IV. 510(K) SUMMARY: CARESIDE™ ALP 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 30, 1998

II. Device Information

A.	Device Name (Trade)	**CARESIDE™ ALP**
B.	Device Name (Classification)	Alkaline phosphatase test system
C.	Device Classification	Clinical chemistry panel Alkaline phosphatase test system Regulation Number: 21 CFR 862.1050 Regulatory Class 2 Classification Number: 75CJE
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.

Alkaline phosphatase *in vitro* diagnostic products, in both dry film and other formats, are already on the U.S. market, including alkaline phosphatase products which utilize p-nitrophenyl phosphate substrate.

B. Specific equivalency claim

This CARESIDE™ ALP test is substantially equivalent in principle, intended use, and clinical performance to the currently marketed Vitros slides for the quantitative measurement of alkaline phosphatase using the Vitros DT 60 II with the DTSC II module.

Name of Predicate Device:	Johnson and Johnson's (formerly Eastman Kodak, Inc.) **Vitros ALKP Slides** for Johnson and Johnson's **Vitros DT 60 II System with the DTSC II module** (formerly Eastman Kodak's DT 60 II).
Predicate Device 510K number:	**K912844/A**
Product Code:	75CJE

IV. Device Description

CARESIDE™ ALP cartridges are used with the CARESIDE *Analyzer*™ to measure alkaline phosphatase activity in anticoagulated whole blood, serum or plasma specimens. The CARESIDE™ ALP cartridge, a single use disposable *in vitro* diagnostic test cartridge, delivers a measured volume of serum or plasma to a dry film to initiate the measurement of alkaline phosphatase activity. The film cartridge (patent pending) contains all reagents necessary to measure alkaline phosphatase activity.

A. Explanation of Device Function

Each CARESIDE™ ALP cartridge consists of an alkaline phosphatase-specific multi-layer reagent film mounted in a plastic base with a hinged lid. The user introduces the specimen into the cartridge Sample Well, closes the lid and inserts the cartridge into the CARESIDE *Analyzer*™

Once loaded, the CARESIDE A*nalyzer*™ 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. 8.5 microliters of sample remains in the metering passage. Any excess sample flows into an overflow well.

The sample is automatically dispensed onto the multi-layer reagent film. The spreading and substrate layer distributes the sample uniformly. Under alkaline pH conditions, ALP catalyzes the conversion of pNPP to pNP. pNP diffuses through the detection layer and into the underlying buffer where pNP converts non-enzymatically to p-nitrophenoxide which has an intense yellow color. The rate of change of color intensity of the resulting yellow dye, as measured by the amount of reflected light at 425 nanometers, directly relates to the alkaline phosphatase activity of the specimen.

Test Reaction Sequence:

p-Nitrophenyl Phosphate + H_2O

ALP ↓

p-Nitrophenol + Phosphoric Acid

As the cartridges spin, a photodiode measures reflectance of light emitted by a wavelength-specific light emitting diode (LED) over a fixed time period. The analyzer uses the reflectance measurements and the lot-specific standard curve to calculate alkaline phosphatase activity.

B. Test Summary

Alkaline phosphatase consists of a group of at least five isoenzymes which catalyze the hydrolysis of phosphate mono-esters optimally at an alkaline pH. These isoenzymes vary in their tissue distribution. ALP is found in the kidney, small intestine, osteoblasts, placenta, and liver. Significant elevations of ALP activity in the blood result from hepatobiliary disorders and bone disease associated with increased osteoblastic activity. Modest ALP elevation occurs in pregnancy, congestive heart failure, ulcerative colitis, intra-abdominal infections, Hodgkin's disease and other malignancies. Certain drugs can cause elevation in ALP activity in the blood *in vivo*.

V. Intended Use

A. Intended Use

The CARESIDE™ ALP cartridge is intended for *in vitro* diagnostic use in conjunction with the CARESIDE *Analyzer*™ to quantitatively measure alkaline phosphatase activity in anticoagulated whole blood, serum or plasma.

B. Indications for Use

This product is indicated for use in the diagnosis and treatment of patients with diseases of the liver, pancreas, bone, parathyroid, and intestines.

VI. Technological Characteristics

A. Similarities

	CARESIDE™ ALP	Vitros ALKP DT Slides
Intended Use	Primarily to aid in the diagnosis and treatment of patients with diseases of the liver, pancreas, bone, parathyroid, and intestines.	Primarily to aid in the diagnosis of heptobiliary and bone diseases.
Indications	For *in vitro* diagnostic use. For professional laboratory: not for point of care or physician office laboratory use.	For *in vitro* diagnostic use
Measurement	Quantitative	Same
Method Principle	Dry film based already on the U.S. market, including alkaline phosphatase products which utilize p-nitrophenyl phosphate substrate.	Same
Specimen dilution	Not required	Same
Materials	p-Nitrophenyl phosphate	Same
Detector	Reflectance (425 nm)	Reflectance (400 nm)
Test time	Approx. 4-minute warm-up (on-board) plus 6 minute test time.	15 minutes slide warm-up (off-line) plus 5 minutes test time.
Reference Method	IFCC, 1983	Bretaudiere, 1977, 37 °C
Sample Type	Whole blood, serum or plasma	Serum or plasma
Specimen volume	8.5 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	U/L	Same
Reaction Temp.	37 °C	Same

B. Differences

	CARESIDE™ ALP	Vitros ALKP DT Slides
Specimen Processing	Not required	Required
Accurate pipetting	Not required	Required
Reagent pre-warming	Not required	Required

C. Comparative Performance Characteristics

	CARESIDE™ ALP	Vitros ALKP DT Slides
Detection limit	30 U/L	15 U/L
Reportable range	30 to 2500 U/L	15 to 1500 U/L
Accuracy	Mean recovery 94%	Not provided
Precision	Total CV, 32 U/L, 12%	Total CV, 74 U/L, 5%
Method comparison	CARESIDE™ = 0.93 (Trace Scientific ALP) +76 U/L, r = 0.99 CARESIDE™ = 1.29 (Vitros ALKP DT) – 10.2 U/L, r = 0.98	
Linearity	Linearity studies yielded slope and correlation coefficient within acceptable limits.	Not provided
Interference	No significant interference observed at tested concentration of interferent: Ascorbic Acid, 10 mg/dL Hemoglobin, 100 mg/dL Triglycerides 1500 mg/dL	Theophylline causes slight negative interference.

D. Conclusion

The nonclinical and clinical data provided demonstrate that the CARESIDE™ ALP product 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

JAN 13 1999

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

Re: K990024
Trade Name: CARESIDE™ ALP
Regulatory Class: II
Product Code: CJE
Dated: December 30, 1998
Received: January 5, 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: K990024

Device Name: CARESIDE™ ALP

Indications for use: For *in vitro* diagnostic use with the CARESIDE *Analyzer*™ to measure alkaline phosphatase from anticoagulated whole blood, serum or plasma specimens to aid in the diagnosis and treatment of patients with diseases of the liver, pancreas, bone, parathyroid, and intestines.

Jean Cooper
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K990024

(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)