DEC 2 6 2002

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Date of Preparation of this Summary:	**November 12, 2002**
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: K023807.

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 the sample 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 404 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 modified Alkaline Phosphatase assay is substantially equivalent to the cleared Alkaline Phosphatase assay (K981806) on the AEROSET® System for the serum or plasma applications. The modifications included changes in the assay parameters for sample volume, main read time, absorbance limit and calibration factor. These modifications did not significantly change the safety and effectiveness profile of the device as demonstrated in the Performance Characteristics Summary.

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Intended Use:

The modified 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 AEROSET® System and the ARCHITECT®c8000™ System. For the AEROSET System, the modified Alkaline Phosphatase assay method comparison yielded acceptable correlation with the Roche Alkaline Phosphatase assay on the Hitachi 717 Analyzer. Three (3) AEROSET systems were used for the comparative studies with the Hitachi system. Forty samples were run on each of the three AEROSET systems. The correlation coefficient of the pooled data = 0.999, slope = 1.06, and Y-intercept = -0.12 U/L. For the ARCHITECT c8000 System, the modified Alkaline Phosphatase assay method comparison yielded acceptable correlation with the AEROSET System. Three (3) ARCHITECT c8000 Systems were used for the comparative performance studies with the AEROSET system. The correlation coefficients were =1.000. 1.000, 1.000, slopes = 0.99, 0.99, 0.98, and Y-intercepts = -2.89, -1.67, 1.21 U/L respectively. Twenty (20) day precision studies were conducted using the original Alkaline Phosphatase assay parameters on the AEROSET and ARCHITECT c8000 systems. Five (5) day precision studies using the original and modified parameters were conducted on the AEROSET and ARCHITECT c8000 systems to determine the impact of the change in parameters on the assay precision performance. A statistical analysis was performed to compare the results obtained from the original parameters to the results obtained with the modified parameters. This analysis demonstrated equivalent precision performance between the original and modified parameters on both systems, with the F-test yielding p-values greater than 0.05. The parameter changes did not impact the precision performance, therefore results from the 20 day studies will be used for the AEROSETand ARCHITECT c8000 claims. Within-run, between-run, and between-day studies were performed using two levels of control material. On the AEROSET, the total

%CV for Level 1 is 3.2% and Level II is 2.5%. On the ARCHITECT c8000 System, the total %CV for Level I ranged from 4.1% to 5.7%, and for Level II the total %CV ranged from 1.9% to 2.2%. The modified Alkaline Phosphatase assay is linear up to 4,555 U/L. The limit of quantitation (sensitivity) of the modified Alkaline Phosphatase assay is 4.6 U/L. These data demonstrate that the performance of the modified Alkaline Phosphatase assay is substantially equivalent to the performance of the cleared Alkaline Phosphatase.

Conclusion:

The modified Alkaline Phosphatase assay is substantially equivalent to the Alkaline Phosphatase (K981806) 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

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DEC 26 2002

Re: k023807
Trade/Device Name: Alkaline Phosphatase
Regulation Number: 21 CFR 862.1050
Regulation Name: Alkaline phosphatase or isoenzymes test system
Regulatory Class: Class II
Product Code: CJE
Dated: November 12, 2002
Received: November 14, 2002

Dear Ms. Morris:

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). Other general information on your responsibilities under the Act may be obtained 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

510(k) Number (if known): K023807

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.

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K023807

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use ____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)