

K981245

MAY 20 1998

# 510(k) Summary

**Submitter's Name/Address**

Abbott Laboratories  
1920 Hurd Drive  
Irving, Texas 75038

**Contact Person**

Mark Littlefield  
Section Manager MS 1-8  
ADD Regulatory Affairs  
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**Date of Preparation of this Summary:**

April 3, 1998

**Device Trade or Proprietary Name:**

AlkP

**Device Common/Usual Name or Classification Name:** Alkaline Phosphatase

**Classification Number/Class:**

75CJE/Class II

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: \_\_\_\_\_.

**Test Description:**

Alkaline Phosphatase is an *in vitro* diagnostic assay for the quantitative determination of alkaline phosphatase in human serum or plasma. Alkaline phosphatase in serum catalyzes the hydrolysis of colorless p-nitrophenyl phosphate (p-NPP) to give p-nitrophenol and inorganic phosphate. At the pH of the assay (alkaline), the p-nitrophenol is in the yellow phenoxide form. The rate of absorbance increase at 405 nm is directly proportional to the alkaline phosphatase activity in the sample. Optimized concentrations of zinc and magnesium ions are present to activate the alkaline phosphatase in the sample.

**Substantial Equivalence:**

The Alkaline Phosphatase assay is substantially equivalent to the Roche® Cobas Mira® Plus Automated Chemistry System Alkaline Phosphatase assay (K902560). Both assays are *in vitro* clinical chemistry methods. Both assays can be used for the

quantitative determination of Alkaline Phosphatase in human serum. Both assays yield similar clinical results.

**Intended Use:**

The Alkaline Phosphatase assay is used for the quantitation of alkaline phosphatase in human serum or plasma.

**Performance Characteristics:**

Comparative performance studies were conducted using the ALCYON™ Analyzer. The Alkaline Phosphatase assay method comparison yielded acceptable correlation with the Roche Cobas Mira Plus Automated Chemistry System Alkaline Phosphatase assay. The correlation coefficient = 0.9981, slope = 1.167, and Y-intercept = -2.324 U/L. Precision studies were conducted using the Alkaline Phosphatase assay. Within-run, between-run, and between-day studies were performed using two levels of control material. The total %CV for Level 1/Panel 111 is 3.8% and Level 2/Panel 112 is 2.6%. The Alkaline Phosphatase assay is linear up to 2,000 U/L. The sensitivity of the Alkaline Phosphatase assay is 6 U/L. These data demonstrate that the performance of the Alkaline Phosphatase assay is substantially equivalent to the performance of the Roche Cobas Mira Plus Automated Chemistry System Alkaline Phosphatase assay.

**Conclusion:**

The Alkaline Phosphatase assay is substantially equivalent to the Roche Cobas Mira Plus Automated Chemistry System Alkaline Phosphatase assay as demonstrated by results obtained in the studies.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

MAY 20 1998

Mark Littlefield  
Section Manager, Regulatory Affairs  
Abbott Laboratories  
1920 Hurd Drive  
Irving, Texas 75038

Re: K981245  
AlkP  
Regulatory Class: II  
Product Code: CJE  
Dated: April 3, 1998  
Received: April 6, 1998

Dear Mr. Littlefield:

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 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 (Pre-market 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 pre-market 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.

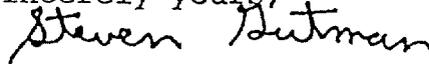
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Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

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" (21 CFR 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/dsmamain.html>".

Sincerely yours,



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): \_\_\_\_\_

Device Name: Alkaline Phosphatase

Indications For Use:

The Alkaline Phosphatase assay is intended to measure alkaline phosphatase in serum or plasma. Measurement of alkaline phosphatase is used in the diagnosis and treatment of liver, bone, parathyroid, and intestinal diseases.

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

\_\_\_\_\_ Concurrence of CDRH, Office of Device Evaluation (ODE) \_\_\_\_\_

Prescription Use   
(Per 21 CFR 801.109)

OR

Over-The-Counter Use \_\_\_\_\_

(Optional Format 1-2-96)

  
\_\_\_\_\_  
(Division Sign-Off)  
Division of Clinical Laboratory Devices  
510(k) Number 12981245

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