February 27, 2018

Awareness Technology, Inc.
Steve Andrus
Quality Assurance Manager
1935 SW Martin Hwy
Palm City, FL 34990

Re: K171476
Trade/Device Name: SelectaLyte Electrolyte Analyzer (Na+, K+, Cl-)
Regulation Number: 21 CFR 862.1665
Regulation Name: Sodium test system
Regulatory Class: Class II
Product Code: JGS, CEM, CGZ, JJE
Dated: December 29, 2017
Received: January 18, 2018

Dear Steve Andrus:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. 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 Part 801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR

Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Kellie B. Kelm -S

for Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
k171476

Device Name

SelectaLyte Electrolyte Analyzer (Na+, K+, Cl-)

Indications for Use *(Describe)*

The SelectaLyte Electrolyte Analyzer (Na+, K+, Cl-) is an in vitro device intended to be used for the measurement of ionized Sodium (Na+), Potassium (K+), and Chloride (Cl-) in serum and lithium heparin venous whole blood samples. The measurements are to be conducted by a trained professional in a clinical laboratory.
For in-vitro diagnostic use only.

The SelectaLyte Sodium (Na+) assay is intended to measure sodium. Measurements obtained by this device are used to monitor electrolyte balance in the diagnosis and treatment of aldosteronism, diabetes insipidus, adrenal hypertension, Addison's disease, dehydration, inappropriate antidiuretic hormone secretion, or other diseases involving electrolyte imbalance.

The SelectaLyte Potassium (K+) assay is intended to measure potassium. Measurements obtained by this device are used to monitor electrolyte balance in the diagnosis and treatment of disease conditions characterized by low or high blood potassium levels.

The SelectaLyte Chloride (Cl-) assays is intended to measure chloride. Measurements are used in the diagnosis and treatment of electrolyte and metabolic disorders such as cystic fibrosis and diabetic acidosis.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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5 510(k)171476 Summary

Applicant: Awareness Technology
1935 SW Martin Highway
Palm City, FL 34990

Contact Person: Steve Andrus
Quality Assurance Manager
Phone: 772.283.6540 ext. 220
Fax: 772.283.8020
Email: sandrus@awaretech.com

Date of Preparation: 02/22/2018

Trade Name: SelectaLyte™ Electrolyte Analyzer (Na^+, K^+, Cl^-)
Common Name: Ion-specific electrolyte analyzer for sodium, potassium and chloride

Product Nomenclature	Class	Product Code	Regulation Number	Review Panel
Electrode, Ion-Specific, Sodium	II	JGS	862.1665	Clinical Chemistry
Electrode, Ion-Specific, Potassium	II	CEM	862.1600	Clinical Chemistry
Electrode, Ion-Specific, Chloride	II	CGZ	862.1170	Clinical Chemistry
Analyzer, Chemistry (Photometric, Discrete), For Clinical Use	I	JJE	862.2160	Clinical Chemistry

Substantial Equivalence

Awareness Technology is claiming substantial equivalence to the predicate device, AVL 9180 Electrolyte Analyzer, 510(k) number K961458.

Description

The SelectaLyte™ Electrolyte Analyzer (Na^+, K^+, Cl^-) is an automated, microprocessor-controlled electrolyte analyzer for measurement of Sodium (Na^+), Potassium (K^+), and Chloride (Cl^-) in serum, whole blood and QC aqueous solutions. The SelectaLyte™ Electrolyte Analyzer (Na^+, K^+, Cl^-) utilizes ion selective electrodes (ISE) to measure test samples, and display the results automatically. The instrument features automatic and on-demand calibration, patient data storage, and interactive LCD touch screen.

Indications of Use

The SelectaLyte™ Electrolyte Analyzer (Na+, K+, Cl-) is an in vitro device intended to be used for the measurement of ionized Sodium (Na+), Potassium (K+), and Chloride (Cl-) in serum and lithium heparin venous whole blood samples. The measurements are to be conducted by a trained professional in a clinical laboratory.

For in vitro diagnostic use only.

The SelectaLyte Sodium (Na+) assay is intended to measure sodium. Measurements obtained by this device are used to monitor electrolyte balance in the diagnosis and treatment of aldosteronism, diabetes insipidus, adrenal hypertension, Addison's disease, dehydration, inappropriate antidiuretic hormone secretion, or other diseases involving electrolyte imbalance.

The SelectaLyte Potassium (K+) assay is intended to measure potassium. Measurements obtained by this device are used to monitor electrolyte balance in the diagnosis and treatment of disease conditions characterized by low or high blood potassium levels.

