. Jong, G, et al.: The Biology of Transferrin. Clin. Chim. Acta, 190:1-46, 1990.

September 17, 1999
Wako Diagnostics
Wako Chemicals USA, Inc.
1600 Bellwood Road
Richmond, VA 23237

Telephone (804) 271-7677 Facsimile (804) 271-7791

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

NOV 1 2 1999

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

Re: K993162
Trade Name: Wako Transferrin, Transferrin Calibrator
Regulatory Class: II
Product Code: DDG
Dated: September 17, 1999
Received: September 22, 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.

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): K993162

Device Name: Wako Transferrin assay
Wako Transferrin Calibrator

Indications For Use:

Measurement of transferrin levels aid in the diagnosis of malnutrition, acute inflammation, infection, and red blood cell disorders, such as iron deficiency anemia.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K993162

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ___

(Optional Format 1-2-96)