K102959

1. 510(k) Summary– *PROLYTE* Electrolyte Analyzer

(1) Submitted by:

Diamond Diagnostics
333 Fiske St.
Holliston, MA 01746

JAN 14 2011

(2) Contact Person:

Liann Voo, Director, QA and Scientific Development
Phone: 508-429-0450 (x351)
Fax: 508-429-0452
E-mail: lvoo@diamonddiagnostics.com

(3) Summary Prepared:

January 07, 2011

(4) Device Trade Name:

PROLYTE Electrolyte Analyzer $Na^+/K^+/Cl^-$

(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

Panel: Chemistry, 75

(6) Predicate Devices:

Description	510(k)	Analytes
PROLYTE Electrolyte Analyzer	K070104	Sodium, Potassium, Chloride

Statement of Technology Characteristics of the Device Compared to Predicate Device:

Operating Principle	Predicate Device	PROLYTE
Potentiometric Na+, K+, Cl- Electrodes	K070104	SAME

(7) Device Description:

The PROLYTE is an automated, microprocessor-controlled analyzer which utilizes ion-selective electrodes for the measurement of sodium, potassium and chloride in serum, plasma, whole blood and pre-diluted urine samples. The PROLYTE analyzer is designed with the user in mind. It is fully automated with simple 'Yes' or 'No' commands for menu navigation. This simple interface ensures that the analyzer be easy to use for quick analysis, (one minute for most samples), but also that the testing of samples can be done by even non-skilled operators with relative ease. The analyzer can be programmed to self-calibrate using Mission Diagnostics Fluid Pack Na/K/Cl (510(k) 031159) at set intervals or on request. Sodium, potassium and chloride are commonly measured for use in the diagnosis and management of patients with a broad range of renal, metabolic and cardiovascular disorders. Mission Controls (510(k) 033063) are the recommended quality control material to be used daily.

(8) Intended Use:

a. Intended use(s):

The PROLYTE is intended to be a direct replacement for the PROLYTE Electrolyte Analyzer (k070104).

The PROLYTE Electrolyte Analyzer is designed for clinical laboratory use by laboratory professionals to assess the levels of Sodium, Potassium, and Chloride found in whole blood, serum, plasma, and urine of patients. The analysis is performed *in-vitro*, and neither the analyzer nor any of its components come in contact with the patient.

This analyzer is used by laboratory trained technicians in clinical laboratories to aid in the diagnosis and treatment of patients with electrolyte imbalance. These locations routinely conform to CLIA regulations, and conduct daily quality control programs.

b. Indication(s) for use:

The PROLYTE is an automated, microprocessor-controlled analyzer which utilizes ion-selective electrodes for the measurement of sodium, potassium, and chloride in whole blood, plasma, serum, and pre-diluted urine samples.

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

For In Vitro Diagnostic Use

(9) Technological Characteristics of the Device:

Measurement Principles:
The principles of measurement used in the PROLYTE Electrolyte Analyzer are identical to those principles existing in the Predicate electrolyte analyzer k070104 PROLYTE.

The PROLYTE measures sodium, potassium and chloride in whole blood, serum, plasma, and urine, using ion selective electrode technology. The sodium electrode contains a glass tube, specially formulated to be sensitive to sodium ions. The potassium incorporates a neutral carrier ionophore membrane. 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 Device:
The software for the PROLYTE has been rewritten. However, the functionality has remained primarily unchanged from the Predicate. The major change is in QC storage which allows for 3 control levels instead of 2 to be stored. In addition, the reportable range for the PROLYTE is wider for Na and K in Urine. Blood analysis time is slightly longer in the PROLYTE than the Predicate. Urine analysis time is shorter.

Comparison Table below shows primary similarities and differences.