The SelectaLyte Chloride (Cl-) assays is intended to measure chloride. Measurements are used in the diagnosis and treatment of electrolyte and metabolic disorders such as cystic fibrosis and diabetic acidosis.

Principles of Measurement

The principles of measurement used in the SelectaLyte™ Electrolyte Analyzer (Na^+, K^+, Cl^-), Model 3910 are identical to the principles existing in the electrolyte analyzer to which substantial equivalence is claimed.

The SelectaLyte™ Electrolyte Analyzer (Na^+, K^+, Cl^-) measures sodium, potassium, and chloride in dialysate using ion selective electrode technology. The sodium electrode contains a glass tube, specially formulated to be sensitive to sodium ions. The potassium electrode incorporates neutral carrier ionophore membranes which are highly selective for their respective ions. The chloride electrode contains an ionophore covalently bound to a substrate which is sensitive to negatively charged ions. The potential of each electrode is measured relative to a fixed, stable reference established by a silver/silver chloride electrode in concentrated salt solution. The measured potential varies with the concentration of the ion sensed by the electrode.

Calibration

The SelectaLyte™ Electrolyte Analyzer (Na^+, K^+, Cl^-), Model 3910 preforms a 2-point calibration every 4 hours and by request with a known fluid from the SelectaLyte™ Reagent Pack. A 1-point calibration is preformed automatically during each measurement.

Predicate Comparison

Model	SelectaLyte	AVL
Manufacturer	Awareness Technology Inc.	Roche Diagnostic AVL 9180
Technology	Ion Selective Electrode	Ion Selective Electrode
Intended Use	The SelectaLyte Electrolyte Analyzer (Na+, K+, Cl-) is designed for clinical laboratory use by laboratory professionals to assess the levels of Sodium, Potassium, and Chloride found in serum and lithium heparin venous whole blood. The analysis is performed in-vitro, and neither the analyzer nor any of its components come in contact with the patient. The instrument should be used in laboratories that routinely conform to government regulations or accreditation requirements for quality. On each day of use, analyze the SelectaLyte™ Quality Control Kit Tri Level at least once.	The AVL 9180 Electrolyte Analyzer is intended to be used for the measurement of sodium, potassium, chloride, ionized calcium and lithium in whole blood, serum or plasma, urine, dialysate solutions, or QC materials as appropriate by minimally trained personnel qualified to preform and to report these values in a clinical laboratory setting. These analytes are commonly used in the diagnosis and management of patients with a broad range of renal, metabolic and cardiovascular disorders and, as such, have come to be among those which are considered by the American Association of Clinical Chemistry to have a potential of being life threatening if left uncontrolled.
Electrolytes Measured	Sodium (Na^+), Potassium (K^+), and Chloride (Cl^-)	Sodium (Na^+), Potassium (K^+), Chloride (Cl^-), Lithium(Li^+), Calcium(Ca^{2+})
Samples Type Measured	Serum and lithium heparin venous whole blood	Whole blood, serum or plasma, urine, dialysate solutions, or QC materials
Sample Volume	85 µL	95 µL
Sample Detection Sensor	Yes	No
SE Sample Measurement Range for all Types	Na^+: 40 - 205 mmol/L K^+: 1.5 – 15.0 mmol/L Cl^-: 50 – 200 mmol/L	Na^+: 40 - 205 mmol/L K^+: 1.5 – 15.0 mmol/L Cl^-: 50 – 200 mmol/L

Predicate Comparison Continued

Model	SelectaLyte	AVL
Reagent Pack	Cal Standard: 650mL SLOPE Standard: 125mL Reference Solution: 125 mL Waste bag	Standard A 350 mL Standard B 85 mL Reference Solution 85 mL Waste bag
Results Storage	Sample Results: 200 QC Results: 270	Sample Results: 200 QC Results: 35
Display	Interactive touch screen 8.9cm (3.5”) LCD, color graphic display	32 character, 2 line display
Output	Thermal printer with graphic capability, 29-character width. USB Memory Stick	Thermal paper 32 character, 2-line alphanumeric display
Power Requirements:	100-240VAC, 50/60Hz 55W maximum	100-115 - VAC 50-60 Hz, 0.8 A

Precision Study

In accordance with CLSI EP05-A2 precision evaluation of within-run (Sr), between-run (Srr), and within-lab (ST) precision was determined using two machines and multiple users for 2 runs per day over the duration of 20 days for each matrix.

