



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

APR 23 2004

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

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

Re: k033860  
Trade/Device Name: Wako Total Ketone Body Calibrators  
Regulation Number: 21 CFR 862.1150  
Regulation Name: Calibrator  
Regulatory Class: Class II  
Product Code: JIT  
Dated: March 26, 2004  
Received: March 29, 2004

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.

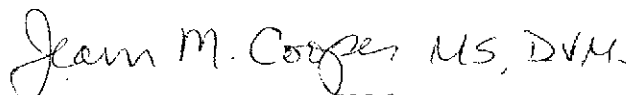
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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).

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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,

A handwritten signature in dark ink, reading "Jean M. Cooper MS, D.V.M." in a cursive style.

Jean M. Cooper, MS, D.V.M.

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): K033860

Device Name: Wako Total Ketone Body Calibrators

The Wako Total Ketone Body Calibrators are intended to be used with the Wako Autokit Total Ketone Bodies and Wako Autokit 3-HB test kits to establish points of reference that are used in the determination of values in the measurement of total ketone bodies and 3-hydroxybutyrate in human serum or plasma.

**Proprietary Name:** Wako Total Ketone Body Calibrators

**Established Registration Number:** 1627434

**Premarket Notification 510 (k) Number:** K033860

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use \_\_\_\_\_  
(Optional Format 1-2-96)

Carol C Benson  
Division Sign-Off

Office of In Vitro Diagnostic  
Device Evaluation and Safety

510(k) K033860