Wako

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

DEC 3 0 2005

K053132

510(K) Summary of Safety and Effectiveness

Serum and plasma measurement is widely used as a screening test for liver functions. The methods most widely used for determination of serum bilirubin are the diazo coupling method [1,2,3] and the bilirubin oxidase enzymatic method[4]. However, these methods have disadvantages such as interference by coexistent serum substances unsatisfactory stability of reagents after preparation. Wako Direct Bilirubin V is based on a chemical oxidation method, utilizing vanadate as an oxidating agent, shows good correlation with conventional methods, practically no interference by coexistent serum and plasma substances, and is convenient ready-to-use liquid type reagent[5].

When a sample is mixed with the reagent containing the detergent and the vanadate, at around pH3, direct bilirubin in the sample is oxidized to biliverdin. This causes the absorbance of yellow, specific to bilirubin, to decrease. Therefore, the direct bilirubin concentration in the sample can be obtained by measuring the adsorbances before and after the vanadate oxidation.

The safety and effectiveness of the Wako Direct Bilirubin V assay is demonstrated by its substantial equivalency to our previous Direct Bilirubin assay (510(K) # 970986). The previously marketed device (510k# 970986) was marketed for serum samples and this submission adds the use of plasma as a sample. There are no changes to performance claims already established in 510(k) # 970986.

References:

(1) Malloy H. T., Evelyn K. L. The determination of bilirubin with the photoelectric colorimetry. J. Biol. Chem., 199: 481-490, (1937).
(2) Jendrassik L., Cleghorn R. A. Photometrische bilirubinbestimmung. Biochem. Z., 289: 1-14, (1937).
(3) Michaelsson M. Bilirubin determination in serum and urine. Scand. J. Clin. Lab. Invest., 12 (Suppl 56): 1-80, (1937).
(4) Murao S., Tanaka N. A new enzyme "bilirubin oxidase" produced by Myrothecium varrucaria MT-1. Agric. Biol. Chem. 45: 2383-2384, (1981).
(5) Tokuda K. and Tanimoto K. New method of measuring serum bilirubin using vanadic acid. Jpn. J. Clin. Chem., 22 (2), 116-122 (1993).
(6) Carl A.Burtis, Edward R. Ashwood, TIETZ TEXTBOOK of Clinical Chemistry, second edition, P1468 (SAUNDERS).

Lori Creasy
November 7, 2005
Regulatory Affairs Specialist
Wako Diagnostics
1600 Bellwood Road
Richmond, VA 23237

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC 3 0 2005

Ms. Lori Creasy
Regulatory Affairs Specialist
Wako Chemicals, USA Inc.
1600 Bellwood Road
Richmond VA, 23237

Re: k053132
Trade/Device Name: Wako Direct Bilirubin V
Regulation Number: 21 CFR 862.1110
Regulation Name: Bilirubin (total or direct) test system
Regulatory Class: Class II
Product Code: LFM
Dated: November 7, 2005
Received: November 9, 2005

Dear Ms. Creasy:

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 (240) 276-0484. 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/industry/support/index.html.

Sincerely yours,

Alberto Gutierrez, Ph.D.
Director
Division of Chemistry and Toxicology
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE:

510(k) Number (if known):

Device Name: Wako Direct Bilirubin V

Indications For Use:
Determination of serum and plasma bilirubin is useful in the screening of liver function disorders or in the diagnosis of jaundice.

Prescription Use ✓ AND/OR Over-The-Counter Use

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of [illegible] Device Evaluation and Safety

510(k) K053132