



NOV 26 1999

élan diagnostics

K992842

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[®] ISE Electrolyte Reference is intended for the quantitative determination of sodium, potassium, chloride, and total CO₂ in serum and plasma, and sodium, potassium and chloride in urine, and chloride in cerebrospinal fluid on the Beckman[®] SYNCHRON[®] CX[®] and CX[®] DELTA Systems. On appropriately configured SYNCHRON[®] CX[®] DELTA Systems, HiChem[®] ISE Electrolyte Reference will also determine calcium in serum, plasma and urine.

The HiChem[®] ISE Electrolyte Reference Kit is substantially equivalent to the SYNCHRON[®] CX[®] Systems ISE Electrolyte Reference Kit, product no. 450214, manufactured by Beckman Coulter, Inc.

The effectiveness of the ISE Electrolyte Reference Kit is shown by the following studies.

Precision

Serum and CSF controls, and urine pools were each assayed for calcium, chloride, potassium, sodium, and total CO₂ twice per day in triplicate on a SYNCHRON[®] CX[®] DELTA System using both HiChem[®] and Beckman[®] flow cell reagents, wash solutions and calibrators. Data were collected on ten different days over a thirty day period. Estimates of within run and total imprecision were calculated as described in NCCLS publication EP3-T.

Precision Statistics

Analyte Sample	n	mean	HiChem [®] Reagents				n	mean	Beckman [®] Reagents			
			Within Run		Total				Within Run		Total	
			1SD	%CV	1SD	%CV		1SD	%CV	1SD	%CV	
Calcium in mg/dL												
Serum 1	60	7.9	0.16	2.1%	0.15	1.9%	60	7.9	0.16	2.0%	0.15	2.0%
Serum 2	60	11.1	0.09	0.8%	0.11	1.0%	60	11.2	0.09	0.8%	0.12	1.1%
Serum 3	60	14.2	0.13	0.9%	0.16	1.1%	60	14.4	0.10	0.7%	0.16	1.1%
Urine 1	59	3.4	0.12	3.5%	0.13	3.9%	60	3.5	0.12	3.5%	0.14	4.2%
Urine 2	60	10.9	0.33	3.1%	0.30	2.8%	60	11.1	0.33	2.9%	0.31	2.8%
Chloride in mmol/L												
Serum 1	60	84.5	1.16	1.4%	1.21	1.4%	60	84.6	0.86	1.0%	1.27	1.5%
Serum 2	60	103.2	0.60	0.6%	1.04	1.0%	60	103.4	0.74	0.7%	1.01	1.0%
Serum 3	60	122.6	1.01	0.8%	1.34	1.1%	60	122.2	0.77	0.6%	1.00	0.8%
Urine 1	59	64.1	1.16	1.8%	1.21	1.9%	60	64.1	1.28	2.0%	1.24	1.9%
Urine 2	60	235.6	2.33	1.0%	5.67	2.4%	60	229.6	2.61	1.1%	5.07	2.2%
CSF 1	58	117.5	1.37	1.2%	1.65	1.4%	59	117.3	1.57	1.3%	1.73	1.5%
CSF 2	58	99.1	1.00	1.0%	1.45	1.5%	58	99.2	1.37	1.4%	1.50	1.5%
Potassium in meq/L												
Serum 1	60	2.64	0.021	0.8%	0.034	1.3%	60	2.59	0.019	0.8%	0.035	1.4%
Serum 2	60	5.21	0.031	0.6%	0.040	0.8%	60	5.22	0.037	0.7%	0.043	0.8%
Serum 3	60	7.88	0.074	0.9%	0.083	1.1%	60	7.93	0.057	0.7%	0.065	0.8%
Urine 1	59	27.1	0.23	0.9%	0.27	1.0%	60	27.3	0.31	1.1%	0.32	1.2%
Urine 2	60	123.7	1.67	1.4%	1.67	1.4%	60	124.5	2.22	1.8%	2.10	1.7%

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Precision Statistics (continued)

Analyte	Sample	n	HiChem® Reagents				Beckman® Reagents						
			Within Run		Total		Within Run		Total				
			1SD	%CV	1SD	%CV	n	mean	1SD	%CV	1SD	%CV	
Sodium in meq/L													
	Serum 1	60	114.7	1.71	1.5%	1.51	1.3%	60	114.9	1.72	1.5%	1.69	1.5%
	Serum 2	60	144.4	0.87	0.6%	0.94	0.7%	60	144.9	0.97	0.7%	1.22	0.8%
	Serum 3	60	173.3	1.54	0.9%	1.59	0.9%	60	174.0	1.08	0.6%	1.31	0.8%
	Urine 1	59	45.7	2.02	4.4%	1.78	3.9%	60	45.8	2.51	5.5%	2.15	4.7%
	Urine 2	60	159.9	2.19	1.4%	1.98	1.2%	60	160.4	2.67	1.7%	2.39	1.5%
Total CO ₂ in mmol/L													
	Serum 1	60	12.6	0.40	3.2%	0.38	3.0%	60	12.7	0.38	3.0%	0.36	2.9%
	Serum 2	60	22.2	0.32	1.4%	0.36	1.6%	60	22.3	0.33	1.5%	0.37	1.7%
	Serum 3	60	30.9	0.53	1.7%	0.66	2.1%	60	31.1	0.36	1.2%	0.48	1.5%

