K092462

5. 510(k) Summary – GemLyte Electrolyte Analyzer

(1) Submitted by:

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(3) Summary Prepared:

August 25, 2008

(4) Device Trade Name:

GemLyte Electrolyte Analyzer $Na^+/K^+/Cl^-/Ca^{++}/Li^+$

(5) Regulatory Information

Description	CFR Section	Device Class	Product Code
Sodium Test System	862.1665	Class II	JGS
Potassium Test System	862.1600	Class II	CEM
Chloride Test System	862.1170	Class II	CGZ
Calcium Test System	862.1145	Class II	JFP
Lithium Test System	862.3560	Class II	JIH

(6) Predicate Devices:

Description	510(k)	Analytes
AVL9180	K961458	Sodium, Potassium, Chloride, Calcium and Lithium
IL 943 Flame Photometer	K823480	Sodium, Potassium, Chloride
EasyLyte	K000926	Sodium, Potassium, Chloride
925 Chloridometer	K810615	Chloride

Statement of Technology Characteristics of the Device Compared to Predicate Device

Operating Principle	Predicate Device	GemLyte
Potentiometric Na^+, K^+, Cl^-, Ca^{++}, Li^+	K000926 K961458	Same

(7) Device Description and Indications for Use:

The *GemLyte* is an automated, microprocessor-controlled analyzer which utilizes ion-selective electrodes for the measurement of sodium, potassium, chloride, calcium and lithium in serum, plasma, whole blood and prediluted urine samples. *GemLyte* analyzer is designed with the user in mind, it is fully automated with simple 'Yes' or 'No' commands for menu navigation. This simple interface insures that not only will the analyzer be easy to use for quick analysis, (less than a minute for samples), but also that the testing of samples can be done by even non-skilled operators with relative ease. The analyzer self-calibrates using Diamond Diagnostics Fluid Pack (510(k) 013850) every 4 hours through out the day or on request. Sodium, potassium, chloride and calcium are commonly measured for use in the diagnosis and management of patients with a broad range of renal, metabolic and cardiovascular disorders. Lithium is a drug used to treat mental illness. Mission controls (510 (k) 033063) are the recommended quality control material to be used daily.

The GemLyte Potassium Assay is intended to measure potassium in whole blood, serum, plasma, and urine on the GemLyte Electrolyte Analyzer. Measurements obtained by this device are used to monitor electrolyte balance in the diagnosis and treatment of diseases conditions characterized by low or high blood potassium levels.

The GemLyte Sodium Assay is intended to measure sodium in serum, plasma, and urine on the GemLyte Electrolyte Analyzer. Measurements obtained by this device are used to monitor electrolyte balance in 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 imbalance.

The GemLyte Chloride Assay is intended to measure the level of chloride in plasma, serum, sweat, and urine. Chloride measurements are used in the diagnosis and treatment of electrolyte and metabolic disorders such as cystic fibrosis and diabetic acidosis.

The GemLyte Calcium Assay is intended to measure the total calcium level in serum. Calcium measurements are used in the diagnosis and treatment of parathyroid disease, a variety of bone diseases, chronic renal disease and tetany (intermittent muscular contractions or spasms).

The GemLyte Lithium Assay is intended to measure lithium (from the drug lithium carbonate) in serum or plasma. Measurements of lithium are used to assure that the proper drug dosage is administered in the treatment of patients with mental disturbances, such as manic-depressive illness (bipolar disorder).

(8) Technological Characteristics of the Device:
Principal of Measurement

The principles of measurements used in the *GemLyte* Electrolyte Analyzer are identical to those principles existing in the electrolyte analyzers K000926 (EasyLyte) and K961458 (AVL 9180) and are substantially equivalent to the K823480 (IL Flame Photometer) and K810615 (925 Chloridometer)

Calibration:

The *GemLyte* performs a 2-point calibration (3-point calibration if lithium) every 4 hours or software permits calibration on demand. A 1-point calibration is performed automatically with each measurement.

