DEC 27 2004

510(k) SUMMARY
K040977

1.0 Submitted By:

C.C. Allain, Ph.D.
Chief Scientific Officer
GenChem, Inc.
471 W. Lambert Road, Ste 107
Brea, CA 92821
Telephone: (714) 529-7125
FAX: (714) 529-3339

2.0 Date of Preparation: June 1, 2004

3.0 Regulatory Information:

3.1 Regulation section: GenChem Electrolyte Buffer
21 CFR § 862.1665
Electrode, Ion Specific, Sodium, Potassium, Chloride, CO2, Calcium

3.2 Clasification : Class II

3.3 Product Code: JGS

3.4 Panel: Clinical Chemistry (75)

4.0 Device Description:

Sodium, Potassium, Chloride, CO2 and Calcium are determined by the use of Ion Specific Electrodes, the conductivity of which is proportional to the concentration of electrolyte in the sample which is mixed with high ionic strength buffer using the ISE Solution as the reference.

5.0 **a.** Predicate Device Name: Electrode, Ion Specific, Sodium, Potassium, Chloride, CO2, Calcium
b. Predicate K Number: K801896
c. Comparison with Predicate: Both Reagents are similar in design, function and chemical principle as well as ingredient composition and concentration.

6.0 Performance Characteristics: All studies were performed on the Beckman CX3® Synchron Analyzer

6.1 Precision/Reproducibility:
Within-Day and Day-to-Day precision was determined according to NCCLS EP5-A. Results are summarized below:

Within-Day; N=60

	S-1	S-2	S-3	U-1	U-2
Mean (mmol/L)	7.1	35.4	63.8	21.7	112.2
SD	0.65	0.62	0.50	0.89	0.75
%CV	9.1	1.9	1.3	3.8	1.1

Day-To-Day (30 Days); N=60

	S-1	S-2	S-3	U-1	U-2
Mean (mmol/L)	7.1	35.4	63.8	21.7	112.2
SD	0.66	0.66	0.80	0.82	1.25
%CV	9.4	1.9	1.3	3.9	1.1

6.2 Linearity/assay reportable range:

Linearity was performed according to NCCLS Guideline EP6-A. Commercially available linearity standards were analyzed in triplicate on the Beckman CX3® and the results analyzed by the Least Squares method. The results are shown below. Specimens exceeding these limits should be diluted with normal saline and reanalyzed. Multiply the result by the appropriate dilution factor.

	Intercept	Slope	R^2	Se_y	Range
Calcium	0.34	0.911	1.000	0.35	0.8 – 14.3 mg/dL
Na	2.37	0.968	1.000	2.61	0 – 200 mmol/L
K	-0.09	1.017	1.000	0.03	0.9 – 15.2 mmol/L
CL	-0.71	0.999	1.000	0.99	0 – 197 mmol/L
CO_2	0.15	1.000	1.000	0.41	0 – 40 mmol/L

The results show this method is linear as shown below:

Calcium	0.8 to 14.3 mg/dl
Chloride	0 to 150 mmol/L
Potassium	0.9 to 15.2 mmol/L
Sodium	0 to 200 mmol/L
Total CO_2	0 to 40 mmol/L

6.3 SENSITIVITY:

The sensitivity of this methodology was documented through the repetitive assay of a serum control first with a known concentration and then diluting the sample until the minimum result was obtained and then run in replicates of 10 on the Beckman Synchron® System. Under the conditions described, the following limits of detection were established:

Analyte	**Limit of Detection**
Calcium	1.5 mg/dL
Sodium	10 mmol/L
Potassium	1.0 mmol/L
Chloride	15 mmol/L
Total CO_2	5.0 mmol/L

6.4 Analytical Specificity:

Determined according to NCCLS EP7-A. Hemoglobin levels up to 500 mg/dL, Bilirubin levels up to 20 mg/dL, and Lipemia levels up to 1800 mg/dL were tested and did not show any adverse effect on a stock sample with levels of sodium at 148 mmol/L, potassium at 5.2 mmol/L, chloride at 119 mmol/L, CO_2 at 19 mmol/L, and calcium at 9.4 mg/dL. Stock solutions of the substance to be tested were prepared at 20x concentrations and 0.5 ml of this stock was placed in a 10 ml volumetric flask and made up to volume with the base pool. The control stock was prepared similarly but with water as the diluent. Only Sodium Heparin, Lithium Heparin and Ammonium Heparin up to 45 Units/mL are acceptable anticoagulants.

