

V. 510(K) SUMMARY: CARESIDE™ AMMONIA 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	April 16, 1999

II. Device Information

A. Device Name (Trade)	CARESIDE™ Ammonia
B. Device Name (Classification)	Ammonia test system
C. Device Classification	Clinical chemistry panel Ammonia test system Regulation Number: 21 CFR 862.1065 Regulatory Class 1 Classification Number: 75JID
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.

Ammonia *in vitro* diagnostic products, in both dry film and other formats, are already on the U.S. market. Ammonia products include those that use bromophenol blue as an ammonia indicator.

B. Specific equivalency claim

This CARESIDE™ Ammonia test is substantially equivalent in intended use and clinical performance to the currently marketed Vitros slides for the quantitative measurement of ammonia on the Vitros DT 60 II system. Both are based on the principle of dry film, both use the bromphenol blue ammonia indicator, and both are read by reflectance photometry.

Name of Predicate Device:	Johnson and Johnson's (formerly Eastman Kodak, Inc.) Vitros NH ₃ Slides for Johnson and Johnson's Vitros DT 60 II system (formerly Eastman Kodak's DT 60 II).
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Predicate Device 510K number:	K912844/A
Product Code:	75JID

IV. Device Description

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

A. Explanation of Device Function

Each CARESIDE™ Ammonia cartridge consists of an ammonia-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 the Overflow Well.

The 8.5 microliters of sample is automatically dispensed onto the multi-layer reagent film. The spreading layer distributes the sample evenly on the film before the sample moves through the reaction, porous, and detection layers where a blue-green dye forms in the presence of ammonia. The color intensity of the resulting blue-green dye, as measured by the amount of reflected light at 590 nanometers, directly relates to the ammonia concentration of the specimen.

Test Reaction Sequence:

Bromophenol blue (yellow) + NH₃ ———> Blue-green dye

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 ammonia concentration.

B. Test Summary

The majority of ammonia in the body is generated in the gastrointestinal tract through the action of bacterial enzymes on dietary protein in the colon and from the catabolism of amino acids. Ammonia is detoxified in the liver by conversion to urea. Elevated ammonia levels are caused by liver dysfunction resulting from such causes as viral hepatitis, cirrhosis, or Reye's syndrome, and inherited deficiencies of enzymes involved in the conversion of ammonia to urea. Excess ammonia exerts toxic effects on the central nervous system.

V. Intended Use

A. Intended Use

The CARESIDE™ Ammonia cartridge is intended for *in vitro* diagnostic use in conjunction with the CARESIDE *Analyzer*™ to quantitatively measure ammonia in anti-coagulated whole blood or plasma.

B. Indications for Use

This product is indicated for use in the diagnosis and treatment of patients with severe liver disorders such as cirrhosis, hepatitis, and Reye's syndrome.

VI. Technological Characteristics

A. Similarities

	CARESIDE™ Ammonia	Vitros NH ₃ DT Slides
Intended Use	Primarily to aid in the diagnosis and treatment of patients with severe liver disorders such as cirrhosis, hepatitis, and Reye's syndrome.	Primarily to aid in the diagnosis of hepatic coma and Reye's syndrome, as an indicator during the final stages of terminal cirrhosis.
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, bromophenol blue dye.	Dry film, bromophenol blue dye.
Materials	Bromophenol blue	Bromophenol blue
Detector	Reflectance (590 nm)	Reflectance (605 nm)
Test time	4 minute warm-up (on-board) plus 3 minute test time.	15 minute warm-up (off-line) plus 5 minutes test time.
Reference Method	Glutamate dehydrogenase	Glutamate dehydrogenase
Sample Type	Anti-coagulated whole blood or plasma.	Heparinized 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	µmol/L NH ₃	Same
Reaction Temp.	37 °C	Same

B. Differences

	CARESIDE™ Ammonia	Vitros NH ₃ DT Slides
Specimen Processing	Not required	Required
Accurate pipetting	Not required	Required
Reagent pre-warming	Not required	Required

C. Comparative Performance Characteristics

	CARESIDE™ Ammonia	Vitros NH ₃ DT Slides
Detection limit	7 µmol/L	1 µmol/L
Reportable range	7 to 350 µmol/L	1 to 500 µmol/L
Accuracy	Mean recovery 99%	Not provided
Precision	Total CV, 109 µmol/L, 11%	Total CV, 100 µmol/L, 10%
Method comparison	CARESIDE™ = 0.98 (RAICHEM) + 3.9 µmol/L, r = 0.99	
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 Total Protein, 12 g/dL Hemoglobin 500 mg/dL Triglycerides3000 mg/dL Urea (BUN).....40 mg/dL	No reported interference

D. Conclusion

The nonclinical and clinical data provided demonstrate that the CARESIDE™ Ammonia 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

AUG - 3 1999

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

Re: K991371
Trade Name: CARESIDE™ AMMONIA
Regulatory Class: I reserved
Product Code: JID
Dated: June 15, 1999
Received: June 16, 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.

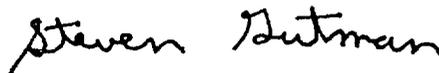
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Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

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 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:

Device Name: CARESIDE™ Ammonia

Indications for use: For *in vitro* diagnostic use with the CARESIDE Analyzer™ to measure ammonia from anti-coagulated whole blood or plasma specimens to aid in the diagnosis and treatment of patients with severe liver disorders such as cirrhosis, hepatitis, and Reye's syndrome.



(Division Sign-Off) ✓
Division of Clinical Laboratory Devices
510(k) Number K991371

(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)