K070104

MAY - 7 2008

5. 510(k) Summary– *proLYTE* Electrolyte Analyzer

(1) Submitted by:

Diamond Diagnostics
333 Fiske St.
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(2) Contact Person:

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(3) Summary Prepared:

April 22, 2008

(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

(6) Predicate Devices:

Description	510(k)	Analytes
IL 943 Flame Photometer	K823480	Sodium, Potassium
EasyLyte	K000926	Sodium, Potassium, Chloride
AVL 9180	K961458	Sodium, Potassium, Chloride
925 Chloridometer	K810615	Chloride

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

Operating Principle	Predicate Device	*proLYTE*
Potentiometric Na+, K+, Cl-	K000926	SAME
	K961458	

(7) Device Description and Indications for Use:

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 prediluted urine samples. *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 insures that not only will 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 ILyte 800 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) J33063) are the recommended quality control material to be used daily.

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

The principles of measurement used in the *proLYTE* 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 943 Flame Photometer) and K810615 (925 Chloridometer).

Calibration:

The *proLYTE* performs a 2-point calibration daily and permits calibration on demand. A 1-point calibration is performed automatically with each measurement.

Technical Specifications:

	Analyzer tests samples for $Na^+/K^+/Cl^-$	
Sample:	Whole Blood, Serum, Plasma or Urine	
Sample Size:	100 µL Whole Blood, Serum, Plasma or 400 µL diluted (1:10) Urine	
Measurement Range:	Blood	Na^+: 45 - 205 mmol/L
		K^+: 1.5 - 11 mmol/L
		Cl^-: 45 - 205 mmol/L
	Urine	Na^+: 30 - 1020 mmol/L
		K^+: 20 - 505 mmol/L
		Cl^-: 25 - 505 mmol/L
Display Resolution:	Na^+: 0.1 mmol/L	K^+: 0.01 mmol/L Cl^-: 0.1 mmol/L
Analysis Time	55 sec. (Blood), 90 sec. (Urine)	
Data storage, (on board RAM)	125 Patient results, up to 20 QC results normal and abnormal	
Calibration	automatic and/or on demand	

Analyzer has an output for a printer/computer.

Power
100-115 ~ VAC 50-60 Hz, 0.8 A or
220~VAC 50/60 Hz, 0.4 A
(Factory set)

Size & Weight
9.5" (24cm) W x 16.5" (42cm) H x 8.0" (20cm) D, 13 lbs. (5.8 kg)

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

Precision –

Within-Run Precision is determined for each of the different sample types, blood, serum and urine, by collecting multiple replicates of each sample type, minimum of 30, within a single period of time without re-calibration of the instrument. Samples of blood, plasma and serum are measured in standard blood/plasma/serum mode while urine samples are

measured in 'Urine Mode'. The standard deviation (SD) and Coefficient of Variation (%CV) are calculated. Results were within performance specifications which are similar to predicate device, Easylyte (K000926).

	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%

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 Coefficient of Variation (%CV) are calculated. Results were within performance specifications summarized below and are similar to predicate device, Easylyte (K000926).

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

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 *proLYTE* Analyzer to predicate devices operated by trained personnel. All sample types, whole blood, plasma, serum and urine were collected for testing on the proLYTE as well as another predicate device, the Easylyte. 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.

(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 *proLYTE* ISE Analyzer (with Na+, K+, Cl-) is safe, effective and equivalent to those predicate devices to which it is compared.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Diamond Diagnostics, Inc.
c/o Ms. Liann Voo
333 Fiske Street
Holliston, MA 01746

MAY - 7 2008

Re: k070104
Trade Name: proLYTE Electrolyte Analyzer
Regulation Number: 21 CFR 862.1665
Regulation Name: Sodium Test System.
Regulatory Class: Class II
Product Code: JGS, CEM, CGZ
Dated: April 24, 2008
Received: April 24, 2008

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 (240) 276-0490. 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 (240) 276-3150 or at its Internet address at http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Jean M. Cooper, M.S., D.V.M.

Jean M. Cooper, M.S., D.V.M.
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 Statement

510(k) Number (if known): K070104

Device Name: *proLYTE* Electrolyte Analyzer

Indications For Use:

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.

For *In Vitro* Diagnostic Use

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K070104