JUL 20 1998

K981794

Smart Solutions

HiChem
DIAGNOSTICS

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 Calcium Reagent is intended for the quantitative determination of total calcium in serum, plasma and urine. Calcium measurements are used in the diagnosis and treatment of parathyroid disease, a variety of bone diseases, chronic renal disease and tetany.

The HiChem Calcium Reagent determines calcium by its reaction with arsenazo III to form a blue complex. The resulting increase in absorbance at 650 nm is proportional to the calcium concentration in the sample.

The HiChem Calcium Reagent is an adaptation of the arsenazo III calcium method, first reported by Michaylova and Illkova and is intended to be used either as a manual procedure or on clinical analyzers which can automate the required manipulations.

The HiChem Calcium Reagent is substantially equivalent to the Beckman® SYNCHRON® Systems Calcium Reagent, product no. 442755, manufactured by Beckman® Instruments, Brea, CA. Both reagents support the same intended use and produce substantially equivalent results with the same clinical purpose. In addition, they are both based on the same methodology which determines total calcium through the colorimetric measurement the calcium - arsenazo III complex.

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 Beckman® Calcium Reagent and the validation of the chemical additives and sensitivity claims.

The recovery of total calcium using HiChem Calcium Reagent as a manual procedure is linear between 0.1 to 16 mg/dL as shown by the recovery of linearity standards which span 0 to 18 mg/dL. Regression statistics are shown below.

(HiChem Recoveries) = -0.1 mg/dL + 0.980 x (Standard Conc.), $r^2 = 1.000$, $s_{y.x} = 0.14$ mg/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	6.69 mg/dL	0.21 mg/dL	0.24 mg/dL
Serum control 2	30	12.68 mg/dL	0.29 mg/dL	0.30 mg/dL
Urine Pool 1	30	2.41 mg/dL	0.11 mg/dL	0.11 mg/dL
Urine Pool 2	30	11.10 mg/dL	0.13 mg/dL	0.16 mg/dL

Calcium recoveries of 92 mixed serum and plasma specimens and 44 urine specimens are compared between the HiChem manual procedure and the Beckman® SYNCHRON® Calcium Reagent, used on the SYNCHRON CX® Systems. Least squares regression statistics are shown below.

Serum/ Plasma Comparisons:

(HiChem Results) = -0.3 mg/dL + 1.020 x (BMD® Results) $r^2 = 0.887$ $s_{(y.x)} = 0.21$ mg/dL

Urine Comparisons:

(HiChem Results) = 0.2 mg/dL + 1.022 x (BMD® Results) $r^2 = 0.998$ $s_{(y.x)} = 0.15$ mg/dL

The use of sodium heparin, lithium heparin, ammonium heparin and lithium iodoacetate 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 mg/dL.

The sensitivity claim of 0.2 mg/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 0.15 mg/dL and is below the claimed limit of 0.2 mg/dL.

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an élan company

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 Calcium Reagent.

The recovery of total calcium using the HiChem CA Reagent on the SYNCHRON CX® Systems is linear from at least 2.0 mg/dL to 15.0 mg/dL as shown by the recovery of six linearity standards which span the claimed linear range. Regression statistics are shown below.

(HiChem Recoveries) = 0.0 mg/dL + 0.967 x (Standard Conc.), r^2 = 1.000, $s_{y.x}$ = 0.08 mg/dL, df = 29

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	6.89 mg/dL	0.056 mg/dL	0.064 mg/dL
Serum control 2	60	10.03 mg/dL	0.085 mg/dL	0.089 mg/dL
Serum control 3	60	13.21 mg/dL	0.088 mg/dL	0.090 mg/dL
Urine Pool 1	60	3.24 mg/dL	0.048 mg/dL	0.059 mg/dL
Urine Pool 2	60	11.64 mg/dL	0.075 mg/dL	0.095 mg/dL

Calcium recoveries of 153 mixed serum and plasma specimens and 77 urine specimens are compared between the HiChem and Beckman® CA Reagents on the SYNCHRON CX® Systems. Least squares regression statistics are shown below.

Serum/ Plasma Comparisons:

(HiChem Results) = -0.3 mg/dL + 1.005 x (Beckman® Results) r^2 = 0.924 s(y.x) = 0.20 mg/dL

Urine Comparisons:

(HiChem Results) = 0.1 mg/dL + 1.031 x (Beckman® Results) r^2 = 0.996 s(y.x) = 0.16 mg/dL

The use of sodium heparin, lithium heparin, ammonium heparin and lithium iodoacetate are shown to be acceptable chemical additives by comparison of spiked and unspiked serum pools. In all cases, the observed biases were less than 0.2 mg/dL.

The sensitivity claim of 2.0 mg/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 less than 0.15 mg/dL and is well below the claimed limit of 2.0 mg/dL.

The 14 day onboard 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 calcium recoveries over the claimed intervals are less than the greater of 0.26 mg/dL or 2.6%, which is the manufacturer's total precision claim for the SYNCHRON® Analyzer.

The HiChem Calcium Reagent is shown to be safe and effective and substantially equivalent to the Beckman® SYNCHRON® Systems Calcium Reagent, product no. 442755, manufactured by Beckman® Instruments, Brea, CA.

Wynn Stocking

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

JUL 29 1998

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

Re: K981794
HiChem Calcium Reagent
Regulatory Class: II
Product Code: CJY
Dated: May 20, 1998
Received: May 21, 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.

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 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

510(k) Number (if known): K981794

Device Name: HiChem Calcium Reagent Kit

Indications For Use:

HiChem Calcium Reagent is intended for the quantitative determination of total calcium in serum, plasma and urine for the diagnosis and treatment of parathyroid disease, a variety of bone diseases, chronic renal disease and tetany (intermittent muscular contractions or spasms).

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)

(Division Sign-Off)
Division of Clinical Laboratory Devices
(ODE) Number K981794

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

(Optional Format 1-2-96)