The precision results for Sodium

Pooled Human Serum	N	Mean (mmol/L)	Within Run SD (mmol/L)	Within Run CV (%)	Run to Run SD (mmol/L)	Run to Run CV (%)	Within Lab SD (mmol/L)	Within Lab CV (%)
(Level 1)	80	95.2	0.27	0.29%	0.53	0.55%	0.78	0.82%
(Level 2)	80	134.7	0.33	0.25%	0.59	0.44%	0.72	0.54%
(Level 3)	80	178.8	0.28	0.16%	1.38	0.77%	1.51	0.84%

The precision results for Potassium

Pooled Human Serum	N	Mean (mmol/L)	Within Run SD (mmol/L)	Within Run CV (%)	Run to Run SD (mmol/L)	Run to Run CV (%)	Within Lab SD (mmol/L)	Within Lab CV (%)
(Level 1)	80	2.77	0.02	0.64%	0.01	0.43%	0.02	0.79%
(Level 2)	80	4.01	0.02	0.52%	0.02	0.51%	0.03	0.78%
(Level 3)	80	6.59	0.02	0.24%	0.06	0.90%	0.06	0.97%

The precision results for Chloride

Pooled Human Serum	N	Mean (mmol/L)	Within Run SD (mmol/L)	Within Run CV (%)	Run to Run SD (mmol/L)	Run to Run CV (%)	Within Lab SD (mmol/L)	Within Lab CV (%)
(Level 1)	80	63.2	0.29	0.46%	0.30	0.48%	0.58	0.91%
(Level 2)	80	90.1	0.31	0.34%	0.62	0.69%	0.74	0.82%
(Level 3)	80	114.4	0.30	0.26%	0.98	0.86%	1.06	0.93%

Precision values for whole blood reported from testing with calibrations every consecutive replicates of 10 to total 40 replicates for each sample.

The precision results for Sodium

Human Whole Blood	N	Mean (mmol/L)	Within Run SD (mmol/L)	Within Run CV (%)	Within Lab SD (mmol/L)	Within Lab CV (%)
(Level 1)	40	98.9	0.69	0.70%	0.42	0.43%
(Level 2)	40	136.8	0.58	0.42%	0.32	0.24%
(Level 3)	40	161.0	0.35	0.22%	0.23	0.14%

The precision results for Potassium

Pooled Human Serum	N	Mean (mmol/L)	Within Run SD (mmol/L)	Within Run CV (%)	Within Lab SD (mmol/L)	Within Lab CV (%)
(Level 1)	40	2.14	0.03	1.33%	0.03	1.27%
(Level 2)	40	3.29	0.07	2.03%	0.07	2.07%
(Level 3)	40	7.78	0.06	0.79%	0.08	1.07%

The precision results for Chloride

Human Whole Blood	N	Mean (mmol/L)	Within Run SD (mmol/L)	Within Run CV (%)	Within Lab SD (mmol/L)	Within Lab CV (%)
(Level 1)	40	69.5	0.88	1.26%	0.57	0.81%
(Level 2)	40	104.4	0.95	0.91%	0.52	0.50%
(Level 3)	40	129.9	0.70	0.54%	0.53	0.40%

Linearity Study

In accordance with CLSI EP06-A equally spaced intermediate concentration samples were prepared accurately by proportionately mixing high and low concentration pools. 4 replicates were read at each level. The testing duration for each analyte was processed on the same day. Acceptable performance criteria by CLIA 88 in 42 CFR 493-931 Routine Chemistry.

Linearity Summary | Matrix: Serum

Analyte	# of Levels	Slope	Intercept	Correlation Coefficient	Tested Range (mmol/L)	Reportable Range (mmol/L)
Sodium	10	0.9878	-3.8077	0.9988	35.9-203.5	40-205
Potassium	11	1.0103	-0.1360	0.9999	1.26-19.62	1.5-15.0
Chloride	11	0.9990	-1.3194	0.9999	30.1-202.3	50-200

Linearity Summary | Matrix: Whole Blood

Analyte	# of Levels	Slope	Intercept	Correlation Coefficient	Tested Range (mmol/L)	Reportable Range (mmol/L)
Sodium	11	1.0064	-4.2822	0.9995	33-217.5	40-205
Potassium	11	1.0083	-0.4117	0.9993	1.45-18.49	1.5-15.0
Chloride	10	1.0003	0.3451	1.0000	33.4-214.6	50-200

Method Correlation Study

In accordance with CLSI EP09-A2 Method comparison to the predicate device was performed with each matrix for each analyte. 10% of the samples were spiked or diluted to fully span the claimed measuring ranges.

