

K981759

JUN 16 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  
Regulatory Affairs  
(972) 518-6062  
Fax (972) 753-3367

**Date of Preparation of this Summary:**

May 18, 1998

**Device Trade or Proprietary Name:**

Phos

**Device Common/Usual Name or Classification Name:** Phosphorus

**Classification Number/Class:**

75CEO/Class I

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:**

Phosphorus is an *in vitro* diagnostic assay for the quantitative determination of inorganic phosphorus in human serum, plasma, or urine. The Phosphorus assay is a clinical chemistry assay in which the inorganic phosphorus in the sample reacts with ammonium molybdate to form a heteropolyacid complex. The absorbance is measured at 340 nm and is directly proportional to the amount of inorganic phosphorus present in the sample.

**Substantial Equivalence:**

The Phosphorus assay is substantially equivalent to the following devices:

- Boehringer Mannheim® Phosphorus Assay (K872494) on the Hitachi® 717 Analyzer

These assays yield similar Performance Characteristics.

**Similarities:**

- Both assays are *in vitro* clinical chemistry methods.
- Both assays can be used for the quantitative determination of inorganic phosphorus.
- Both assays yield similar clinical results.

**Differences:**

- There is a minor difference in the assay range.

**Intended Use:**

The Phosphorus assay is used for the quantitation of inorganic phosphorus in human serum, plasma, or urine.

**Performance Characteristics:**

Comparative performance studies were conducted using the AEROSET™ System. The Phosphorus assay method comparison yielded acceptable correlation with the Boehringer Mannheim Phosphorus assay on the Hitachi 717 Analyzer. The correlation coefficient = 0.9939, slope = 1.067, and the Y-intercept = 0.166 mg/dL. For the urine application, the correlation coefficient = 0.9872, slope = 1.040, and Y-intercept = 0.970 mg/dL. Precision studies were conducted using the Phosphorus assay. Within-run, between-run, and between-day studies were performed using two levels of control material. For the serum application, the total %CV for Level 1/Panel 101 control is 1.1% and Level 2/Panel 102 is 0.5%. For the urine application, the total %CV for Level 1/Panel 201 control is 1.6% and Level 2/Panel 202 is 1.5%. The Phosphorus assay is linear up to 25.3 mg/dL for the serum application, and 186.2 mg/dL for the urine application. The limit of quantitation (sensitivity) of the Phosphorus assay is 0.10 mg/dL. These data demonstrate that the performance of the Phosphorus assay is substantially equivalent

to the performance of the Boehringer Mannheim Phosphorus assay on the Hitachi 717 Analyzer for both serum and urine applications.

**Conclusion:**

The Phosphorus assay is substantially equivalent to the Boehringer Mannheim Phosphorus assay on the Hitachi 717 Analyzer for the serum and urine applications as demonstrated by results obtained in the studies.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

JUN 16 1998

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

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

Re: K981759  
Phosphorus  
Regulatory Class: I  
Product Code: CEO  
Dated: May 18, 1998  
Received: May 19, 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.

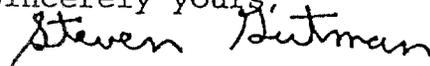
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Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

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

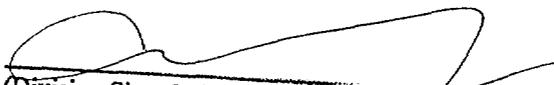
Enclosure

510(k) Number (if known): 62981759

Device Name: Phosphorus

Indications For Use:

The Phosphorus assay is used for the quantitation of inorganic phosphorus in human serum, plasma, or urine. Measurements of phosphorus (inorganic) are used in the diagnosis and treatment of various disorders, including parathyroid gland and kidney diseases, and vitamin D imbalance.

  
(Division Sign-Off)  
Division of Clinical Laboratory Services  
510(k) Number 62981759

(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

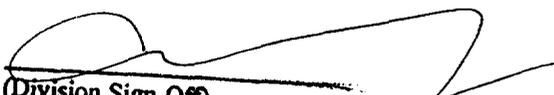
Over-The-Counter Use \_\_\_\_\_  
(Optional Format 1-2-96)

510(k) Number (if known): 62981759

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(Division Sign-Off)  
Division of Clinical Laboratory  
510(k) Number 62981759

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

Prescription Use   
(Per 21 CFR 801.109)

OR

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