JUN 29 1998

Smart Solutions

HiChem
DIAGNOSTICS

K981769

SUMMARY OF 510(K) SAFETY AND EFFECTIVENESS INFORMATION

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.

HiChem Phosphorus Reagent is intended for the quantitative determination of inorganic phosphorus in serum, plasma and urine. Measurements of inorganic phosphorus are used in the diagnosis and treatment of various disorders, including parathyroid gland and kidney diseases, and vitamin D imbalance.

The HiChem Phosphorus Reagent determines phosphorus by its reaction with molybdate in an acidic solution to form a phosphomolybdate complex. The resulting increase in absorbance at 340 nm is proportional to the phosphorus concentration in the sample.

The HiChem Phosphorus Reagent is an adaptation of the method first described by Simonsen and is intended for use with manual spectrophotometers or clinical analyzers which can automate the required manipulations.

The HiChem Phosphorus Reagent is substantially equivalent to the BMD® Phosphorus Reagent, product no. 857427, manufactured by Boehringer Mannheim Corp., Indianapolis, IN., and the Beckman® SYNCHRON® Systems Phosphorus Reagent, product no. 465145, manufactured by Beckman® Instruments, Brea, CA. All three reagents support the same intended use and produce equivalent results with the same clinical purpose. In addition, they are all based on the same methodology which determines inorganic phosphorus through the colorimetric measurement of the phosphomolybdate complex produced in an acidic reagent.

The effectiveness of the manual procedure is shown by the recovery of linearity standards, the precision of control recoveries, the comparison of serum, plasma and urine recoveries to the BMD® Phosphorus Reagent and the validation of the chemical additives and sensitivity claims.

The recovery of inorganic phosphorus using HiChem Phosphorus Reagent as a manual procedure is linear between 0.1 and 15 mgP/dL as shown by the recovery of linearity standards which span the claimed linear range. Regression statistics are shown below.

(HiChem Recoveries) = 0.1 mgP/dL + 1.004 x (Standard Conc.), $r^2 = 1.000$, $s_{y.x} = 0.10$ mgP/dL, df = 23

Precision, demonstrated by replicate assay of urine pools and commercially available control sera, is shown below.

Specimen	n	mean	within-run SD	total SD
Serum control 1	30	2.09 mgP/dL/L	0.02 mgP/dL	0.03 mgP/dL
Serum control 2	30	6.17 mgP/dL/L	0.07 mgP/dL	0.08 mgP/dL
Urine Pool 1	30	2.10 mgP/dL/L	0.00 mgP/dL	0.00 mgP/dL
Urine Pool 2	30	10.43 mgP/dL/L	0.06 mgP/dL	0.07 mgP/dL

Phosphorus recoveries of 95 mixed serum and plasma specimens and 44 urine specimens are compared between the HiChem manual procedure and the BMD® Phosphorus Reagent on the Hitachi® 704. Least squares regression statistics are shown below.

Serum/ Plasma Comparisons:
(HiChem Results) = -0.1 mgP/dL + 0.982 x (BMD® Results), $r^2 = 0.985$, $s_{y.x} = 0.14$ mgP/dL

Urine Comparisons:
(HiChem Results) = 0.2 mgP/dL + 0.966 x (BMD® Results), $r^2 = 0.999$, $s_{y.x} = 0.11$ mgP/dL

The use of sodium, lithium and ammonium heparin are shown to be acceptable chemical additives by comparison of spiked and unspiked serum pools. In all cases, the biases produced by the additive were less than 0.1 mgP/dL.

The sensitivity claim of 0.1 mgP/dL is documented through the repetitive assay of a diluted serum control. The observed sensitivity limit, calculated as three standard deviations of a 30 replicate within run precision study, is 0.05 mgP/dL and less than the claim of 0.1 mgP/dL.

The effectiveness of the HiChem secondary reagent application for the Beckman® SYNCHRON CX® Systems is shown by the recovery of linearity standards, the precision of control recoveries, the recovery of serum controls over both the calibration stability and on-board stability claims, the validation of the chemical additives and sensitivity claims, and the comparison of patient specimen recoveries to the Beckman® SYNCHRON® Systems Phosphorus Reagent.