Method Correlation Summary Data **Matix: Serum**

Analyte	N	Slope	Intercept	R^2	Syx	Tested Range (mmol/L)	Reportable Range (mmol/L)
Sodium	100	0.971	2.794	0.9869	2.37	43.3-194.2	40-205
Potassium	100	1.014	-0.165	0.9959	2.37	1.51-14.72	1.5-15.0
Chloride	100	0.950	6.143	0.9854	2.36	55-192.6	50-200

Method Correlation Summary Data **Matix: Whole Blood**

Analyte	N	Slope	Intercept	R^2	Syx	Tested Range (mmol/L)	Reportable Range (mmol/L)
Sodium	100	1.002	-1.600	0.9865	1.91	43.3-204.6	40-205
Potassium	100	1.028	-0.205	0.9946	1.91	1.58-14.84	1.5-15.0
Chloride	100	0.953	4.923	0.9806	1.88	53-192.2	50-200

Interference Study

In accordance with CLSI EP07-A2 The interference study is an evaluation of the effects of potentially interfering substances to decrease medically significant error within the laboratory and identify potential hazards. Interferent substances were chosen that have the potential to interfere with analytes (sodium, potassium, chloride) as referenced in Drug Interference and Drug Effects in Clinical Chemistry E5 by Tryding. Each interferent was tested higher than the therapeutic concentration of the relevant drug; then evaluated to show the degree of interference.

The highest concentration of each interferent that did not show interference for the serum sodium, potassium, and chloride assays is shown in the table below.

Interference Effect Summary Data

Analyte	Interferent	Highest concentration tested that did not show significant interference
Serum Sodium	Bilirubin Conjugate	1000.0 mg/dL
	Cholesterol	503.1 mg/dL
	Hemoglobin	200.0 mg/dL
	Isoniazid	4.0 mg/dL
	Lithium Acetate	21.1 mg/dL
	Magnesium Acetate	213.6 mg/dL
	Metronidazole	12.0 mg/dL
Serum Potassium	Bilirubin Conjugate	1000.0 mg/dL
	Cholesterol	503.1 mg/dL
	Hemoglobin	200.0 mg/dL
	Isoniazid	4.0 mg/dL
	Lithium Acetate	21.1 mg/dL
	Magnesium Acetate	213.6 mg/dL
	Metronidazole	12.0 mg/dL
	Sodium Fluoride	0.33 mg/dL
	Sodium Heparin	3000.0 U/L
	Sodium Iodide*	5.6 mg/dL
	Triglycerides	2364.3 mg/dL
	Vancomycin	10.3 mg/dL
Serum Chloride	Acetylcysteine	166.5 mg/dL
	Acetylsalicylic Acid	65.2 mg/dL
	Ampicillin	5.3 mg/dL
	Bilirubin Conjugate	1000.0 mg/dL
	Cefoxitin	69.5 mg/dL
	Cholesterol	200.0 mg/dL
	Doxycycline	3.2 mg/dL
	EDTA	0.13 mg/dL
	Hemoglobin	200.0 mg/dL
	Ibuprofen	55.4 mg/dL
	Isoniazid	4.0 mg/dL
	Lithium Acetate	21.1 mg/dL
	Magnesium Acetate	213.6 mg/dL
	Metronidazole	12.0 mg/dL
	Paracetamol	20.0 mg/dL

*Continued Interference

Interference Effect Summary Data

Analyte	Interferent	Highest concentration tested that did not show significant interference
Serum Chloride	pH (High)	~8.0
	Potassium Thiocyanate	25.1 mg/dL
	Rifampicin	6.4 mg/dL
	Sodium Bicarbonate	294.0 mg/dL
	Sodium Bromide*	24.1 mg/dL
	Sodium Fluoride	0.33 mg/dL
	Sodium Heparin	3000.0 U/L
	Sodium Iodide	5.6 mg/dL
	Triglycerides	2364.3 mg/dL
	Vancomycin	10.3 mg/dL

*Continued Interference

Serum Interference Observations

Cholesterol showed interference with Chloride assay at concentrations 503 mg/dL, 377 mg/dL, 251 mg/dL with a bias greater than 3.4mmol/L.

Potassium Thiocyanate showed interference with Chloride assay at concentrations 66.9 mg/dL, 33.4 mg/dL, with a bias greater than 4.3mmol/L.

Sodium Bromide showed interference with Chloride assay at all concentrations tested with a bias greater than 4.5mmol/L.

