JUN 25 1998

510(K) SUMMARY: CARESIDE™ PHOSPHORUS 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@worldnet.att.net
G.	Date 510(k) Summary prepared	June 11 1998

II. Device Information

A.	Device Name (Trade)	**CARESIDE™ Phosphorus**
B.	Device Name (Classification)	Phosphate test system
C.	Device Classification	Clinical chemistry panel Phosphate test system Regulation Number: 21 CFR 862.1580 Regulatory Class I Classification Number: 75CEO
D.	Special controls and performance standards	None applicable

III. Substantial Equivalence Claim

A. General equivalency claim

The ability to monitor analyte-specific biochemical reactions in dry film and other formats is widely recognized and has gained widespread acceptance for use in chemistry assays.

Phosphorus *in vitro* diagnostic products, in both dry film and other formats, are already on the U.S. market. These products utilize dry film and other formats. These products utilize either direct complexation of inorganic phosphate or coupled reactions to form a chromogen. For example,

1. Dry film — complexation of inorganic phosphate with ammonium molybdate coupled to conversion to heteropolymolbydate blue dye by reaction with p-methylaminophenol sulfate.

   example: **Vitros PHOS DT 60 slides** for Vitros DT 60 II (formerly Kodak DT 60 II), Johnson & Johnson Clinical Diagnostics, Inc.

2. Wet chemistry — complexation of inorganic phosphate with ammonium molybdate. Ammonium molybdate complex is reduced and the resulting change in absorbance at 340/660 nanometers is proportional to the amount of inorganic phosphorous present in the sample.

   example: **Phosphate - XTS™** for Olympus AU5200, Olympus America, Inc.

B. Specific equivalency claim

This CARESIDE™ Phosphorus test is substantially equivalent in principle, intended use, and clinical performance to the currently marketed Vitros slides for the quantitative measurement of phosphorus on the Vitros DT 60 II.

Name of Predicate Device:	Johnson and Johnson's (formerly Eastman Kodak, Inc.) **Vitros PHOS Slides** for Johnson and Johnson's **Vitros DT 60** (formerly Eastman Kodak's DT 60 II).
Predicate Device 510K number:	**K912844/A**
Product Code:	**75CEO**

IV. Device Description

CARESIDE™ Phosphorus cartridges are used with the CARESIDE™ Analyzer to quantitatively measure phosphorus concentration in anti-coagulated whole blood, plasma or serum specimens. The CARESIDE™ Phosphorus cartridge, a single use disposable *in vitro* diagnostic test cartridge, aids in specimen separation and delivers a measured volume of plasma or serum to a dry film to initiate the measurement of phosphorus concentration. The film cartridge (patent pending) contains all reagents necessary to measure phosphorus concentration.

A. Explanation of Device Function

Each CARESIDE™ Phosphorus cartridge consists of a phosphorus-specific multi-layer reagent film mounted in a plastic base with a hinged lid. The user introduces the anti-coagulated whole blood, serum, or plasma specimen into the cartridge sample deposition 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 deposition well into the cartridge channels and chambers. As the cartridge continues to spin, the blood cells are separated from the plasma/serum and the cells accumulate in the separation well. Approximately ten microliters of plasma (or serum, as applicable) remain in the metering passage. Any excess sample flows into an overflow well.

The plasma (or serum, as applicable) is automatically dispensed onto the multi-layer reagent film. The test specimen is distributed uniformly by the spreading layer. Large molecular components, such as proteins and dye components are filtered out as the specimen passes into the reaction layer. Purine nucleoside phosphorylase (PNP) catalyzes the reaction of the inorganic phosphorus ($H_2PO_4^-$, HPO_4^{-2}) reacts with xanthosine to form xanthine and ribose-1-phosphoric acid. Xanthine oxidase (XOD) then catalyzes the oxidation of xanthine in the presence of water and oxygen to produce uric acid and hydrogen peroxide. Peroxidase (POD) then catalyzes the conversion of leuco dye and hydrogen peroxide to produce an imidazole blue dye and water. The intensity of the color as measured by the amount of reflected light at 655 nanometers directly relates to the specimen inorganic phosphorus concentration.

Test Reaction Sequence:

Xanthosine + inorganic phosphate → Xanthine + Ribose-1-phosphoric acid

Xanthine + H_2O + Oxygen → Uric Acid + Hydrogen Peroxide

Hydrogen Peroxide + Leuco-dye → Imidazole Blue Dye + 2 H_20

As the cartridge spins, a photodiode measures film reflectance of light emitted from a wavelength-specific light emitting diode (LED) at a fixed time. The analyzer uses the reflectance measurements and the lot-specific standard curve to calculate phosphorus concentration.

B. Test Summary

Phosphate is required for generation of bony tissue and functions in the metabolism of glucose and lipids, in the maintenance of acid-base balance, and in the storage and transfer on energy from one site in the body to another. Phosphate enters the cell with glucose and is lowered after carbohydrate ingestion. For these reasons, blood phosphate levels must be controlled within narrow limits.

Determination of whole blood, serum or plasma phosphorus levels is used in the diagnosis and treatment of various disorders including parathyroid gland and kidney diseases, and vitamin D imbalance. Phosphorus levels are always evaluated in relation to calcium levels because there is an inverse relationship between the two. When phosphate rises rapidly and calcium drops, there is a high risk of arrhythmias and muscle twitching. Excess serum levels of one causes the kidneys to excrete the other.

Hypophosphatemia may be seen in hyperparathyroidism, Fanconi's syndrome, vitamin D deficiency in children (rickets) and adults (osteomalacia), chronic use of antacids, chronic alcoholism, malabsorption syndromes, hyperinsulinism and occasionally during hyperalimentation therapy.