SIMILARITIES		
Item	**Device**	**Predicate**
Measurement Method	Ion Selective Electrodes	Same
Analytes Measured	Sodium, Potassium, Chloride	Same
Sample Matrix	Whole Blood, Plasma, Serum, Urine	Same
Calibration	Automatic and On-Demand	Same
Measuring Range Whole Blood, Plasma, Serum	Na: 45 - 205 mEq/L K: 1.5 - 11 mEq/L Cl: 45 - 205 mEq/L	Same
Measuring Range Urine	Cl: 25 - 505 mEq/L	Same

DIFFERENCES		
Item	**Device**	**Predicate**
Measuring Range Urine	Na: 25 - 1020 mEq/L K: 10 - 505 mEq/L	Na: 30 - 1020 mEq/L K: 20 - 505 mEq/L
Blood Analysis Time	59 seconds	57 seconds
Urine Analysis Time	69 seconds	93 seconds
QC Storage	Low, Normal, High, 30 each	Normal, Abnormal, 20 each

(10) Summary of non-clinical tests:

Precision –

Within run precision was calculated with results from three whole blood, serum, plasma, and urine samples for each analyte. 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. Sodium, potassium and chloride all demonstrated precision within the limits defined below.

	Serum/Blood	Urine (1:10 dilution)
Na+	C.V. ≤ 1%	C.V. ≤ 2.5%
K+	C.V. ≤ 2%	C.V. ≤ 2.5%
Cl-	C.V. ≤ 2%	C.V. ≤ 2.5%

Typical Within Run Imprecision Results:

Whole Blood, mEq/L

	Na+	K+	Cl-
Mean	114.27	2.678	70.79
SD	0.69	0.021	0.57
%CV	**0.60**	**0.79**	**0.80**
N	30	30	30
Pass/Fail	P	P	P

	Na+	K+	Cl-
Mean	136.11	4.103	96.02
SD	0.80	0.032	0.62
%CV	**0.58**	**0.78**	0.64
N	30	30	30
Pass/Fail	P	P	P

	Na+	K+	Cl-
Mean	160.57	6.887	125.42
SD	1.47	0.083	0.91
%CV	**0.91**	**1.20**	0.72
N	30	30	30
Pass/Fail	P	P	P

Plasma, mEq/L

	Na+	K+	Cl-
Mean	93.07	2.376	61.27
SD	0.89	0.036	0.46
%CV	0.95	1.50	0.75
N	30	30	30
PASS/FAIL	P	P	P

	Na+	K+	Cl-
Mean	142.95	4.354	103.69
SD	0.78	0.037	0.59
%CV	0.55	0.85	0.57
N	32	32	32
PASS/FAIL	P	P	P

	Na+	K+	Cl-
Mean	165.80	6.622	123.57
SD	1.04	0.031	0.58
%CV	0.63	0.46	0.47
N	30	30	30
PASS/FAIL	P	P	P

Serum, mEq/L

	Na+	K+	Cl-
Mean	120.10	3.026	70.30
SD	0.77	0.020	1.03
%CV	0.64	0.66	1.47
N	30	30	30
PASS/FAIL	P	P	P

	Na+	K+	Cl-
Mean	145.16	4.755	97.02
SD	0.86	0.034	0.65
%CV	0.59	0.70	0.67
N	30	30	30
PASS/FAIL	P	P	P

	Na+	K+	Cl-
Mean	163.21	6.536	118.80
SD	1.12	0.056	1.48
%CV	0.68	0.85	1.25
N	30	30	30
PASS/FAIL	P	P	P

Urine, mEq/L

	Na+	K+	Cl-
Mean	33.26	31.967	52.89
SD	0.18	0.290	0.91
%CV	0.54	0.91	1.72
N	30	30	30
PASS/FAIL	P	P	P

	Na+	K+	Cl-
Mean	121.83	78.548	184.34
SD	0.83	0.384	1.15
%CV	0.68	0.49	0.62
N	30	30	30
PASS/FAIL	P	P	P

	Na+	K+	Cl-
Mean	202.84	112.432	274.38
SD	1.11	0.945	1.52
%CV	0.55	0.84	0.56
N	30	30	30
PASS/FAIL	P	P	P