The recovery of inorganic phosphorus using the HiChem PO4 Reagent in the SYNCHRON CX® Systems is linear from at least 1.0 mgP/dL to 12.0 mgP/dL as shown by the recovery of six linearity standards which span the claimed linear range. Regression statistics are shown below.

(HiChem Recoveries) = -0.2 mgP/dL + 0.971 x (Standard Conc.), r^2 = 1.000, $s_{y.x}$ = 0.08 mgP/dL, df = 35

Precision, demonstrated by replicate assay of urine pools and commercially available control sera, is shown below.

Specimen	n	mean	within-run SD	total SD
Serum control 1	60	1.89 mgP/dL/L	0.08 mgP/dL	0.09 mgP/dL
Serum control 2	60	4.13 mgP/dL/L	0.11 mgP/dL	0.11 mgP/dL
Serum control 3	60	6.44 mgP/dL/L	0.10 mgP/dL	0.10 mgP/dL
Urine Pool 1	60	2.75 mgP/dL/L	0.11 mgP/dL	0.11 mgP/dL
Urine Pool 2	60	9.46 mgP/dL/L	0.08 mgP/dL	0.13 mgP/dL

Phosphorus recoveries of 153 mixed serum and plasma specimens and 79 urine specimens are compared between the HiChem and Beckman® PO4 Reagents on the SYNCHRON CX® Systems. Least squares regression statistics are shown below.

Serum/ Plasma Comparisons:

(HiChem Results) = -0.4 mgP/dL + 1.040 x (BMD® Results), r^2 = 0.972, $s_{y.x}$ = 0.15 mgP/dL

Urine Comparisons:

(HiChem Results) = -0.2 mgP/dL + 1.001 x (BMD® Results), r^2 = 0.996, $s_{y.x}$ = 0.15 mgP/dL

The use of sodium, lithium and ammonium heparin are shown to be acceptable chemical additives by comparison of spiked and unspiked serum pools. In all cases, the observed biases were less than 0.15 mgP/dL.

The sensitivity claim of 1.0 mgP/dL is documented through the repetitive assay of a diluted serum control. The observed sensitivity limit, calculated as three standard deviations of a 30 replicate within run precision study, is 0.3 mgP/dL and is well below the claimed limit of 0.1 mgP/dL.

The 14 day onboard calibration stability, the 60 day within lot calibration stability and the 30 day on board reagent stability claims are documented through the assay of serum controls and urine pools over the claimed periods. In all cases, estimates of imprecision of phosphorus recoveries over the claimed intervals are less than the greater of 0.3 mgP/dL or 3.%, which is the manufacturer's total precision claim for the SYNCHRON® Analyzer.

The HiChem Phosphorus Reagent is shown to be safe and effective and substantially equivalent to the BMD® Phosphorus Reagent, product no. 857427, manufactured by Boehringer Mannheim Corp., Indianapolis, IN., and the Beckman® SYNCHRON® Systems PO4 Reagent, product no. 465145, manufactured by Beckman® Instruments, Brea, CA.

Wynn Stocking
Manager of Regulatory Affairs
HiChem Diagnostics

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUN 29 1998

Wynn Stocking
Manager, Regulatory Affairs
HiChem Diagnostics
231 North Puente Street
Brea, California 92821

Re: K981769
HiChem Phosphorus Reagent
Regulatory Class: I
Product Code: CEO
Dated: May 18, 1998
Received: May 19, 1998

Dear Mr. Stocking:

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 (Premarket 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 premarket 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.

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 "dsmo@fdadr.cdrh.fda.gov".

Sincerely yours,

Steven Gutman

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

K981769/A

510(k) Number (if known): K981769

Device Name: HiChem Phosphorus Reagent Kit

Indications For Use:

HiChem Phosphorus Reagent is intended for the quantitative determination of inorganic phosphorus in serum, plasma and urine for the diagnosis and treatment of various disorders including parathyroid gland and kidney diseases, and vitamin D imbalance.

This reagent is intended to be used in a professional setting or by trained personnel and is not intended for home use.

Respectfully,

Wynn Stocking

Wynn Stocking
Regulatory Affairs Manager
HiChem Diagnostics

2 June, 1998

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Anon

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K981769

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ____

(Optional Format 1-2-96)

SK-6