510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY AND INSTRUMENT COMBINATION TEMPLATE

A. 510(k) Number:

k121040

B. Purpose for Submission:

Add a new matrix type, dialysate, to a previously cleared device- SMARTLYTE Electrolyte analyzer (k082462) for Sodium, Potassium, Chloride, and Calcium

C. Measurand:

Sodium, Potassium, Chloride, Calcium, Lithium

D. Type of Test:

Ion Selective Electrode

E. Applicant:

Diamond Diagnostics, Inc.

F. Proprietary and Established Names:

SMARTLYTE Electrolyte Analyzer

G. Regulatory Information:

1. Regulation section:

   21 CFR 862.1665 – Sodium Test System

   21 CFR 862.1600 – Potassium Test System

   21 CFR 862.1170 – Chloride Test System

   21 CFR 862.1145 – Calcium Test System

   21 CFR 862.3560 – Lithium Test System

2. Classification:

   Class II

3. Product code:

   JGS, CEM, CGZ, JFP, and JIH, respectively

4. Panel:

   75 – Chemistry (Sodium, Potassium, Chloride, and Calcium)
   91 – Toxicology (Lithium)

H. Intended Use:

1. Intended use(s):

   See indications for use below.

2. Indication(s) 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, dialysate and 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, 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 on the SMARTLYTE 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 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).

3. Special conditions for use statement(s):

   For prescription use only

   Bicarbonate based dialysis fluid should be analyzed in the Bicarbonate mode. Analysis should be carried out as quickly as possible after collection of the sample into an air tight container to prevent changes in Bicarbonate concentration.

4. Special instrument requirements:

   Diamond Diagnostics SMARTLYTE Electrolyte Analyzer

I. Device Description:

The SMARTLYTE is an automated, microprocessor-controlled analyzer which utilizes ion-selective electrodes for the measurement of sodium, potassium, chloride, calcium and lithium. The analyzer self- calibrates using Diamond Diagnostics Fluid Pack (k013850) every 4 hours through out the day or on request. Mission controls (k033063) are the recommended quality control material to be used daily.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   Roche AVL Electrolyte Analyzer 9180

2. Predicate 510(k) number(s):

   k961458 for Roche Electrolyte Analyzer

3. Comparison with predicate:

Characteristics		Predicate k961458 Roche Electrolyte Analyzer 9180	Proposed k121040 SMARTLYTE Electrolyte Analyzer
Intended Use /Indications for use		An automated analyzer for the measurement of sodium, potassium, chloride, calcium, and lithium	Same
Methodology		Same	Same
Sample Type		Whole blood, serum and plasma, urine and dialysate	Same
Measuring Range (Whole blood, plasma, serum and dialysate)	Na^+	40 -205 mEq/L	40 -200 mEq/L
	K^+	1.5 -15 mEq/L	1.7 -15 mEq/L
	Cl^-	50 -200 mEq/L	50 -200 mEq/L
	Ca^{2+}	0.2 -5 mmol/L	0.3 -5 mmol/L
	Li^+	0.1 -6.0 mEq/L	0.2 -5.5 mEq/L
Measuring Range Urine	Na^+	1 -300 mEq/L	3 -300 mEq/L
	K^+	4.5 -120 mEq/L	5 -120 mEq/L
	Cl^-	1 -300 mEq/L	15 -300 mEq/L
R/W RFID TAG for monitoring individual fluid pack consumption		No	Yes

K. Standard/Guidance Document Referenced (if applicable):

None were referenced.

L. Test Principle:

The SMARTLYTE measures sodium, potassium, chloride, ionized calcium, and lithium using ion selective electrode technology. The flow-through sodium electrode contains a glass tube, specially formulated to be sensitive to sodium ions. The flow-through potassium, chloride, ionized calcium, and lithium electrodes incorporate a neutral carrier ionophore membrane. The potential of each electrode is measured relative to a fixed, stable voltage established by the silver/silver chloride reference electrode. An ion selective electrode develops a voltage that varies with the concentration of the ion to which it responds. The relationship between the voltage developed and the concentration of the sensed ion is logarithmic.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

Performance studies for this submission are limited to dialysate samples only. Please refer to the original submission (k082462) for the studies performed on whole blood, serum, plasma, and urine samples for each analyte.

a. Precision/Reproducibility:

Three levels (spent dialysates) of each analyte across the measuring range were used for the study. Within run precision was performed by running 30 replicates of each level without calibration between measurements. The replicates were run consecutively in one day. For run-to-run precision, the samples were measured twice a day in duplicate for ten consecutive days resulting in n=40 replicates. The acceptance criteria for sodium, potassium and chloride were expressed as %CV, while SD was used for Calcium. The results are summarized below.