Within Run Imprecision at Instrument Reporting Limits

Whole Blood, mEq/L

	Na+	K+	Cl-
Mean	53.15	1.678	47.90
SD	0.53	0.025	0.88
%CV	1.0	1.5	1.8
N	30	30	30
Pass/Fail	P	P	P

	Na+	K+	Cl-
Mean	193.33	10.363	196.26
SD	1.48	0.056	2.00
%CV	0.76	0.54	1.0
N	30	30	30
Pass/Fail	P	P	P

Plasma, mEq/L

	Na+	K+	Cl-
Mean	53.10	1.753	49.64
SD	0.65	0.025	0.83
%CV	1.23	1.41	1.68
N	30	30	30
Pass/Fail	P	P	P

	Na+	K+	Cl-
Mean	189.21	9.6407	197.15
SD	1.10	0.0934	1.26
%CV	0.58	0.97	0.64
N	30	30	30
Pass/Fail	P	P	P

Serum, mEq/L

	Na+	K+	Cl-
Mean	54.01	1.693	53.38
SD	0.46	0.024	0.88
%CV	0.85	1.41	1.65
N	30	30	30
Pass/Fail	P	P	P

	Na+	K+	Cl-
Mean	187.37	9.914	180.09
SD	0.94	0.070	1.42
%CV	0.50	0.71	0.79
N	30	30	30
Pass/Fail	P	P	P

Urine, mEq/L

	Na+	K+	Cl-
Mean	28.52	11.63	39.91
SD	0.56	0.14	0.99
%CV	1.95	1.17	2.47
N	30	30	30
Pass/Fail	P	P	P

	Na+	K+	Cl-
Mean	908.9	493.1	420.9
SD	6.4	3.1	1.8
%CV	0.70	0.62	0.42
N	30	30	30
Pass/Fail	P	P	P

Total precision was calculated with results from three whole blood, serum, plasma, and urine samples for each analyte. The samples concentrations were at the low and high end of reference ranges and near the mid point range. The serum, plasma and urine samples were measured twice each morning and twice each afternoon for ten consecutive days resulting in 40 replicates. Whole blood total precision was conducted on 2 different instruments with calibrations every consecutive replicates of 10 to total 40 replicates for each sample. Sodium, potassium and chloride all demonstrated total precision within the limits defined below.

	Serum/Blood	Urine (1:10 dilution)
Na+	C.V. ≤ 2%	C.V. ≤ 5%
K+	C.V. ≤ 2.5%	C.V. ≤ 5%
Cl-	C.V. ≤ 2.5%	C.V. ≤ 5%

Typical Total Imprecision Results:

Whole Blood, mEq/L

	Na+	K+	Cl-
Mean	113.69	2.649	71.24
SD	1.06	0.032	0.92
%CV	**0.93**	**1.23**	**1.30**
N	40	40	40
Pass/Fail	P	P	P

	Na+	K+	Cl-
Mean	136.36	4.103	96.51
SD	0.99	0.024	1.09
%CV	**0.72**	**0.59**	1.13
N	39	40	39
Pass/Fail	P	P	P

	Na+	K+	Cl-
Mean	161.22	6.924	126.41
SD	1.37	0.149	1.37
%CV	**0.85**	**2.15**	**1.09**
N	40	40	40
Pass/Fail	P	P	P

Plasma, mEq/L

	Na+	K+	Cl-
Mean	118.98	2.902	74.01
SD	0.85	0.050	0.93
%CV	0.71	1.73	1.25
N	40	40	40
PASS/FAIL	P	P	P

	Na+	K+	Cl-
Mean	143.89	4.502	99.58
SD	1.00	0.056	0.83
%CV	0.70	1.25	0.83
N	40	40	40
PASS/FAIL	P	P	P

	Na+	K+	Cl-
Mean	160.66	6.230	121.81
SD	0.94	0.092	0.99
%CV	0.59	1.48	0.81
N	40	40	40
PASS/FAIL	P	P	P