Causes of hyperphosphatemia include chronic renal failure, Addison's disease, excessive ingestion of vitamin D, cytotoxic treatment of certain leukemias and lymphomas, metastatic bone tumors, hypocalcemia, diabetic ketoacidosis, and healing bone fractures.

V. Intended Use

A. Intended Use

The CARESIDE™ Phosphorus cartridge is intended for *in vitro* diagnostic use in conjunction with the CARESIDE™ Analyzer to quantitatively measure phosphorus concentration in anti-coagulated whole blood, plasma or serum. The CARESIDE™ Phosphorus test aids in the diagnosis and treatment of various disorders including parathyroid gland and kidney diseases, and vitamin D imbalance.

B. Indications for Use

For *in vitro* diagnostic use with the CARESIDE™ Analyzer to quantitatively measure inorganic phosphorus from anti-coagulated whole blood, plasma or serum specimens to aid in the diagnosis and treatment of various disorders, including parathyroid gland and kidney diseases, and vitamin D imbalance. It is intended for professional laboratory use: not for point of care or physician office laboratory use.

VI. Technological Characteristics

A. Similarities

	CARESIDE™ Phosphorus	Vitros PHOS DT Slides
Intended Use	Primarily to aid in the diagnosis and treatment of phosphate regulation disorders such as parathyroid gland disease, kidney disease, or vitamin D imbalance.	Same
Indications	For *in vitro* diagnostic use. For laboratory professional use: not for point of care or physician office laboratory use.	For *in vitro* diagnostic use
Measurement	Quantitative	Same
Method Principle	Dry film based enzymatic generation of hydrogen peroxide from inorganic phosphate. Reaction of chromogen with hydrogen peroxide to form blue. Dye quantitated by reflectance measurement after fixed time.	Dry film, complexation of inorganic phosphate with ammonium molybdate coupled to conversion to heteropolymolbydate blue dye by reaction with p-methylaminophenol sulfate
Specimen dilution	Not required	Same
Materials	Xanthosine purine nucleoside phosphorylase, Diarylimidazole leuco-dye	p-methylaminophenol sulfate, ammonium molybdate
Detector	Reflectance (655 nm)	Reflectance (660 nm)
Test time	Approximately 4 minute warm-up (on-board) plus 5 minute test time.	15 minutes slide warm-up (off-line) plus 5 minutes test time.
Reference Method	Phosphomolybdate Reduced	Phosphomolybdate Reduced
Sample Type	Serum, plasma, anti-coagulated (wb) [wb applied sample, plasma test sample]	serum, plasma
Specimen volume	10 µl test volume (85 ± 15 µl applied volume)	10 µl
Calibration	Calibration information bar-coded on each cartridge. Calibration information may change with each lot.	Run Vitros DT II calibrators whenever a new slide lot is used or when necessary.
Quality Control	2 levels	Same
Reporting Units	mg/dL or mmol/L	Same
Reaction Temp.	37 °C	Same

B. Differences

	CARESIDE™ Phosphorus	**Vitros PHOS DT Slides**
Direct blood specimen	Yes, whole blood	No, requires separation of whole blood prior to sample application
Reportable range	0.5 to 15 mg/dL	0.5 to 13 mg/dL
Accurate pipetting	Not required	Required
Reagent pre-warming	Not required	Required

C. Comparative Performance Characteristics

	CARESIDE™ Phosphorus	**Vitros PHOS DT Slides**
Detection limit	0.5 mg/dL	0.5 mg/dL
Reportable range	0.5 to 15 mg/dL	0.5 to 13 mg/dL
Accuracy	Mean recovery 97%	Not provided
Precision	Total CV, 3.5 mg/dL, 4.0%	Total CV, 4.9 mg/dL, 3.7%
Method comparison	CARESIDE™ = 0.99 (Vitros PHOS DT) + 0.49, r = 1.00	
Linearity	Linearity by mixing and by dilution yielded slope and correlation coefficients within acceptable limits.	Not provided
Interference	No significant interference observed at tested concentration of interferent: Ascorbic Acid, 10 mg/dL Bilirubin, 20 mg/dL Hemoglobin, 100 mg/dL d-Mannitol 800 mg/dL Triglycerides 1500 mg/dL	Not provided
Specimen Types & Anticoagulants	No clinically significant difference between sodium heparinized whole blood, serum, sodium heparin plasma, and EDTA plasma.	No clinically significant difference between serum, heparin plasma, or EDTA plasma. Whole blood is unsuitable.
Expected Values	2.2 to 4.4 mg/dL Central 95%	2.5 to 4.5 mg/dL Central 95%

D. Conclusion

The nonclinical and clinical data provided demonstrate that the CARESIDE™ Phosphorus product is as safe, effective, and performs as well as or better than the legally marketed Vitros DT 60.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUN 25 1998

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

Re: K981610
CareSide™ Phosphorus
Regulatory Class: I
Product Code: CEO
Dated: April 27, 1998
Received: April 30, 1998

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 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/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

INDICATIONS FOR USE

510(k) Number: K981610

Device Name: CARESIDE™ Phosphorus

Indications for use: For *in vitro* diagnostic use with the CARESIDE™ Analyzer to quantitatively measure inorganic phosphorus from anti-coagulated whole blood, plasma or serum specimens to aid in the diagnosis and treatment of various disorders, including parathyroid gland and kidney diseases, and vitamin D imbalance. It is intended for professional laboratory use: not for point of care or physician office laboratory use.

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K981610

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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