IV. 510(K) SUMMARY: CARESIDE® *ALT* 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	Renate A. MacLaren, Ph.D.
E.	FAX Number	310-670-6986
F.	e-Mail Address	rmaclaren@CARESIDE.com
G.	Date 510(k) Summary prepared	April 30, 2002

II. Device Information

A.	Device Name (Trade)	CARESIDE® *ALT*
B.	Device Name (Classification)	ALT test system
C.	Device Classification	Clinical chemistry panel ALT test system Regulation Number: 21 CFR 862.1030 Regulatory Class I Classification Number: to be assigned
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. ALT *in vitro* diagnostic products, in both dry film and other formats, are already on the U.S. market.

B. Specific equivalency claim

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

Name of Predicate Device:	Johnson and Johnson's (formerly Eastman Kodak, Inc.) Vitros ALT DT Slides for Johnson and Johnson's Vitros DT 60 (formerly Eastman Kodak's DT 60 II).

Predicate Device 510K number: K912844/A
Product Code: 75CKA

IV. Device Description

CARESIDE *ALT* cartridges are used with the CARESIDE, Inc. CARESIDE *Analyzer* to measure ALT activity in anti-coagulated whole blood, plasma, or serum specimens. The CARESIDE® *ALT* cartridge, a single use disposable *in vitro* diagnostic test cartridge, delivers a measured volume of sample to a dry film to initiate the measurement of ALT activity. The patented film cartridge contains all reagents necessary to measure ALT activity.

A. Explanation of Device Function

Each CARESIDE *ALT* cartridge consists of an ALT-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 *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. Approximately 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 uniformly distributes the specimen. As the specimen passes through the spreading and substrate layer, ALT in the specimen catalyzes the reaction of L-aspartate and α-ketotglutaric acid to form pyruvic acid and L-glutamic acid (see Test Reaction Sequence). The pyruvic acid is converted to acetyl phosphoric acid, CO_2, and hydrogen peroxide in the reaction layer. Peroxidase in the reaction layer then catalyzes the oxidation of a diaryliminidazole leuco dye by hydrogen peroxide to form a green dye. The rate of change of intensity of the color as measured by the amount of reflected light at 655 directly relates to the amount of ALT activity in the specimen.

Test Reaction Sequence:

$$\text{L-alanine} + \alpha\text{-ketoglutaric acid} \xrightarrow{ALT} \text{Pyruvic acid} + \text{L-glutamic acid}$$

$$\text{Pyruvic acid} + O_2 + \text{phosphoric acid} \rightarrow H_2O_2 + CO_2 + \text{acetyl phosphoric acid}$$

$$\text{Diarylimidazole leuco dye} + H_2O_2 \xrightarrow{POD} \text{Green dye} + H_2O$$

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 ALT activity.

B. Test Summary

Alanine aminotransferase, formerly known as serum glutamate pyruvate transaminase (SGPT), is an enzyme involved in the metabolism of amino acids. It is found in numerous organs and tissues with the highest levels in the kidneys and liver. ALT is released into the bloodstream as a result of tissue damage and in a variety of diseases involving the liver, such as hepatitis, cirrhosis, and mononucleosis.

V. Intended Use

A. Intended Use

The CARESIDE® *ALT* cartridge is intended for *in vitro* diagnostic use in conjunction with the CARESIDE® *Analyzer* to quantitatively measure ALT activity in anti-coagulated whole blood, plasma, or serum.

B. Indications for Use

For in vitro diagnostic use with the CARESIDE *Analyzer* to quantitatively measure ALT from anti-coagulated whole blood, plasma, or serum specimens to aid in the diagnosis and treatment of patients with certain types of liver and heart disease.

VI. Technological Characteristics

A. Similarities

	CARESIDE *ALT*	Vitros ALT DT Slides
Intended Use	For *in vitro* diagnostic use.	For *in vitro* diagnostic use
Indications	Primarily to aid in the diagnosis and treatment of patients with certain types of liver and heart disease.	Same
Measurement	Quantitative	Same
Method Principle	Dry film based quantitation of enzymatic activity by reflectance photometry using POP/POD coupling of ALT catalyzed generation of pyruvate	Dry film based. LDH coupling of ALT catalyzed generation of pyruvate.
Specimen Dilution	Not required	Same
Materials	L-alanine, α-ketoglutaric acid, phosphoric acid, pyruvate oxidase, peroxidase and diarylimidazole leuco dye.	Lactate deydrogenase, L-alanine, sodium α-ketoglutarate, nicotinamide adenine dinucleotide reduced, and sodium pyridoxal-5-phosphate.
Detector	Reflectance (655 nm)	Reflectance (340 nm)
Test Time	Approx. 4-minute warm-up (on-board) plus 4 minute test time.	15 minutes slide warm-up (off-line) plus 5 minutes test time.
Reference Method	NADH/NAD coupled reduction of pyruvate by lactate dehydrogenase	IFCC, 1978
Sample Type	Anti-coagulated whole blood, plasma, or serum	Same
Specimen Volume	8.5µl test volume (90 ± 10 µl applied volume)	10 µl
Calibration	Calibration information bar-coded on each cartridge. Calibration information may change with 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 *ALT*	**Vitros ALT DT Slides**
Specimen Pre-treatment	Not Required	Same
Reportable Range	15 – 1000 U/L	3 – 950 U/L
Accurate Pipetting	Not required	Required
Reagent Pre-warming	Not required	Required

C. Comparative Performance Characteristics

	CARESIDE *ALT*	**Vitros ALT DT Slides**
Detection limit	15 U/L	3 U/L
Reportable Range	15 – 1000 U/L	3 – 950 U/L
Accuracy	Mean recovery 106%	Not available
Precision	Total CV, 22 U/L, 4.5%	Total CV, 40 U/L, 9.5%
Method Comparison	CARESIDE® = 0.98 (BM/Hitachi 902) + 4.75 U/L, r = 1.00	
Linearity	Linearity by mixing yielded slope and correlation coefficient within acceptable limits	Not available
Interference	No significant interference observed at tested concentration of interferent: Ascorbic Acid, 10 mg/dL Bilirubin, 20 mg/dL Triglycerides 3000 mg/dL Gamma globulin 4200 mg/dL	High gamma globulin

D. Conclusion

The nonclinical and clinical data provided demonstrate that the CARESIDE *ALT* product is as safe, effective, and performs as well as or better than the legally marketed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Renate A. MacLauren, Ph.D.
Clinical Affairs Manager
Careside
6100 Bristol Parkway
Culver City, CA 90230

JUN 04 2002

Re: k020487
Trade/Device Name: Careside® *ALT*
Regulation Number: 21 CFR 862.1030
Regulation Name: Alanine amino transferase (ALT/SGPT) test system
Regulatory Class: Class I, reserved
Product Code: CKA
Dated: April 30, 2002
Received: May 2, 2002

Dear Dr. MacLauren:

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 the Code of Federal Regulations, Title 21, Parts 800 to 898. 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 Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer 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: K020487

Device Name: CARESIDE® *ALT*

Indications for use: For in vitro diagnostic use with the CARESIDE *Analyzer* to quantitatively measure ALT from anti-coagulated whole blood, plasma, or serum specimens to aid in the diagnosis and treatment of patients with certain types of liver and heart disease

Jean Cooper

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K020487

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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)