k 121040

510(k) Summary

(1) Submitted by:

Diamond Diagnostics
333 Fiske St.
Holliston, MA 01746

AUG 3 0 2012

(2) Contact Person:

Liann Voo, Director of Quality Assurance and Scientific Development
Phone: 508-429-0450 (x 351)
Fax: 508-429-0452
E-mail: lvoo@diamonddiagnostics.com

(3) Summary Prepared:

March 26, 2012

(4) Device Trade Name:

SMARTLYTE Electrolyte Analyzer

(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)	Measurand
AVL 9180	K961458	Sodium, Potassium, Chloride, Calcium and Lithium

Statement of Technology Characteristics of the Device Compared to Predicate Device

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

(7) Indications for Use:

The SMARTLYTE 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, pre-diluted urine samples. In addition, the analyzer can also measure sodium, potassium, chloride and calcium in dialysate samples.

The SMARTLYTE Sodium Assay is intended to measure sodium in whole blood, serum, plasma, pre-diluted urine and dialysate on the SMARTLYTE 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 SMARTLYTE Potassium Assay is intended to measure potassium in whole blood, serum, plasma, urine and dialysate. 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 SMARTLYTE Chloride Assay is intended to measure the level of chloride in whole blood, serum, plasma, urine and dialysate. Chloride measurements are used in the diagnosis and treatment of electrolyte and metabolic disorders such as cystic fibrosis and diabetic acidosis.

The SMARTLYTE Calcium Assay is intended to measure ionized calcium levels in whole blood, plasma, serum, and dialysate. 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 SMARTLYTE 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).

(8) Device Descriptions:

The SMARTLYTE Na^+, K^+, Cl^-, Ca^{++}, Li^+ Electrolyte Analyzer which can test serum, plasma, whole blood, pre-diluted urine samples, dialysate solutions and QC materials is identical to GEMLYTE Electrolyte Analyzer (cleared under k082462) which tests serum, plasma, whole blood, pre-diluted urine samples, and QC materials. Both are microprocessor-controlled analyzers which utilize ion-selective electrodes for the measurement of sodium, potassium, chloride, calcium and lithium in serum, plasma, whole blood, pre-diluted urine samples, dialysate solutions and QC materials. 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.

(9) Technological Characteristics of the Device:

Principal of Measurement
The principles of measurements used in the SMARTLYTE Electrolyte Analyzer are identical to those principles existing in the current SMARTLYTE electrolyte analyzer (K082462) and AVL 9180 (K961458) and are substantially equivalent to the K823480 (IL Flame Photometer) and K810615 (925 Chloridometer).

The SMARTLYTE measures sodium, potassium, chloride and calcium in dialysate using ion selective electrode technology. The sodium electrode contains a glass tube, specially formulated to be sensitive to sodium ions. The potassium and calcium each incorporate neutral carrier ionophore membranes which are highly selective for their respective ions. The chloride 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.

Comparison to Predicate Devices:
The software has been modified to add a Dialysate mode. In addition the hardware was changed to allow saving of more than one sample or calibration result and increased QC storage capacity as well. Moreover, an RFID board was added to the CPU board so that individual reagent packs can be monitored for fluid consumption. All other functionality has remained unchanged from the Predicate SMARTLTYE. The Dialysate Mode added is similar to the 9180 Bicarbonate Dialysate Mode.

The table below compares the Candidate Device to its predicates.

