K020972

SEP 9 2002

Wako

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

510(k) Summary of Safety and Effectiveness

The Wako RF HA2 test is an in vitro diagnostic assay for the quantitative determination of rheumatoid factor activity in serum.

Summary:
Rheumatoid factor (RF) is contained in the serum of rheumatoid arthritis patients. Because of this high degree of specificity, the detection of RF by serologic test has proved to be useful in the clinical diagnosis and prognosis of rheumatoid arthritis.

RF is an autoantibody of human immunoglobulin G (IgG). The most conventional serologic test for RF is the method dependent upon agglutination of particles (e.g., latex and erythrocytes) which have been sensitized with human gamma-globulin. Assays for RF have been improved and more quantitative RF tests have been reported (eg., nephelometric immunoassay and turbidimetric immunoassay).

The turbidimetric immunoassay method (TIA) has the advantages of : ease of use, accurate quantitation, and it is applicable to automated analyzers.

The Wako RF-HA(2) test is a highly specific reagent based on turbidimetric immunoassay.

Principle:
When the sample is mixed with Buffer and RF Reagent, rheumatoid factor in the sample combines specifically with the heat-aggregated human IgG in thereagents to yield an insoluble aggregate which causes increased turbidity in the solution. The degree of turbidity can be measured optically and is proportional to the amount of rheumatoid factor in the sample.

The safety and effectiveness of the Wako RF-HA(2) assay is demonstrated by its substantial equivalency to the Wako Autokit RF product. Both test systems are used to measure rheumatoid factor in serum. In comparison studies against the predicate assay, a correlation coefficient of 0.9946 and a regression equation of $y = 1.018x - 9.91$ 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 IU/mL.

Tonya Mallory
March 25, 2002
Wako Diagnostics
Wako Chemicals USA, Inc.
1600 Bellwood Road
Richmond, VA 23237

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

SEP 9 2002

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

Re: k020972
Trade/Device Name: Wako RF-HA (2), RF Calibrator, RF Calibrator Set
Regulation Number: 21 CFR 866.5775
Regulation Name: Rheumatoid Factor Immunological Test System
Regulatory Class: Class II
Product Code: DHR, JIT
Dated: August 26, 2002
Received: August 27, 2002

Dear Ms. Mallory:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 International and Consumer 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

ı or Use:

510(k) Number: K020972

The Wako RF-HA(2) test system is an in vitro diagnostic assay for the quantitative determination of rheumatoid factor activity in serum. Measurement of rheumatoid factor may aid in the diagnosis of rheumatoid arthritis.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Sonsun S. Altaire

(Division Sign-Off)
Division of Clinical Laboratory Devices

510(k) Number K020972

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

(Optional Format 1-2-96)