Technical Specifications: Analyzer tests samples for $Na^+/K^+/Cl^-/Ca^+/Li^+$

Sample Types: Whole Blood, Serum, Plasma or Urine

Sample Size: 95uL blood, plasma, serum
95uL 1:3 dilution of urine

Measurement Range:

Parameter	Matrix	Specified range
Na+	B/P/S/Q	40 - 200 mmol/L
	U	1 - 300 mmol/L
K+	B/P/S/Q	1.5 - 15 mmol/L
	U	5 - 120 mmol/L
Cl-	B/P/S/Q	50 - 200 mmol/L
	U	1 - 300 mmol/L
iCa++	B/P/S/Q	0.3 - 5 mmol/L
Li+	B/P/S/Q	0.2 - 5.5 mmol/L

B = Whole blood P = Plasma S = Serum
Q = Aqueous QC U = Urine

Display Resolution:

Blood, Plasma, Serum, Aqueous QC

Na^+: 0.1 mmol/L
K^+: 0.1 mmol/L or 0.01 mmol/L
Cl^-: 0.1 mmol/L
Ca^{++}: 0.1 mmol/L or 0.01 mmol/L
Li^+: 0.1 mmol/L or 0.01 mmol/L

Urine

Na^+: 0 mmol/L
K^+: 0.1 mmol/L
Cl^-: 0 mmol/L

Reproducibility:

Blood, Plasma, Serum

	Na^+	K^+	Cl^-	Ca^{++}	Li^+
Within Range (n=30)	C.V. ≤1%	C.V. ≤1.5%	C.V. ≤ 2%	SD ≤0.02	SD ≤0.03
Between Run (10 days)	C.V. ≤2%	C.V. ≤3%	C.V. ≤ 3%	SD ≤0.06	SD ≤0.09

Urine

	Na^+	K^+	Cl^-
Within Range (n=30)	C.V. ≤ 5%	C.V. ≤ 5%	C.V. ≤ 5%
Between Run (10 days)	C.V. ≤ 5%	C.V. ≤ 5%	C.V. ≤ 5%

Analysis Time	57 seconds
Calibration	Every 4 hours on demand 2 point calibration Na^+,K^+,Cl^-,Ca^{++} 3 point calibration Li^+

Power

120 VAC	5 Hz, 6 A or
220-240 VAC	24 Hz, 2 A
(Factory set)	

Size and Weight

12.4" (31.5cm) W x 13.2" (33.5cm) H x 11.6" (29.5cm) D, 13 lbs. (<6 kg)

(9) Summary of nonclinical tests submitted with the premarket notification for device.

Precision –

Within-Run Precision is determined for each different sample types, blood, serum and urine, by collecting multiple replicates of each sample type, 30, within a single period of time with out re-calibration of the instrument. Samples of blood and serum are measure in standard blood/serum mode while urine samples are measured in 'Urine Mode'. The standard deviation (SD) and Coefficient Variation (%CV) are calculated. Results are within performance specifications which are not different from the predicate device, AVL 9180(K961458).

	Blood/Plasma/Serum	Urine (1:10 dilution)
Na+	C.V. ≤0.6%	C.V. ≤5%
K+	C.V. ≤1.5%	C.V. ≤5%
Cl-	C.V. ≤1%	C.V. ≤2%
Ca^{++}	SD ≤0.02	
Li^+	SD ≤0.04	

Between-Run or Total Precision is determined by testing 2 runs per day (AM & PM) with 2 replicates per run for 10 days for each sample type. The standard deviation (SD) and/or Coefficient of Variation (%CV) are calculated. Results are summarized below and are similar to predicate device, AVL 9180(K961458) and with in specifications.

	Serum/Blood/Serum	Urine (1:3 dilution)
Na+	C.V. ≤1.5%	C.V. ≤4%
K+	C.V. ≤3%	C.V. ≤5%
Cl-	C.V. ≤3%	C.V. ≤3%
Ca^{++}	SD ≤0.06	
Li^+	SD ≤0.09	

Note: Because potassium in whole blood is unstable, and clinically significant changes are observed within 2 hours of sample collection, a total imprecision test was conducted using multiple instruments (4). Results were collected over a period of an hour.

Linearity

Whole blood, Plasma, Serum and Urine are linear across the claimed performance range. A minimum of 5 levels were tested for each type of sample. Dilutions were made from starting stock solutions and regression analysis done. Correlation coefficients were all greater than 0.99.

(10) Summary of clinical tests submitted with the pre-market notification for the device.