7.0 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 CX3® System using GenChem and Beckman flow cell reagents, wash solutions and calibrators. Results were compared by least squares linear regression where X = Beckman Results and Y = GenChem Results.

		Regression Statistics			Summary Statistics	
Analyte	**Specimen**	**Unit**	**n**	**m**	**b**	**r**	**range**
Calcium							
	Serum	mg/dL	80	0.989	0.0	0.985	7.1 - 10.6
	Plasma	mg/dL	80	0.990	0.0	0.995	7.1 – 10.7
	Urine	mg/dL	74	1.007	-0.2	0.998	2.4 - 15.2
Chloride							
	Serum	mmol/L	80	0.988	1.0	0.935	98 - 127
	Plasma	mmol/L	80	0.998	0.8	0.985	98 - 127
	Urine	mmol/L	78	1.049	-5.1	0.999	22 - 289
	CSF	mmol/L	44	1.024	-3.4	0.985	113 - 152
Potassium							
	Serum	mmol/L	80	0.969	0.13	1.000	3.2 - 10.8
	Plasma	mmol/L	80	0.987	0.15	1.000	3.2 – 10.8
	Urine	mmol/L	80	0.993	0.01	1.000	3.5 - 136
Sodium							
	Serum	mmol/L	80	0.930	9.1	0.938	132 - 159
	Urine	mmol/L	78	1.000	-0.3	1.000	17 - 288
Total CO2							
	Serum	mmol/L	80	0.949	1.2	0.953	9.5 - 29
	Plasma	mmol/L	80	0.965	0.9	0.960	9.5 - 29

8.0 Expected Values/ Reference Range:

The expected values for calcium, chloride, potassium, sodium, and total CO2 are listed below. Use these ranges only as guides. Each laboratory should establish its own reference ranges.

Reference Ranges[1]

Analyte	**Specimen**	**Conventional Units**	**SI Units**
Calcium	Serum/Plasma	8.4 - 10.2 mg/dL	2.10 - 2.55 mmol/L
	Urine	100 - 300 mg/day	2.5 - 7.5 mmol/day
Chloride	Serum/Plasma	101 - 111 mmol/L	same
	Urine	110 - 250 mmol/day	same
	CSF	118 - 132 mmol/L	same
Potassium	Serum/Plasma	3.5 - 5.1 mmol/L	same
	Urine	25 - 125 mmol/day	same
Sodium	Serum/Plasma	136 - 145 mmol/L	same
	Urine	40 - 220 mmol/day	same
Total CO2	Serum/Plasma	22 - 28 mmol/L	same

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC 27 2004

C.C. Allain, Ph.D.
Chief Scientific Officer
GenChem, Inc.
471 W. Lambert Road, Suite 107
Brea, CA 92821

Re: k040977
Trade/Device Name: GenChem ISE Electrolyte Buffer
Regulation Number: 21 CFR 862.1665
Regulation Name: Sodium test system
Regulatory Class: Class II
Product Code: JGS, CEM, CGZ, JFL, JFP
Dated: October 15, 2004
Received: October 15, 2004

Dear Dr. Allain:

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). You may obtain other general information on your responsibilities under the Act 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,

Cornelia B. Rooks

Cornelia B. Rooks, MA
Acting Director
Division of Chemistry and Toxicology
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number: K040977

Device Name: GenChem ISE Electrolyte Buffer

Indications For Use:

GenChem ISE Electrolyte Buffer, when used in conjunction with the GenChem ISE Electrolyte Reference, GenChem CO_2 Acid Reagent, GenChem CO_2 Alkaline Buffer, GenChem Wash Concentrate, and appropriate Calibrators or Calibration Standards, is intended for the quantitative determination of sodium, potassium, chloride, and total CO_2 in serum and plasma, and sodium, potassium and chloride in urine, and chloride in cerebrospinal fluid on the Beckman® SYNCHRON CX3® System. GenChem 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 the destruction of the adrenal glands), dehydration, inappropriate antidiuretic hormone secretion, or other diseases involving electrolyte imbalance. 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 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 spasm).

Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K040977

Prescription Use X AND/OR Over-The-Counter Use

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)