3/18/99

K990036

IV. 510(K) SUMMARY: CARESIDE LYTES™ SAFETY AND EFFECTIVENESS

I. Applicant Information

A.	Applicant Name	**CARESIDE, Inc.**
B.	Applicant/Manufacturer Address	6100 Bristol Parkway Culver City, CA 90230
C.	Telephone Number	310-338-6767
D.	Contact Person	Kenneth B. Asarch, Pharm.D., Ph.D.
E.	FAX Number	310-338-6789
F.	e-Mail Address	AsarchK@CARESIDE.com
G.	Date 510(k) Summary prepared	December 29, 1998

II. Device Information

A. Device Name (Trade): **CARESIDE LYTES™, CARESIDE *Analyzer*™**

B. Device Name (Classification):
Sodium Test System ..... (75JGS)
Potassium Test System ..... (75CEM)
Chloride Test System ..... (75CGZ)
Micro chemistry analyzer for clinical use ..... (75JJF)

C. Device Classification

Clinical Chemistry Panel Test System Name	Regulation Number	Regulatory Class
Sodium test System	862.1665	2
Potassium Test System	862.1600	2
Chloride Test system	862.1170	2
Micro chemistry analyzer for clinical use	862.2170	1

D. Special controls and performance standards: None applicable

III. Substantial Equivalence Claim

A. General equivalency claim

The ability to monitor sodium, potassium and chloride by ion-selective electrodes based upon the technique of direct differential potentiometry is widely recognized and has gained widespread acceptance.

Sodium, Potassium and Chloride *in vitro* diagnostic products and associated instruments to measure these analytes using direct and indirect differential potentiometry in conjunction with ion-specific electrodes are already on the U.S. market.

B. Specific equivalency claim

The CARESIDE LYTES™ test cartridge is substantially equivalent in principle, intended use, and clinical performance to the currently marketed Vitros slides for the quantitative measurement of sodium, potassium and chloride ions on the Vitros DT 60 II / DTE II. The CARESIDE *Analyzer*™ is substantially equivalent in principle, intended use, and clinical performance to the currently marketed Vitros DT 60 II / DTE II. Johnson and Johnson (formerly Eastman Kodak, Inc.) manufactures all three slides and the instrument.

Name of Predicate Devices:	Predicate Device 510K number	Product Code
Vitros Na^+ DT Slides	K912844	75JGS/75CHH
Vitros K^+ DT Slides	K912844	75CEM/75CHH
Vitros Cl^- DT Slides	K912844	75CGZ/75CHH
Vitros DT 60 II / DTE II	K912844	75JFF/75CHH

IV. Device Description

The CARESIDE LYTES™, a single-use disposable *in vitro* diagnostic test cartridge, is used with the CARESIDE *Analyzer*™ to perform a simultaneous quantitative measurement of sodium, potassium and chloride ion concentrations from a single sample of anti-coagulated whole blood, plasma or serum. Each cartridge has a test element containing sodium-, potassium-, and chloride-selective electrodes. The CARESIDE LYTES™ test cartridge aids in specimen separation and delivers a measured volume of plasma or serum to the electrochemistry to initiate the measurement of sodium, potassium and chloride ion concentrations. The cartridge (patent pending) contains all reagents necessary to measure the concentration of sodium, potassium and chloride ions.

A. Explanation of Device Function

The measurement of sodium, potassium, and chloride ion concentration is each based upon the technique of differential potentiometry using a direct (undiluted) specimen. Each CARESIDE LYTES™ cartridge consists of a slide containing two identical sodium-, potassium-, and chloride-selective electrodes mounted in a plastic base with a hinged lid. Each electrode consists of a silver and silver chloride layer with an overlying membrane that is selective for the particular ion. A reference solution containing known concentrations of sodium, potassium, and chloride ions is contained within a pouch in the test cartridge.

The user introduces the whole blood specimen into the cartridge Sample Well, closes the lid and inserts the cartridge into the CARESIDE *Analyzer*™. Once loaded, the CARESIDE *Analyzer*™ scans the cartridge barcode, brings the cartridge and the contained specimen to 37°C, and spins the cartridge to move the sample from the Sample Well into the cartridge channels and chambers. Forty-five microliters of sample remain in the metering passage. Any excess sample flows into an overflow well. A plunger opens the reference solution pouch and dispenses the reference solution. The metered volume of specimen is dispensed onto the test element by a plunger displacing a flexible seal that covers the Sample Well while a second plunger seals the cartridge vent. As the flexible seal is displaced, air is pushed through the metering passage, forcing the specimen onto the test element. Reference fluid is applied to one set of electrodes (reference electrodes) at the same time as the specimen is applied to the second set of electrodes (specimen electrode). The reference and specimen fluids spread towards each other over a thread that serves as an ionic bridge, forming a stable liquid junction at the center. A voltage develops at each electrode in response to the concentration of the ion to which it is selective. Terminals move into contact with the test element electrodes and measure the voltage difference between the specimen and reference side of the test element.