Within Run precision for dialysate:

Sample 1	**Na+(**mEq/L)	**K+(**mEq/L)	**Cl-(**mEq/L)	**Ca2+**(mmol/L)
Mean	122.45	2.7073	83.93	0.8013
%CV	0.32	0.87	0.89	SD=0.0087
n	30	30	30	30

Sample 2	**Na+(**mEq/L)	**K+(**mEq/L)	**Cl-(**mEq/L)	**Ca2+**(mmol/L)
Mean	139.56	4.0400	107.32	1.2491
%CV	0.32	0.28	0.33	SD=0.0143
n	30	30	30	30

Sample 3	**Na+(**mEq/L)	**K+(**mEq/L)	**Cl-(**mEq/L)	**Ca2+**(mmol/L)
Mean	158.12	6.7653	123.05	0.8013
%CV	0.47	0.39	0.24	SD=0.0155
n	30	30	30	30

Run-to-Run Precision for dialysate:

Sample 1	**Na+(**mEq/L)	**K+(**mEq/L)	**Cl-(**mEq/L)	**Ca2+**(mmol/L)
Mean	122.41	2.7243	83.48	0.7975
%CV	0.32	1.27	1.44	SD=0.0074
n	40	40	40	40

Sample 2	**Na+(**mEq/L)	**K+(**mEq/L)	**Cl-(**mEq/L)	**Ca2+**(mmol/L)
Mean	140.59	4.4718	107.91	1.2347
%CV	0.54	0.88	0.53	SD=0.0158
n	40	40	40	40

Sample 3	**Na+(**mEq/L)	**K+(**mEq/L)	**Cl-(**mEq/L)	**Ca2+**(mmol/L)
Mean	158.12	6.7653	123.05	0.8013
%CV	0.51	1.02	0.59	SD=0.0226
n	40	40	40	40

b. Linearity/assay reportable range:

Linearity was evaluated by preparing serially diluted solutions with 17 different concentrations covering entire measuring range of Na+, K+, Cl-, Ca2+ in spent dialysates. Linear regression was performed on the results using expected values based on the stock sample dilution. The results are shown below.

Parameter	Slope	Intercept	R2	Claimed Measuring	n
Sodium	0.980	2.53	0.999	40-200 mEq/L	34
Potassium	1.003	-0.37	0.997	1.7-15 mEq/L	36
Chloride	0.999	1.60	0.999	50-200 mEq/L	34
Calcium	0.985	0.06	0.997	0.3-5 mmol/L	48

The data provided in the linearity studies supports the sponsor's claimed measuring ranges.

c. Traceability, Stability, Expected values (controls, calibrators, or methods):

Calibrators were previously cleared under k013850 and controls under k033063.

d. Detection limit:

Reportable ranges were determined based on the linearity studies (see M.1.b. above)

e. Analytical specificity:

Prepared dialysate solutions are aqueous solutions of salts typically consisting of the analytes at the concentrations close to the following: 140 mEq/L Sodium, 1.25 mmol/L Calcium, 1.0 mEq/L Potassium, 1.0 mEq/L Magnesium, 105.5 mEq/L Chloride, 4.00 mEq/L Acetate, 0.1 % Dextrose, and 39 mEq/L Bicarbonate. The effects of endogenous and exogenous factors would vary depending upon the formulation of the membrane used in the electrode. Spent dialysate may contain urea, lactate, glucose and creatinine and other small molecules from the hemodialysis process. Interference studies were performed on the possible interferents found in spent dialysates using dialysates spiked with the potential interference substances. The % biases were calculated between the spiked and un-spiked samples. All samples were tested in replicates of ten. The % bias between the spiked samples and un-spiked samples were all within ± 10% bias for the following concentrations tested.

Endogenous Interference:

Interferent tested	Concentration tested
Urea	30.81 mg/dL
Lactate	108.11 mg/dL
Glucose	216.22 mg/dL
Creatinine	5.66 mg/dL

The sponsor has placed the following limitations in the labeling:

"A number of substances have been reported to cause physiological changes in blood, serum and plasma analyte concentrations. These substances can also alter dialysates. Medications and endogenous substances can affect results and clinicians must evaluate results based on the patient's entire clinical situation."

"Bicarbonate based dialysis fluid should be analyzed in the Bicarbonate mode. Analysis should be carried out as quickly as possible after collection of the sample into an air tight container to prevent changes in Bicarbonate concentration."

f. Assay cut-off:

No Applicable

2. Comparison studies:

a. Method comparison with predicate device:

Method comparisons to the predicate device (Roche Electrolyte 9180 analyzer) were performed with spent dialysate samples. Some samples were spiked or diluted to fully span the claimed measuring ranges. The results are summarized below.