	Candidate Device	Predicate
Trade/proprietary name	Diamond Electrolyte Analyzer	Roche Electrolyte Analyzer
Model number	SMARTLYTE	9180
Manufacturer	Diamond Diagnostics Corp	Roche Diagnostics GmBh
510(k)/PMA reference number		K961458
Intended use	Sodium, Potassium, Chloride, Calcium, Lithium Determination	Same
Sample Type	Blood, serum, plasma, urine, aqueous QC, Dialysate	Also has Acetate Dialysate Mode
Measurement Principle	Ion Selective Electrodes	Same
Analysis time	57 sec	Same
Measurement Range, Whole Blood, Plasma, Serum, Dialysate		
Na^+	40 - 200 mEq/L	40 - 205 mEq/L
K^+	1.7 - 15 mEq/L	1.5 - 15 mEq/L
Cl^-	50 - 200 mEq/L	50 - 200 mEq/L
Ca^{++}	0.3 - 5 mmol/L	0.2 - 5.0 mmol/L
Li^+	0.2 - 5.5 mEq/L	0.1 - 6.0 mEq/L
Measurement Range, Urine		
Na^+	3 - 300 mEq/L	1 - 300 mEq/L
K^+	5 - 120 mEq/L	4.5 - 120 mEq/L
Cl^-	15 - 300 mEq/L	1 - 300 mEq/L
Expected, within run CV	≤ 1 %	≤ 1 %
Expected, between run CV	≤ 2 %	≤ 1 %
Expected, within run CV	≤ 1.5 %	≤ 2 %
Expected, between run CV	≤ 3 %	≤ 3 %
Expected, within run CV	≤ 1 %	≤ 1 %
Expected, between run CV	≤ 3 %	≤ 1 %
Expected, within run sd	≤ 0.02	≤ 0.02
Expected, between run sd	≤ 0.06	≤ 0.04
Expected, within run sd	≤ 0.03	≤ 0.02
Expected, between run sd	≤ 0.09	≤ 0.08
Urine Precision, Na		
Expected, within run CV	≤ 5 %	Same
Expected, between run CV	≤ 5 %	≤ 7 %
Urine Precision, K		
Expected, within run CV	≤ 5 %	Same
Expected, between run CV	≤ 5 %	Same
Urine Precision, Cl		
Expected, within run CV	≤ 5 %	Same
Expected, between run CV	≤ 5 %	Same
Calibration	Automatic and on Demand	Same
Reagent Pack	Standard A 350 ml Standard B 85 ml Standard C 85 ml Reference Solution 85 ml Waste bag R/W RFID Tag for monitoring individual fluid pack consumption	No RFID Tag
Results Storage	Measurement results, 1000 QC Levels 1, 2, 3 results, each 500 Calibration Results, 5	Measurement results, 1 QC Levels 1, 2, 3 results, total 35 Calibration Results, 1
Output	32 character, 2 line alphanumeric display thermal printer RS-232 Serial port USB ports (2) RFID Board to R/W RFID Tag	Same Same Same
Power	100-115 ~ VAC 50-60 Hz, 0.8 A or 220~VAC 50/60 Hz, 0.4 A	Same Same Same

Calibration:

The SMARTLYTE performs a 2-point calibration (3-point calibration if lithium) every 4 hours. The software also 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, Urine, Dialysate

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

Measurement Range:

Parameter	Matrix	Specified range
Na+	B/P/S/D/Q	40 - 200 mEq/L
	U	1 - 300 mEq/L
K+	B/P/S/D/Q	1.5 - 15 mEq/L
	U	5 - 120 mEq/L (60 – 120 mEq/L with additional dilutions)
Cl-	B/P/S/D/Q	50 - 200 mEq/L
	U	1 - 300 mEq/L
iCa++	B/P/S/D/Q	0.3 - 5 mmol/L
Li+	B/P/S/Q	0.2 - 5.5 mEq/L

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

Display Resolution:

Blood, Plasma, Serum, Dialysate, Aqueous QC

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

Urine

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

Reproducibility:

Blood, Plasma, Serum, Dialysate

	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)

---

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

Precision – Whole blood, serum, plasma and urine were previously cleared (K082462).

Within run precision was calculated from three dialysate samples for each measurand. The sample concentrations were at the low and high end of reference ranges and near the mid point range. The protocol called for running 30 replicates of each sample without calibration between measurements. The replicates were run consecutively in one day.

	Within Run
Na+	C.V. ≤ 1%
K+	C.V. ≤ 2%
Cl-	C.V. ≤ 2%
Ca++	SD ≤ 0.02

Total precision was calculated for 3 samples with concentrations spanning the reportable range. The dialysate samples were run in groups of 10, with a calibration between each group of 10 replicates. This procedure was adopted due to the inherent instability of Calcium in the carbonate/bicarbonate environment which would result in Ca shifts.

Dialysate

	Between Run
Na+	C.V. ≤ 2%
K+	C.V. ≤ 3%

Cl- C.V. ≤ 3%
Ca++ SD ≤ 0.06

Precision Dialysate, mEq/L

Within Run	Na^+	K+	Cl-	Ca^{++}
Mean	122.45	2.7073	83.93	0.8013
SD	0.39	0.0235	0.75	0.0087
%CV	0.32	0.87	0.89	
N	30	30	30	30
Run to Run	Na^+	K+	Cl-	Ca^{++}
Mean	122.41	2.7243	83.48	0.7975
SD	0.40	0.0347	1.20	0.0076
%CV	0.32	1.27	1.44	
N	40	40	40	40

	Na^+	K+	Cl-	Ca^{++}
Mean	139.56	4.0400	107.32	1.2491
SD	0.45	0.0111	0.35	0.0143
%CV	0.32	0.28	0.33	
N	30	30	30	30
	Na^+	K+	Cl-	Ca^{++}
Mean	140.59	4.0718	107.91	1.2347
SD	0.76	0.0359	0.58	0.0158
%CV	0.54	0.88	0.53	
N	40	40	40	40