Serum, mEq/L

	Na+	K+	Cl-
Mean	119.04	2.970	69.02
SD	0.91	0.027	1.24
%CV	0.76	0.91	1.80
N	40	40	40
PASS/FAIL	P	P	P

	Na+	K+	Cl-
Mean	144.03	4.732	100.13
SD	1.26	0.038	0.83
%CV	0.88	0.80	0.83
N	40	40	40
PASS/FAIL	P	P	P

	Na+	K+	Cl-
Mean	160.71	6.502	119.93
SD	1.66	0.078	1.05
%CV	1.03	1.19	0.87
N	40	40	40
PASS/FAIL	P	P	P

Urine, mEq/L

	Na+	K+	Cl-
Mean	39.32	25.452	109.67
SD	1.50	0.398	2.77
%CV	3.82	1.57	2.53
N	40	40	40
PASS/FAIL	P	P	P

	Na+	K+	Cl-
Mean	116.87	79.485	183.51
SD	1.19	0.845	3.11
%CV	1.02	1.06	1.69
N	40	40	40
PASS/FAIL	P	P	P

	Na+	K+	Cl-
Mean	227.06	129.180	253.35
SD	3.35	1.178	4.45
%CV	1.48	0.91	1.76
N	40	40	40
PASS/FAIL	P	P	P

Total Imprecision at Instrument Reporting Limits

Whole Blood, mEq/L

	Na+	K+	Cl-
Mean	53.46	1.667	48.93
SD	0.71	0.030	0.83
%CV	1.33	1.82	1.70
N	40	40	40
Pass/Fail	P	P	P

	Na+	K+	Cl-
Mean	195.85	10.337	190.47
SD	1.91	0.109	3.05
%CV	0.98	1.05	1.60
N	40	18	40
Pass/Fail	P	P	P

Plasma, mEq/L

	Na+	K+	Cl-
Mean	55.43	1.7795	50.07
SD	0.83	0.0297	0.87
%CV	1.49	1.67	1.73
N	40	40	40
Pass/Fail	P	P	P

	Na+	K+	Cl-
Mean	189.28	9.709	198.86
SD	1.39	0.065	1.97
%CV	0.74	0.67	0.99
N	40	40	40
Pass/Fail	P	P	P

Serum, mEq/L

	Na+	K+	Cl-
Mean	55.26	1.700	53.56
SD	0.75	0.028	0.93
%CV	1.36	1.66	1.73
N	40	40	40
Pass/Fail	P	P	P

	Na+	K+	Cl-
Mean	187.10	9.9300	181.39
SD	1.70	0.1050	1.68
%CV	0.91	1.06	0.93
N	40	40	40
Pass/Fail	P	P	P

Urine, mEq/L

	Na+	K+	Cl-
Mean	28.67	11.48	35.52
SD	0.66	0.17	1.01
%CV	2.30	1.44	2.83
N	40	40	40
Pass/Fail	P	P	P

	Na+	K+	Cl-
Mean	907.82	501.53	447.05
SD	6.26	6.06	2.89
%CV	0.69	1.21	0.65
N	40	40	40
Pass/Fail	P	P	P

Linearity

Linearity was evaluated by preparing stock solutions with high concentrations of Na+, K+, and Cl- in whole blood, plasma, serum, and urine. 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.

Whole blood Linearity, Measured compared to Expected Values

Parameter	Slope	Intercept	R^2	Range	n
Sodium	1.0050	-3.8	0.9993	23 – 204	42
Potassium	1.0112	-0.24	0.9994	0.7 – 11.6	36
Chloride	1.0005	3.4	0.9973	33 - 211	42

Plasma Linearity, Measured compared to Expected Values

Parameter	Slope	Intercept	R^2	Range	n
Sodium	0.9806	1.666	0.9993	30 - 205	42
Potassium	0.999	0.0555	0.9995	0.9 – 11.2	54
Chloride	0.9777	1.555	0.9985	31 – 209	42

Serum Linearity, Measured Concentration compared to Expected Values

Parameter	Slope	Intercept	R^2	Range	n
Sodium	1.0021	0.3748	0.9997	20 – 219	33
Potassium	0.9989	0.0184	0.9995	1.3 – 13.1	33
Chloride	1.0264	-1.0423	0.9965	15 – 238	27

Urine, Measured Concentration compared to Expected Values

Parameter	Slope	Intercept	R^2	Range	n
Sodium	1.0002	-2.1049	0.9996	16 – 1085	40
Potassium	1.0082	3.1433	0.9991	9 – 547	36
Chloride	0.9860	1.965	0.9991	22 - 504	34

The linearity studies support the following reportable range.

