JUN - 6 2003

K024280

Wako

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

510(K) Summary of Safety and Effectiveness

Intended use

The Wako CRP test is an in vitro assay for the quantitative determination of C-reactive protein in serum.

Summary and explanation of the test

A protein that binds the C-polysaccharide on the cell wall of *Streptococcus pneumoniae* presents in the sera of acutely ill patients. This protein is called C-reactive protein (CRP), which has been recognized as one of the acute phase reactants that rise dramatically in the case of inflammation or tissue destruction. Determination of CRP is clinically useful for detecting inflammation and infections. Various methods can be used for the determination of CRP (e.g. turbidimetric immunoassay (TIA), nephelometric immunoassay (NIA) and latex immunoassay (LIA). The Wako CRP test is a highly specific reagent based on turbidimetric immunoassay. [1,2] The Wako CRP test with one –point calibration shows the linearity up to 150 mg/L. The Wako CRP test with multi-point calibrations shows the linearity up to the highest value of calibrator set (more than 250 mg/L).

Principle of the method

When a sample is mixed with Buffer and Antibody, CRP in the sample combines specifically with anti-human CRP antibody (goat) in the Antibody to yield an insoluble aggregate that causes increased turbidity in the solution. The degree of turbidity of solution can be measured optically and is proportional to the concentration of CRP in the patient's sample.

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 1mg/L . The assay is linear to 230 mg/L when using the Wako CRP Calibrator Set and 200 mg/L when using the Wako single point CRP Calibrator.

References

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

Lothar Thomas, M.D., Ed.: Clinical Laboratory Diagnostics

DG Klinische Chemie Mitteilungen 26 (1995) page5.

Tracy RP, Lemaltro RN, Peaty BM, Ives DG, Evans RW, Cushman M, Mellahn EN, Kuller LH. Relationship of C-reactive protein to risk of cardiovascular disease in the elderly; results from the Cardiovascular Health Study and the Rural Hearth Promotion Project. Arterioscler Thrombo Vaso Biol, 1997; 17:1121-1127

Tonya Mallory, Executive Manager
April 7, 2003

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUN - 6 2003

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

Re: k024280
Trade/Device Name: Wako CRP, Wako CRP Calibrator and Wako CRP Calibrator Set
Regulation Number: 21 CFR 866.5270
Regulation Name: C-reactive protein immunological test system
Regulatory Class: Class II
Product Code: DCK; JIT; JJX
Dated: March 31, 2003
Received: April 1, 2003

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 Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 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 information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act 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
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use:
A C-reactive protein immunological test system us a device that consists of the reagents used to measure by immunological techniques the C-reactive protein in serum and other body fluids. Measurement of C-reactive protein aids in evaluation of the amount of injury to body tissues.

The Wako CRP Calibrator and Wako CRP Calibrator Set are designed to be used with the Wako CRP test for the determination of the C-Reactive protein in serum.

Proprietary Name:
Wako CRP, Wako CRP Calibrator and Wako CRP Calibrator Set

Establishment Registration Number: 1627434

Premarket Notification 510(k) Number: K024280

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

Concurrence of CDRH, ODE

Prescription Use ✓ OR Over-the-Counter Use _____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

Jean Cooper
Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K024280