	Na^+	K+	Cl-	Ca^{++}
Mean	158.12	6.7653	123.05	1.7015
SD	0.74	0.0265	0.29	0.0155
%CV	0.47	0.39	0.24	
N	30	30	30	30
	Na^+	K+	Cl-	Ca^{++}
Mean	158.77	6.7618	123.55	1.6788
SD	0.80	0.0693	0.72	0.0226
%CV	0.51	1.02	0.59	
N	40	40	40	40

Linearity - Whole blood, serum, plasma and urine were previously cleared (K082462).
Linearity was evaluated by preparing stock solutions with high concentrations of Na^+, K^+, Cl and Ca^{++} in dialysate. These stocks were diluted to concentrations across the measuring ranges of each analyte and matrix. Linear regression was performed on the results using expected values based on the stock sample dilution. The results are shown below.

Dialysate, Measured compared to Expected Values, mEq/L

Parameter	Slope	Intercept	R^2	Range	Ste_{yx}	n
Sodium	0.9806	2.53	0.9995	24 – 205	1.12	34
Potassium	1.0031	-0.37	0.9976	1.4 – 15.1	0.20	36
Chloride	0.9996	1.60	0.9998	40 - 202	0.74	34
Calcium	0.9857	0.06	0.9972	0.4 - 5.0	0.07	48

The linearity studies support the following reportable range.

Measuring Range Dialysate
Na: 40 - 200 mEq /L
K: 1.7 - 15 mEq /L
Cl: 50 - 200 mEq /L
Ca: 0.3 - 5.5 mmol/L

(11) Summary of clinical tests - Whole blood, serum, plasma and urine were previously cleared (K082462).

Clinical testing was conducted to demonstrate the correlation of Diamond Diagnostics SMARTLYTE Analyzer to predicate devices operated by trained personnel. Dialysates were collected for testing on the SMARTLYTE and the predicate device, the Roche 9180. Some samples were spiked or diluted to fully span the claimed measuring ranges. The results are summarized below. Regression analysis show good correlation to predicate with correlation coefficients typically greater than 0.99 and slope values between 0.96 and 1.04.

Dialysate Comparison SMARTLYTE versus AVL 9180 (k961458)

Parameter	Slope	Intercept	R^2	Range	n	St_{yx}
Sodium	1.0183	-2.52	0.9989	49 – 179	43	1.31
Potassium	0.9882	0.04	0.9996	1.5 - 14	56	0.08
Chloride	0.9825	2.86	0.9966	52 - 199	51	2.25
Calcium	1.0021	0.03	0.9956	0.25 – 4.5	43	0.08

The method comparison study supports correlation in the following reportable range.

Measuring Range Dialysate

Na: 40 - 205 mEq /L
K: 1.7 - 11 mEq /L
Cl: 50 - 205 mEq /L
Ca: 0.3 - 5.5 mmol/L

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

Analysis of the dialysate comparative measurements 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 SMARTLYTE Electrolyte Analyzer (with Na^+, K^+, Cl^-, Ca^{++}, Li^+) is safe, effective and substantially equivalent to the predicate devices, AVL 9180 (k961248).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

10903 New Hampshire Avenue
Silver Spring, MD 20993

Diamond Diagnostics, Inc.
c/o Kathy Cruz
333 Fiske St.
Holliston, MA 01746

AUG 30 2012

Re: k121040
Trade Name: SMARTLYTE 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: August 2, 2012
Received: August 3, 2012

Dear Kathy Cruz:

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. 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...

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) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm

Sincerely yours,

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): k121040

Device Name: SMARTLYTE Electrolyte Analyzer

Indications For Use:

The SMARTLYTE 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, pre-diluted urine samples. In addition, the analyzer can also measure sodium, potassium, chloride and calcium in dialysate samples.

The SMARTLYTE Sodium Assay is intended to measure sodium in whole blood, serum, plasma, pre-diluted urine and dialysate on the SMARTLYTE 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 SMARTLYTE Potassium Assay is intended to measure potassium in whole blood, serum, plasma, urine and dialysate. 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 SMARTLYTE Chloride Assay is intended to measure the level of chloride in whole blood, serum, plasma, urine and dialysate. Chloride measurements are used in the diagnosis and treatment of electrolyte and metabolic disorders such as cystic fibrosis and diabetic acidosis.

The SMARTLYTE Calcium Assay is intended to measure ionized calcium levels in whole blood, plasma, serum, and dialysate. 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 SMARTLYTE 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___ And/Or Over the Counter Use _____
(21 CFR Part 801 Subpart D) (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)

Yung Chan

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

510(k) k121040