Sodium Fluoride showed interference with Chloride and Potassium assays at concentration 0.44mg/dL with a bias of 12.4mmol/L for chloride and 0.64mmol/L for potassium.

Sodium Iodide showed interference with Chloride and Potassium assays at concentration 44.8mg/dL, 22.5 mg/dL, 11.2mg/dL, with a bias of 3.3mmol/L for chloride and continued interference for potassium with a bias greater than 0.24mmol/L.

The highest concentration of each interferent that did not show interference for the whole blood sodium, potassium, and chloride assays is shown in the table below.

Interference Effect Summary Data

Analyte	Interferent	Highest concentration tested that did not show significant interference
Whole Blood Sodium	Acetone	69.7 mg/dL
	Acetylsalicylic Acid	59.1 mg/dL
	Benzalkonium Chloride	0.67 mg/dL
	Bilirubin Conjugate	1000.0 mg/dL
	Bilirubin, Total	20.0 mg/dL
	Cholesterol	503.1 mg/dL
	Creatinine	5.0 mg/dL
	Ethanol	399.9 mg/dL
	Hemoglobin	200.0 mg/dL
	Potassium Thiocyanate	66.9 mg/dL
	Salicylic Acid	59.9 mg/dL
Whole Blood Potassium	Acetone	69.7 mg/dL
	Acetylsalicylic Acid	59.1 mg/dL
	Bilirubin Conjugate	1000.0 mg/dL
	Bilirubin, Total	10.0 mg/dL
	Cholesterol	503.1 mg/dL
	Creatinine	5.0 mg/dL
	Ethanol	399.9 mg/dL
	Hemoglobin	150.0 mg/dL
	Salicylic Acid	15.0 mg/dL
	Sodium Bromide	48.2 mg/dL
Whole Blood Chloride	Acetone	69.7 mg/dL
	Acetylsalicylic Acid	59.1 mg/dL
	Bilirubin Conjugate	1000.0 mg/dL
	Bilirubin, Total	20.0 mg/dL
	Cholesterol	251.6 mg/dL
	Creatinine	5.0 mg/dL
	Ethanol	399.9 mg/dL
	Hemoglobin	200.0 mg/dL
	Potassium Thiocyanate*	8.4 mg/dL
	Salicylic Acid	45.0 mg/dL
	Sodium Bromide*	24.1 mg/dL
	Sodium Iodide	11.3 mg/dL

*Continued Interference

Whole Blood Interference Observations

Bilirubin, Total showed interference with Potassium assay at concentrations 20 mg/dL, 15 mg/dL, with a bias greater than 0.22mmol/L.

Cholesterol showed interference with Chloride assay at concentrations 503 mg/dL, 377 mg/dL, with a bias greater than 3.6mmol/L.

Hemoglobin showed interference with Potassium assay at concentrations 200 mg/dL, 377 mg/dL, 251 mg/dL with a bias greater than 0.27mmol/L.

Whole Blood Interference Observations Continued

Potassium Thiocyanate showed interference with Chloride assay at all concentrations tested with a bias greater than 4.7mmol/L.

Salicylic Acid showed interference with Chloride assay at concentration 60 mg/dL with a bias greater than 8.5 and Potassium assay at concentrations 60 mg/dL, 45 mg/dL, 29mg/dL, 22.5 mg/dL with a bias greater than 0.24mmol/L.

Sodium Bromide showed interference with Chloride assay at all concentrations tested with a bias greater than 22.1mmol/L and Potassium assay at concentrations 386 mg/dL, 193 mg/dL, 93.5 mg/dL, 22.5 mg/dL with a bias greater than 0.32mmol/L.

Sodium Iodide showed interference with Chloride assay at concentration 44.8mg/dL with a bias of 8.2mmol/L.

Avoid Hemolyzed samples for potassium. Hemolyzed samples may give incorrect elevated potassium.

Reference Ranges

Concentration levels for each analyte represent medical decision levels as stated by Mosby's Diagnostic and Laboratory Test Reference 8ed. 2017 (See pages 260, 750, and 874 for additional information)

Analyte	Reference Range (mmol/L)
	Clinical Range
Sodium	136 - 145
Potassium	3.5 - 5.0
Chloride	98 - 106

Conclusions

Analysis of the comparative measurement presented in the 510(k) for this device, data collected for precision, linearity, and correlation demonstrates that the SelectaLyte Electrolyte Analyzer (with Na^+, K^+, Cl^-) is safe, effective and substantially equivalent to the predicate device to which it is compared.