JUL 1 2002

K020486

510(K) SUMMARY: CARESIDE® *GGT* 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	May 10, 2002

II. Device Information

A.	Device Name (Trade)	CARESIDE® *GGT*
B.	Device Name (Classification)	GGT test system
C.	Device Classification	Clinical chemistry panel GGT test system Regulation Number: 21 CFR 862.1360 Regulatory Class 1 (non-exempt for point of care use) Classification Number: 75JPZ
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.

GGT *in vitro* diagnostic products, in both dry film and other formats, are currently marketed in the U.S., including GGT products which utilize GGT catalyzed generation of p-nitroaniline from the artificial substrate L-γ-glutamyl-p-nitroanilide.

B. Specific equivalency claim

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

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

IV. Device Description

CARESIDE® *GGT* cartridges are used with the CARESIDE *Analyzer*® to measure GGT activity in anti-coagulated whole blood, plasma or serum specimens. The CARESIDE *GGT* 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 GGT activity. The patented film cartridge contains all reagents necessary to measure GGT activity.

A. Explanation of Device Function

Each CARESIDE® *GGT* cartridge consists of a GGT-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 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 8.5 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 spreading and substrate layer distributes the GGT containing specimen uniformly. The GGT in the specimen reacts with the substrate L-γ-glutamyl-p-nitroanilide to release p-nitroaniline resulting in a change in film color. The rate of change of color intensity, as measured by the amount of reflected light at 425 nanometers, directly relates to the specimen GGT activity.

Test Reaction Sequence:

L-γ-glutamyl-p-nitroanilide + glycylglycine

GGT ↓

L-glutamylglycylglycine + p-nitroaniline

As the cartridges spin, photodiodes measure reflectance of light emitted by wavelength-specific light emitting diodes (LEDs) over a fixed time period. The instrument uses the reflectance measurements and the lot-specific standard curve to calculate GGT activity.

B. Test Summary

γ-Glutamyltransferase measurements are used in the diagnosis and treatment of liver diseases including alcoholic cirrhosis and primary and secondary liver tumors. GGT in the serum originates primarily from the hepatobiliary system even though renal tissue contains the highest levels of GGT. GGT is elevated in all forms of liver disease. GGT elevations are observed earlier and are more pronounced than those of other liver enzymes in cases of obstructive jaundice and metastatic neoplasms. In intra- or posthepatic biliary obstruction, GGT levels may reach levels 5 to 30 times higher than in intra- or post-hepatic biliary obstruction

V. Intended Use

A. Intended Use

The CARESIDE® *GGT* cartridge is intended for *in vitro* diagnostic use in conjunction with the CARESIDE® *Analyzer* to quantitatively measure GGT 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 GGT from anti-coagulated whole blood, plasma, or serum specimens to aid in the diagnosis and treatment of liver diseases such as alcoholic cirrhosis and primary and secondary liver tumors.

VI. Technological Characteristics

A. Similarities

	CARESIDE® *GGT*	**Vitros GGT DT Slides**
Intended Use	For *in vitro* Diagnostic use	Same
Indications	Primarily to aid in the diagnosis and treatment of patients with liver diseases such as alcoholic cirrhosis and primary and secondary liver tumors.	Same
Measurement	Quantitative	Same
Method Principle	Dry film based quantitation of enzymatic activity by reflectance photometry using L-g-glutamyl transferase and glycylglycine substrate.	Same
Specimen Dilution	Not required	Same
Materials	L-γ-glutamyl-p-nitroanilide and glycylglycine	L-γ-glutamyl-p-nitroanilide and glycylglycine
Detector	Reflectance (425 nm)	Reflectance (400 nm)
Test Time	Approx. 4 min. warm-up (on-board) plus 5 minute test time.	15 minutes slide warm-up (off-line) plus 5 minutes test time.
Sample Type	Anti-coagulated whole blood, serum or plasma [whole blood applied sample, plasma test sample]	Serum, plasma
Specimen Volume	8.5 µl test volume (90 ± 10 µl applied volume)	10 µl
Calibration	Calibration information bar-coded on each cartridge. Calibration information may change with each lot.	Run Vitros DTSC 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® *GGT*	**Vitros GGT DT Slides**
Direct Blood Specimen	Yes, whole blood	No, requires separation of whole blood prior to sample application
Reportable range	20 to 1000 U/L	5 to 1400 U/L
Accurate Pipetting	Not required	Required
Reagent Pre-warming	Not required	Required

C. Comparative Performance Characteristics

	CARESIDE® *GGT*	**Vitros GGT DT Slides**
Detection limit	20 U/L	5 U/L
Reportable Range	20 to 1000 U/L	5 to 1400 U/L
Accuracy	Mean recovery 101%	Not available
Precision	Total CV, 344 U/L, 2.6%	Total CV, 166 U/L, 2.4%
Method Comparison	CARESIDE = 1.00 (BM/Hitachi 902 GGT) + 0.91 U/L, r= 1.00	
Linearity	Linearity by dilution 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 10 mg/dL Triglycerides 3000 mg/dL	None stated
Specimen Types & Anticoagulants	No clinically significant difference between sodium heparinized whole blood, serum, and sodium heparin plasma.	No clinically significant difference between serum, heparin plasma, or EDTA plasma. Whole blood is unsuitable.

D. Conclusion

The nonclinical and clinical data provided demonstrate that the CARESIDE® *GGT* 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

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

JUL 1 2002

Re: k020486
Trade/Device Name: Careside® GGT
Regulation Number: 21 CFR 862.1360
Regulation Name: Gamma-glutamyl transpeptidase and isoenzymes test system
Regulatory Class: Class I, reserved
Product Code: JPZ
Dated: May10, 2002
Received: May13, 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

INDICATIONS FOR USE

K020486

510(k) Number:

Device Name: CARESIDE® *GGT*

Indications for use: For in vitro diagnostic use with the CARESIDE *Analyzer* to quantitatively measure GGT from anti-coagulated whole blood, plasma, or serum specimens to aid in the diagnosis and treatment of liver diseases such as alcoholic cirrhosis and primary and secondary liver tumors.

Jean Cooper

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K020486

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ___
(Optional Format 1-2-96)