

V. 510(K) SUMMARY: CARESIDE™ AMYLASE 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™ Amylase
B. Device Name (Classification)	Amylase test system
C. Device Classification	Clinical chemistry panel Amylase test system Regulation Number: 21 CFR 862.1070 Regulatory Class 2 Classification Number: 75JFJ
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.

Amylase *in vitro* diagnostic products, in both dry film and other formats, are already on the U.S. market. Amylase products include those that use amylolytic methods (measure the disappearance of substrate and include the iodine-starch method), saccharogenic methods (measure the production of sugars such as maltose and glucose), and chromogenic methods (measure a colored product).

B. Specific equivalency claim

This CARESIDE™ Amylase test is substantially equivalent in intended use and clinical performance to the currently marketed Vitros slides for the quantitative measurement of amylase on the Vitros DT 60 II system with the DTSC II module. Both are based on the principle of dry film and are read by reflectance photometry; however, the Vitros method is based upon the conversion of dyed starch to dyed saccharides while the CARESIDE method is based upon the conversion of a synthetic substrate to a colored product.

Name of Predicate Device: Johnson and Johnson's (formerly Eastman Kodak, Inc.) Vitros AMYL 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: 75CIW

IV. Device Description

CARESIDE™ Amylase cartridges are used with the CARESIDE *Analyzer*™ to measure amylase activity in whole blood, serum or plasma specimens. The CARESIDE™ Amylase 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 amylase activity. The film cartridge (patent pending) contains all reagents necessary to measure amylase activity.

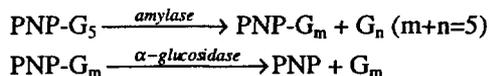
A. Explanation of Device Function

Each CARESIDE™ Amylase cartridge consists of an amylase-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. 8.5 microliters of sample remains in the metering passage. Any excess sample flows into an overflow well.

The 8.5 microliters of sample is automatically dispensed onto the multi-layer reagent film. The spreading and substrate layer distributes the specimen uniformly. Amylase converts p-nitrophenyl- α -D-maltopentaoside to p-nitrophenyl-oligosaccharides (PNP-G_m) and free oligosaccharides (G_n). The sample mixture diffuses into the underlying detection layer where PNP-G_m is converted by α -glucosidase to generate G_m and p-nitrophenol which converts to a yellow dye. The color intensity of the resulting yellow dye, as measured by the amount of reflected light at 425 nanometers, directly relates to the amylase activity of the specimen.

Test Reaction Sequence:



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 amylase activity.

B. Test Summary

Amylase is an enzyme produced by the pancreas and parotid glands that occurs in blood. Amylase catalyzes the hydrolysis of starch and related polysaccharide to yield maltose and other oligosaccharides. Amylase activity in the blood is elevated in inflammation and hemorrhage of the pancreas and is decreased in pancreatic insufficiency. Amylase measurement is useful in the differential diagnosis of disorders of the digestive system. Various other causes of hyperamylasemia include salivary lesions, biliary tract disorders, trauma, neoplastic diseases, ruptured ectopic pregnancy, pulmonary disease, and alcoholic intoxication. Certain drugs can also increase amylase activity in the blood *in vivo*.

V. Intended Use

A. Intended Use

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

B. Indications for Use

This product is indicated for use in the diagnosis and treatment of patients with disease of the pancreas, salivary gland, and kidney.

VI. Technological Characteristics

A. Similarities

	CARESIDE™ Amylase	Vitros AMYL DT Slides
Intended Use	Primarily to aid in the diagnosis and treatment of patients with disease of the pancreas, salivary gland, and kidney.	Primarily to aid in the diagnosis of diseases of the pancreas
Indications	For <i>in vitro</i> diagnostic use. For professional laboratory: not for point of care or physician office laboratory use.	For <i>in vitro</i> diagnostic use
Measurement	Quantitative	Same
Method Principle	Dry film, p-nitrophenyl- α -D-maltopentaoside substrate reaction coupled with α -glucosidase	Dry film conversion by amylase of high molecular weight dyed starch into low molecular weight dyed saccharides
Specimen dilution	Not required	Same
Materials	p-nitrophenyl- α -D-maltopentaoside, α -glucosidase	Dyed amylopectin
Detector	Reflectance (425 nm)	Reflectance (555 nm)
Test time	Approx. 4 minute warm-up (on-board) plus approximately 6 minute test time.	15 minutes slide warm-up (off-line) plus 5 minutes test time.
Reference Method	Rate determination using ethylidene-pNP-G7 substrate, spectrophotometric detection, 37 °C	PNP Maltopentaoside Method, 37 °C
Sample Type	Anti-coagulated whole blood, serum, or heparinized plasma.	Serum or heparinized plasma
Specimen volume	8.5 μ l test volume (85 \pm 15 μ l applied volume)	10 μ l
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™ Amylase	Vitros AMYL DT Slides
Specimen Processing	Not required	Required
Accurate pipetting	Not required	Required
Reagent pre-warming	Not required	Required

C. Comparative Performance Characteristics

	CARESIDE™ Amylase	Vitros AMYL DT Slides
Detection limit	15 U/L	5 U/L
Reportable range	15 to 600 U/L	5 to 900 U/L
Accuracy	Mean recovery 95%	Not provided
Precision	Total CV, 75 U/L, 13%	Total CV, 51 U/L, 13%
Method comparison	CARESIDE™ = 0.94 (Trace Sci. Amylase DST) + 11.5 U/L, r = 0.97 CARESIDE™ = 0.76 (Vitros AMYL DT) + 14.6 U/L, r = 0.95	
Linearity	Linearity yielded slope and correlation coefficient within acceptable limits.	Not provided
Interference	No significant interference observed at tested concentration of interferent: Ascorbic Acid,..... 20 mg/dL Hemoglobin,..... 100 mg/dL Triglycerides 1500 mg/dL	No reported interference

D. Conclusion

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



FEB 8 1999

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

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

Re: K990025
Trade Name: CARESIDE™ Amylase
Regulatory Class: II
Product Code: JFJ
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.

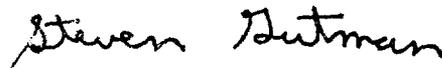
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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,

A handwritten signature in black ink that reads "Steven Gutman". The signature is written in a cursive style with a large initial 'S'.

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

VII. INDICATIONS FOR USE

510(k) Number: K 990025

Device Name: CARESIDE™ Amylase

Indications for use: For *in vitro* diagnostic use with the CARESIDE Analyzer™ to measure amylase from whole blood, serum or plasma specimens to aid in the diagnosis and treatment of patients with disease of the pancreas, salivary gland, and kidney.

Jean Cooper
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K 990025

(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)