3/15/99

K990009

IV. 510(K) SUMMARY: CARESIDE™ AST 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™ AST**
B.	Device Name (Classification)	Aspartate amino transferase test system
C.	Device Classification	Clinical chemistry panel Aspartate amino transferase test system Regulation Number: 21 CFR 862.1100 Regulatory Class II Classification Number: to be assigned
D.	Special controls and performance standards	None applicable

III. Substantial Equivalence Claim

A. <u>General equivalency claim</u>

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.

AST *in vitro* diagnostic products, in both dry film and other formats, are already on the U.S. market.

B. <u>Specific equivalency claim</u>

The CARESIDE™ AST test is substantially equivalent in its principle, intended use, and clinical performance to the currently marketed Vitros slides for the quantitative measurement of AST on the Vitros DT 60 II / DTSC II. A quantitative method comparison is provided to the Raichem Aspartate Aminotransferase method and the Sigma Diagnostics Aspartate Aminotransferase method rather than the Vitros method because the CARESIDE, Raichem, and Sigma Diagnostics methods all measure the reaction without supplementation of the co-factor pyridoxal-5-phosphate. Whereas, the Vitros DT 60 II method uses pyridoxal-5-phosphate supplementation and thus is expected to yield higher results.

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAR 16 1999

Kenneth B. Asarch, Pharm.D., Ph.D.
VP Quality Systems and Regulatory Affairs
CARESIDE, INC.
6100 Bristol Parkway
Culver City, CA 90230

Re: K990009
Trade Name: CARESIDE™ AST
Regulatory Class: II
Product Code: CIT
Dated: December 30, 1998
Received: January 4, 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: K990009

Device Name: CARESIDE™ AST

Indications for use: For in vitro diagnostic use with the CARESIDE *Analyzer*™ to quantitatively measure AST 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. It is intended for professional laboratory use: not for point of care or physician office laboratory use.

Jean Cooper
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K990009

(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)