Wako Chemicals USA, Inc.
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JAN 14 2000

K993924

510(K) Summary of Safety and Effectiveness

The Wako IgM II – HA test is an in vitro assay for the quantitative determination of immunoglobulin M in serum.

Summary:
Immunoglobulin M (IgM) is the most primitive immunoglobulin and the only immunoglobulin that a neonate synthesizes. In adult serum, it accounts for 5 to 10% of the total circulating immunglobulins. Most of the serum IgM is a pentamer of five IgM monomers. Each monomer has a molecular weight of 185,000. The monomers are attached to each other with the J chain. IgM is an efficient complement activator, has high affinity to bacteria and erythrocytes, and plays a major role in protection from Gram-negative bacterial infection.
The quantification of immunoglobulins in serum is important for the diagnosis, monitoring and prognosis of chronic liver diseases, infectious diseases, lymphocytosis, multiple myeloma, primary and secondary immune failure, etc. The conventional test, single radial immunodiffusion (SRID), has been widely used. In recent years, there have been many reports on the use of turbidity or light scattering for the measurement of antigen-antibody complexes formed in solution. Advantages over conventional methods include increased sensitivity, better precision, and shortened assay time. The Wako IgM II-HA test is a highly specific reagent based on turbidimetric immunoassay. [1,2]

Principle:
When a sample is mixed with the Buffer solution and Anti-IgM, IgM in the sample combines specifically with anti-human IgM antibody in the Anti-IgM to yield an insoluble aggregate that causes increased turbidity. The degree of turbidity can be measured optically and is proportional to the amount of IgM in the sample.

The safety and effectiveness of the Wako IgM II-HA is demonstrated by its substantial equivalency to Wako IgM HA-Direct product. Both test systems are used to measure IgM in serum. In comparison studies against the predicate assay, a correlation coefficient of 0.996 and a regression equation of $y = 0.662 x - 6.64$ was obtained. Precision studies indicate acceptable values can be obtained on a day to day basis. The minimum detectable level of this method is 10 mg/dL.

References:
1. Burtis, C.A. and Ashwood, E.R., Ed.: Tietz Textbook of Clinical Chemistry, 2nd Ed., Saunders, Philadelphia, 1994.
2. Tsubaki, K. et al., Japanese J. Clin. Chem., 14,185-191 (1985).
3. DG Klinische Chemie Mitteilungen 26 (1995) Heft 5.

September 30, 1999
LaTonya Mallory
Wako Diagnostics
1600 Bellwood Road, Richmond, VA 23237

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JAN 1 4 2000

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

Re: K993924
Trade Name: Wako IgM II HA Immunoglobulin Calibrator Set
Regulatory Class: II
Product Code: CFN
Dated: September 30, 1999
Received: November 18, 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 at (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/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): K993924

Device Name: IgM II HA

Indications For Use:

Measurement of IgM immunoglobulin aids in the diagnosis of abnormal protein metabolism and the body's lack of ability to resist infectious agents.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Peter E. Maxim

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K993924

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ___

(Optional Format 1-2-96)