The difference in voltage between the reference and specimen electrode for each ion is proportional to the logarithm of the ion concentration in the specimen. Based upon the principle of differential potentiometry, the CARESIDE *Analyzer*™ uses the voltage difference to calculate sodium, potassium, and chloride ions concentrations.

B. Test Summary

Measurement of sodium, potassium, and chloride ions from blood is useful in the diagnosis and treatment of patients with electrolyte imbalance.

Sodium

Blood sodium levels can be elevated due to dehydration, diabetes insipidus, salt poisoning, skin losses, hyperaldosteronism, and CNS disorders. Conditions that can decrease sodium levels include cirrhosis, dehydration, and syndrome of inappropriate anti-diuretic hormone.

Potassium

Blood potassium levels can be elevated due to renal glomerular disease, adrenocortical insufficiency, diabetic ketoacidosis, sepsis, and *in vitro* hemolysis. Decreases in potassium levels can be caused by renal tubular disease, hyperaldostronism, treatment of diabetic ketoacidsosis, hyperinsulinism, metabolic alkalosis, and diuretic therapy.

Chloride

Blood chloride levels can be elevated due to prolonged diarrhea, renal tubular disease, hyperparathyroidism, and dehydration. Decreased blood chloride levels can be caused by prolonged vomiting, burns, salt-losing renal disease, over-hydration, and diuretic therapy.

V. Intended Use

A. Intended Use

The CARESIDE LYTES™ cartridge is intended for *in vitro* diagnostic use in conjunction with the CARESIDE™ *Analyzer* to quantitatively measure sodium, potassium and chloride ion concentrations in anti-coagulated whole blood, plasma or serum.

B. Indications for Use

CARESIDE LYTES™ To be used with the CARESIDE *Analyzer™* to measure sodium, potassium, and chloride ion concentrations using anti-coagulated whole blood, plasma or serum specimens to aid in the diagnosis and treatment of patients with disorders of electrolyte imbalance.

CARESIDE *Analyzer™* For *in vitro* diagnostic use by laboratory professionals. Used in conjunction with reagent cartridges to duplicate manual analytical procedures in order to measure a variety of analytes.

VI. Technological Characteristics

A. Similarities

	CARESIDE LYTES™ Test Cartridge	Vitros Na^+, K^+, Cl^- DT Slides
Intended Use	**CARESIDE LYTES™** To measure sodium, potassium, and chloride ions to aid in the diagnosis and treatment of patients with electrolyte imbalance. **CARESDIE *Analyzer*™** Intended for the measurement of various analytes using reflectance photometry measurements and electrochemical detection.	**Vitros Na^+, K^+, Cl^- Slides** Same. **Vitros DT 60 II / DTE II** Same.
Indications	For *in vitro* diagnostic use. For professional laboratory use.	For *in vitro* diagnostic use
Measurement	Quantitative	Same
Method Principle	Measurement is based upon the technique of differential potentiometry using a direct (undiluted) specimen. The test element contains two identical ion-selective electrodes for each ion. Each electrode consists of a silver and silver chloride layer with an overlying membrane that is selective for the particular electrolyte.	Same
Specimen dilution	Not required	Same
Materials	**Sodium/Potassium/Chloride** The active ingredients include silver, silver chloride, and salts of sodium, potassium, and chloride ions.	Same
Test time	Approx. 4-minute warm-up (on-board) plus 1 minute test time.	3 minutes test time.
Reference Method	**Sodium** Flame Photometry **Potassium** Flame Photometry **Chloride** Coulometry	**Sodium** Flame Photometry **Potassium** Flame Photometry **Chloride** Coulometry
Sample Type	Whole blood, serum, plasma	serum, plasma
Specimen volume	45 µl test volume/3 tests (85 ± 15µl applied volume)	10 µl for each test
Calibration	Calibration information bar-coded on each cartridge. Calibration information may change with each lot.	Run Vitros DT calibrators whenever a new slide lot is used or when necessary.
Quality Control	2 levels	Same
Reporting Units	mEq/L or mmol/L	mmol/L
Reaction Temp.	37 °C	Same

B. Differences

	CARESIDE LYTES™ Test Cartridge	**Vitros Na^+, K^+, Cl^- DT Slides**
Specimen Processing	No. Either unprocessed whole blood or processed serum or plasma may be used	Yes, requires separation of serum or plasma from whole blood prior to sample application
Accurate pipetting	Not required	Required
Reagent pre-warming	Not required	Required
Reagents required	Single cartridge yields results for all three analytes	Three separate (analyte-specific) slides required for the three results.

