JAN 18 2000

K993928

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 IgG II – HA test is an in vitro assay for the quantitative determination of immunoglobulin G in serum.

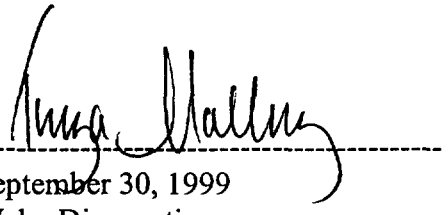
Summary:
Immunoglobulin G (IgG) is the major immunoglobulin, which makes up 70 to 75% of the total immunoglobulins. In electrophoresis, IgG usually migrates in the γ– and slow β-regions; the heterogeneity of the IgG antibody molecules synthesized by different plasma cells causes the region to stain diffusely. IgG antibodies activate complement via the complement cascade, have affinity to receptors on B cells and macrophages, enhance opsonization, and neutralize toxins in tissue spaces.
The quantification of immunoglobulins in serum is important for the diagnosis, monitoring and prognosis of chronic liver disease, infectious disease, 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 IgGII-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-IgG, IgG in the sample combines specifically with anti-human IgG antibody in the Anti-IgG to yield an insoluble aggregate that causes increased turbidity. The degree of turbidity can be measured optically and is proportional to the amount of IgG in the sample.

The safety and effectiveness of the Wako IgG II-HA is demonstrated by its substantial equivalency to Wako IgG HA-Direct product. Both test systems are used to measure IgG in serum. In comparison studies against the predicate assay, a correlation coefficient of 0.997 and a regression equation of $y = 0.769\ x - 60.71$ was obtained. Precision studies indicate acceptable values can be obtained on a day to day basis. The minimum detectable level of this method is 62 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
Wako Diagnostics
Wako Chemicals USA, Inc.
1600 Bellwood Road
Richmond, VA 23237

DEPARTMENT OF HEALTH & HUMAN SERVICES

JAN 18 2000

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

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

Re: K993928
Trade Name: Wako IgG II-HA, Immunoglobulin Calibrator Set, Immunoglobulin Standard
Regulatory Class: II
Product Code: DEW
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.

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 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): K993938

Device Name: Wako IgG II HA

Indications For Use:

Measurement of IgG 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 G. Madoni

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K993938

Prescription Use ✓ OR Over-The-Counter Use ___
(Per 21 CFR 801.109)

(Optional Format 1-2-96)