	Dialysate				
	slope	**intercept**	**R^2**	**n**	**conc. tested**
Sodium	1.0183	-2.52	0.9989	43	49-179 mEq/L
Potassium	0.9882	0.04	0.9996	56	1.5-14 mEq/L
Chloride	0.9825	-2.86	0.9966	51	52-199 mEq/L
Calcium	1.0021	0.03	0.9956	43	0.3-4.5 mmol/L

b. Matrix comparison:

Not applicable

3. Clinical studies:

a. Clinical Sensitivity:

Not Applicable

b. Clinical specificity:

Not Applicable

c. Other clinical supportive data (when a. and b. are not applicable):

Not Applicable

4. Clinical cut-off**:**

Not applicable

5. Expected values/Reference range:

The values given in the tables below are intended to be used only as a guide. Each laboratory or testing site should establish its own range of normal values, taking into account factors such as age, sex, diet, and other determinants of electrolyte levels.

Whole Blood, Serum, Plasma (mmol/L)*

Na^+ 136 - 145 mmol/L
K^+ 3.5 - 5.1 mmol/L
Cl^- 97 - 111 mmol/L
iCa^{++} 1.0 - 1.30 mmol/L
Li^+ 0.6 - 1.2 mmol/L

Urine (mmol/L)*
Na^+ 40 - 220 mmol/L
K^+ 25 - 120 mmol/L
Cl^- 110 - 250 mmol/L

*From Burtis C, Ashwood E (Eds.), Tietz Textbook of Clinical Chemistry, 2nd ed. (Philadelphia: W.B. Saunders, Co., 1994)

N. Instrument Name:

Diamond Diagnostics SMARTLYTE Electrolyte Analyzer

O. System Descriptions:

1. Modes of Operation:

Fully automated with 'Yes' or 'No' commands for menu navigation.

2. Software:

FDA has reviewed applicant's Hazard Analysis and software development processes for this line of product types:

Yes ___X____ or No _____

3. Specimen Identification:

   Manual

4. Specimen Sampling and Handling:

   Samples are manually placed on the instrument one at a time, tested, and removed.

5. Calibration:

   One point automated on board calibration performed every four hours or upon request. The slope is calculated during calibration and stored for sample measurement.

6. Quality Control:

   Controls are run manually and recommended daily. Results can be stored in instrument memory for future use.

P. Other Supportive Instrument Performance Characteristics Data Not Covered In The "Performance Characteristics" Section above:

Matrix Stability Study:

Aliquots of prepared dialysate solution stored in tightly closed air impermeable containers were tested at room temperature, 22 C, in the refrigerator (4 – 8 oC) and in the freezer, -20 oC for 24 hours, and each aliquot was returned to appropriate storage condition for additional 24 hours. The concentration change for each analyte before and after the study was calculated. The test results were shown below:

Sodium Stability				
Date	**Day Stored**	**Temp, ^{O}C**	**Concentration**	**% Decrease**
7/11/2012	0	4	137.2	-
7/12/2012	1	4	137.7	0.4%
7/13/2012	2	4	138.6	1.0%
7/16/2012	0	-	134.2	-
7/17/2012	1	-	130.1	-3.0%
Potassium Stability				
Date	**Day Stored**	**Temp, ^{O}C**	**Concentration**	**% Decrease**
7/11/2012	0	4	1.018	-
7/12/2012	1	4	1.015	-0.3%
7/13/2012	2	4	1.019	0.1%
7/16/2012	0	-	1.038	-
7/17/2012	1	-	1.024	-1.3%
Chloride Stability				
Date	**Day Stored**	**Temp, ^{O}C**	**Concentration**	**% Decrease**
7/11/2012	0	4	108.6	-
7/12/2012	1	4	108.0	-0.6%
7/13/2012	2	4	108.7	0.0%
7/16/2012	0	-	107.6	-

7/17/2012	1	-	106.8	-0.7%
Calcium Stability				
Date	**Day Stored**	**Temp, ^{0}C**	**Concentration**	**% Decrease**
7/11/2012	0	4	1.04	-
7/12/2012	1	4	0.99	-
7/13/2012	2	4	0.72	-31%
7/16/2012	0	-	1.01	-
7/17/2012	1	-	0.59	-41%

The study results indicate that ionized calcium is not stable in bicarbonate dialysate solutions. Since prepared dialysate is not stable, spent dialysate is not expected to be stable during storage. Dialysates should be tested as soon as possible after collection.

Q. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

R. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.