C. Comparative Performance Characteristics

	CARESIDE LYTES™ Test Cartridge	**Vitros Na^+, K^+, Cl^- DT Slides**
Detection limit	Sodium 75 mmol/L Potassium 1.0 mmol/L Chloride 50 mmol/L	Sodium 95 mmol/L Potassium 1.0 mmol/L Chloride 65 mmol/L
Reportable range	Sodium 75 to 240 mmol/L Potassium 1.0 to 14.0 mmol/L Chloride 50 to 170 mmol/L	Sodium 95 to 215 mmol/L Potassium 1.0 to 11.0 mmol/L Chloride 65 to 140 mmol/L
Accuracy	Na Mean recovery 99% K Mean recovery 99% Cl Mean recovery 102%	Not provided
Precision	Na Total CV, 146 mmol/L, 1.5% K Total CV, 5.4 mmol/L, 1.8% Cl Total CV, 107 mmol/L, 1.3%	Na Total CV, 143 mmol/L, 1.3% K Total CV, 5.2 mmol/L, 1.4% Cl Total CV, 108 mmol/L, 1.5%
Method comparison (vs. Reference)	CARESIDE™ Na = 1.01 (Flame Photometry) – 1.34 mmol/L, r= 1.00 CARESIDE™ K=1.00 (Flame Photometry) + 0.01 mmol/L, r= 1.00 CARESIDE™ Cl = 0.98 (Coulometry) + 2.13 mmol/L, r= 0.99	
Method comparison (vs. Predicate)	CARESIDE™ Na = 1.04 (Vitros Na^+) – 2.78 mmol/L, r = 0.99 CARESIDE™ K = 1.07 (Vitros K^+) - 0.16 mmol/L, r = 1.00 CARESIDE™ Cl = 0.97 (Vitros Cl^-) + 2.54 mmol/L, r = 0.99	
Linearity	Linearity yielded slope and correlation coefficient within acceptable limits.	Not provided
Interference	**Sodium/Potassium/Chloride** No significant interference observed at tested concentration of interferent for sodium, potassium, and chloride: Bilirubin ..... 20 mg/dL Ethanol ..... 33 mmol/L Hemoglobin ..... 50 mg/dL Iodide ..... 2 mmol/L Triglyceride ..... 2000 mg/dL **Chloride** Bromide causes positive interference	**Sodium** Ethanol and benzalkonium chloride cause positive interference. **Potassium** None **Chloride** Bromide and iodide cause positive interference.

D. Conclusion

The nonclinical and clinical data provided demonstrate that the individual constituent tests of the CARESIDE LYTES™ cartridge (sodium, potassium, and chloride) and its associated CARESIDE *Analyzer*™ is as safe, effective, and performs as well as or better than the legally marketed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAR 18 1999

Kenneth B. Asarch, Ph.D.
Vice President Quality Systems and
Regulatory Affairs
CARESIDE, Inc.
6100 Bristol Parkway
Culver City, California 90230

Re: K990036
Trade Name: CARESIDE LYTES™, CARESIDE *Analyzer* ™
Regulatory Class: II
Product Code: JGS, CEM, CGZ, JJE
Dated: December 29, 1998
Received: January 6, 1999

Dear Dr. Asarch:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

This letter will allow you to begin marketing your device as described in your 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 advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,

Steven Gutman

Steven I. Gutman, M.D, M.B.A.
Director
Division of Clinical
Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

VI. INDICATIONS FOR USE

510(k) Number:

Device Name: CARESIDE LYTES™ and CARESIDE *Analyzer*™

Indications for use: CARESIDE LYTES™ For *in vitro* diagnostic use with the CARESIDE *Analyzer*™ to measure sodium, potassium and chloride ion concentrations using anti-coagulated whole blood, plasma or serum specimens to aid in the diagnosis and treatment of patients with electrolyte imbalance.

CARESIDE *Analyzer*™ For *in vitro* diagnostic use by laboratory professionals. Used in conjunction with reagent cartridges to duplicate manual analytical procedures in order to measure a variety of analytes.

Jean Cooper

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K990036

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use ___
(Per 21 CFR 801.109) (Optional Format 1-2-96)