Patient Comparison

Serum, plasma, cerebrospinal fluid and urine specimens, collected from adult patients, were assayed for calcium, chloride, potassium, sodium, and total CO₂ on a SYNCHRON® CX® DELTA System using HiChem® and Beckman® flow cell reagents, wash solutions and calibrators. Results were compared by least squares linear regression where X = Beckman® Results and Y = HiChem® Results.

Analyte	Specimen	Unit	n	Regression Statistics			Summary Statistics		
				a	b	r	range	mean X	mean Y
Calcium	Serum/Plasma	mg/dL	160	0.0	0.989	0.985	7.1 - 10.6	9.26	9.13
	Urine	mg/dL	74	-0.2	1.007	0.998	2.4 - 15.2	8.45	8.3
Chloride	Serum/Plasma	mmol/L	160	1.0	0.988	0.935	98.2 - 127.5	107.3	107.0
	Urine	mmol/L	78	-5.1	1.049	0.999	22.4 - 289	126.8	127.9
	CSF	mmol/L	44	-3.4	1.024	0.985	113.8 - 152.4	126.5	126.1
Potassium	Serum/Plasma	meq/L	160	0.13	0.969	1.000	3.20 - 10.82	5.02	5.00
	Urine	meq/L	80	0.01	0.993	1.000	3.48 - 136.0	50.5	50.2
Sodium	Serum/Plasma	meq/L	160	9.1	0.930	0.938	131.8 - 159.1	141.0	140.3
	Urine	meq/L	78	-0.3	1.000	1.000	16.9 - 288.1	118.2	117.8
Total CO ₂	Serum/Plasma	mmol/L	160	1.2	0.949	0.953	9.5 - 29.1	23.3	23.2

Wynn Stocking
 Wynn Stocking
 Manager of Regulatory Affairs
 Elan Diagnostics

20 August, 1999



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

NOV 26 1999

Mr. Wynn Stocking
Manager, Regulatory Affairs
Elan Diagnostics
231 N. Puente Street
Brea, California 92821

Re: K992842
Trade Name: HiChem® ISE Electrolyte Reference
Regulatory Class: II
Product Code: JGS, CEM, CGZ, JFL, JFP
Dated: November 10, 1999
Received: November 12, 1999

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 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). 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.

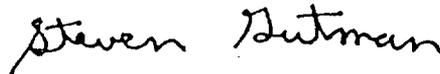
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Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

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/dsma/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): K992842

Device Name: HiChem® ISE Electrolyte Reference

Indications For Use:

HiChem® ISE Electrolyte Reference, when used in conjunction with the HiChem® ISE Electrolyte Buffer, HiChem® CO2 Acid Reagent, HiChem® CO2 Alkaline Buffer, HiChem® Wash Concentrate, and HiChem® Calibrators or Calibration Standards, is intended for the quantitative determination of sodium, potassium, chloride, and total CO2 in serum and plasma, and sodium, potassium and chloride in urine, and chloride in cerebrospinal fluid on the Beckman® SYNCHRON® CX® and CX® DELTA Systems. On appropriately configured SYNCHRON® CX® DELTA Systems, HiChem® ISE Electrolyte Reference will also determine calcium in serum, plasma and urine.

Sodium results are for the diagnosis and treatment of aldosteronism (excessive secretion of the hormone aldosterone), diabetes insipidus (chronic excretion of large amounts of dilute urine, accompanied by extreme thirst), adrenal hypertension, Addison's disease (caused by destruction of the adrenal glands), dehydration, inappropriate antidiuretic hormone secretion, or other diseases involving electrolyte balance. Potassium results are used to monitor electrolyte imbalance in the diagnosis and treatment of diseases and conditions characterized by low or high blood potassium levels. Chloride results are used in the diagnosis and treatment of electrolyte and metabolic disorders such as cystic fibrosis and diabetic acidosis. Carbon dioxide results are used in the diagnosis and treatment of numerous and potentially serious disorders associated with changes in the body's acid-base balance. Calcium results are used in the diagnosis and treatment of parathyroid diseases, chronic renal disease and tetany (intermittent muscular contractions or spasms).

This reagent is intended for professional use only.

Respectfully,

Wynn Stocking
Regulatory Affairs Manager
Elan Diagnostics

10 November, 1999

Jean Cooper
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K992842

(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)