Clinical testing was conducted to demonstrate the correlation of Diamond Diagnostics *GemLyte* Analyzer to predicate devices operated by trained personnel. All sample types, whole blood, plasma, serum and urine were collected for testing on the GemLyte as well as another predicate device, the AVL 9180. Regression analysis show good correlation to predicate devices for all sample types, whole blood, plasma, serum and urine with correlation coefficients typically greater than 0.99.

Correlation Studies

Studies were conducted comparing the Diamond GEMLYTE to the Roche 9180 with whole blood, plasma, serum and spot urine samples.

Whole Blood in mmol/L

Parameter	Slope	Intercept	R^2	Range	n	Ste_{yx}
Sodium	0.988	1.04	0.9962	42.3 – 188.1	128	1.13
Potassium	0.972	0.223	0.9957	1.51 – 14.46	112	0.166
Chloride	1.011	-0.49	0.9882	54.0 – 191.4	123	1.76
Calcium	0.994	0.019	0.9885	0.304 – 4.514	124	0.076
Lithium	0.983	-0.049	0.9919	0.255 – 5.410	123	0.079

Plasma in mmol/L

Parameter	Slope	Intercept	R^2	Range	n	Ste_{yx}
Sodium	0.987	0.87	0.9977	43.5 – 194.4	105	1.06
Potassium	1.006	-0.014	0.9973	1.55 – 13.97	107	0.178
Chloride	1.022	-3.23	0.9879	55.2 – 193.2	115	2.58
Calcium	0.971	0.042	0.9915	0.363 – 4.386	123	0.059
Lithium	0.993	0.002	0.9878	0.298 – 5.071	115	0.092

Serum in mmol/L

Parameter	Slope	Intercept	R^2	Range	n	Ste_{yx}
Sodium	0.99	0.03	0.9964	44.6 – 196.9	122	1.37
Potassium	0.981	0.085	0.9979	1.58 – 14.64	127	0.118
Chloride	1.021	-2.57	0.9687	50.7 – 185.7	125	3.79
Calcium	0.970	0.036	0.9842	0.655 – 4.309	120	0.082
Lithium	1.004	0.092	0.9876	0.213 – 5.149	131	0.122

Urine (Spot) in mmol/L

Parameter	Slope	Intercept	R^2	Range	n	Ste_{yx}
Sodium	0.983	-2.57	0.9843	8– 296	118	8.42
Potassium	0.965	0.34	0.9934	5.3 – 118.2	108	2.22
Chloride	0.976	-1.86	0.9807	15 – 272	118	8.99

(11) Conclusions drawn from the clinical and non-clinical testing.

Analysis of the comparative measurement presented in the 510(k) for this device, together with the linearity and precision data collected during these clinical and non-clinical trails demonstrates that the Diamond Diagnostics *GemLyte* ISE Analyzer (with Na^+, K^+, Cl^-, Ca^{++}, Li^+) is safe, effective and equivalent to the predicate device to which it is compared.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Rockville MD 20850

Diamond Diagnostics, Inc.
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FEB - 6 2009

Re: k082462
Trade Name: GemLyte Electrolyte Analyzer
Regulation Number: 21 CFR 862.1665
Regulation Name: Sodium Test System
Regulatory Class: Class II
Product Codes: JGS, CEM, CGZ, JFP, JIH
Dated: January 27, 2009
Received: January 28, 2009

Dear Ms. Voo:

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,

Courtney C. Harper, Ph.D.
Acting Director
Division of Chemistry and Toxicology
Office of In Vitro Diagnostics Device
Evaluation and Safety
Center for Devices and Radiological Health

Indication for Use

510(k) Number (if known): k082462
Device Name: GemLyte Electrolyte Analyzer
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The GemLyte Calcium Assay is intended to measure the ionized calcium level in whole blood, plasma and serum. Calcium measurements are used in the diagnosis and treatment of parathyroid disease, a variety of bone diseases, chronic renal disease and tetany (intermittent muscular contractions or spasms).

The GemLyte Lithium Assay is intended to measure lithium (from the drug lithium carbonate) in whole blood, plasma and serum. Measurements of lithium are used to assure that the proper drug dosage is administered in the treatment of patients with mental disturbances, such as manic-depressive illness (bipolar disorder).

Prescription Use ___X___ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____. (21 CFR Part 801 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Wesley May acting

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K082462