Measuring Range Whole Blood, Plasma, Serum	Na: 45 - 205 mEq/L K: 1.5 - 11 mEq/L Cl: 45 - 205 mEq/L
Measuring Range Urine	Na: 20 - 1020 mEq/L K: 10 - 505 mEq/L Cl: 25 - 505 mEq/L

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

Method comparisons to predicate device were performed with whole blood, plasma, serum and urine patient samples. A small number of samples were spiked or diluted to fully span the claimed measuring ranges. The results are summarized below.

Whole Blood Comparison, New PROLYTE versus Predicate, Original PROLYTE (k070104)

Parameter	Slope	Intercept	R^2	Range	n
Sodium	1.0054	-2.9043	0.9875	48 – 205	110
Potassium	1.0095	-0.0675	0.9891	1.59 – 10.2	111
Chloride	0.9987	-2.1711	0.9844	45 - 203	108

Plasma Comparison of New PROLYTE and Predicate, Original PROLYTE (k070104)

Parameter	Slope	Intercept	R^2	Range	n
Sodium	1.0243	-4.1003	0.9971	49 - 205	101
Potassium	0.9875	0.1004	0.9961	1.5 – 11.0	104
Chloride	1.0176	-7.9389	0.9965	45 – 204	101

Serum Comparison, of New PROLYTE and Predicate, Original PROLYTE (k170104)

Parameter	Slope	Intercept	R^2	Range	n
Sodium	1.0119	-4.2748	0.9936	46 - 204	103
Potassium	0.9800	0.106	0.9950	1.5 – 10.8	100
Chloride	1.0144	-4.8408	0.9922	49 – 203	106

Urine Comparison, of New PROLYTE and Predicate, Original PROLYTE (k070104)

Parameter	Slope	Intercept	R^2	Range	n
Sodium	0.9798	4.5946	0.9995	25 – 1020	102
Potassium	0.9879	0.0762	0.9991	11 – 499	105
Chloride	1.0179	-1.809	0.9933	26 – 504	101

The method comparison studies support correlation in the reportable range.

Measuring Range Whole Blood, Plasma, Serum	Na: 45 - 205 mEq/L K: 1.5 - 11 mEq/L Cl: 45 - 205 mEq/L
Measuring Range Urine	Na: 25 - 1020 mEq/L K: 10 - 505 mEq/L Cl: 25 - 505 mEq/L

(12) 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 *PROLYTE* Electrolyte Analyzer with new software is safe, effective and substantially equivalent to its predicate device, the original PROLYTE (k070104).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Diamond Diagnostic, Inc.
c/o Liann Voo
Regulatory Affairs Specialist
333 Fiske Street
Holliston, MA 01746

Re: k102959
Trade Name: Prolyte Electrolyte Analyzer
Regulation Number: 21 CFR §862.1665
Regulation Name: Sodium Test System.
Regulatory Class: Class II
Product Codes: JGS, CEM, CGZ
Dated: December 23, 2010
Received: December 23, 2010

JAN 14 2011

Dear Liann 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); 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 Parts 801 and 809), 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 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) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

4. Indications for Use

510 (k) Number (if known):

Device Name: PROLYTE Electrolyte Analyzer

Indication For Use:

The PROLYTE is an automated, microprocessor-controlled analyzer which utilizes ion-selective electrodes for the measurement of sodium, potassium, and chloride in whole blood, plasma, serum, and pre-diluted urine samples.

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

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)

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

510 (k) K102959