K992475

V. 510(K) SUMMARY: CARESIDE™ CO_2 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	Date July 23, 1999

II. Device Information

A.	Device Name (Trade)	**CARESIDE™ CO_2, Total**
B.	Device Name (Classification)	Bicarbonate/Carbon dioxide test system
C.	Device Classification	Clinical chemistry panel Bicarbonate/Carbon dioxide test system Regulation Number: 21 CFR 862.1160 Regulatory Class 2 Classification Number: 75KHS
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.

CO_2 *in vitro* diagnostic products, in both dry film and other formats, are already on the U.S. market. CO_2 products include those that use dry film using a PEP carboxylase coupled enzyme reaction and reflectance photometry technology.

B. Specific equivalency claim

This CARESIDE™ CO_2 test is substantially equivalent in intended use and clinical performance to the currently marketed Vitros CO_2 DT slides for the quantitative measurement of total CO_2 on the Vitros DT 60 II / DTE II system. The CARESIDE CO_2 utilizes the principle of reflectance photometry and the Vitros DT 60 II / DTE II system utilizes differential potentiometry.

Name of Predicate Devices:	Johnson and Johnson's (formerly Eastman Kodak, Inc.): Vitros CO_2 DT Slides for Johnson and Johnson's (formerly Eastman Kodak) Vitros DT 60 II / DTE II system and Vitros ECO_2 DT Slides for Johnson and Johnson's Vitros Chemistry Analyzers.
Predicate Device 510K number:	**K912844/A - K903144**
Predicate Product Code:	-- 75KHS

IV. Device Description

CARESIDE™ CO_2 cartridges are used with the CARESIDE *Analyzer*™ to measure total CO_2 in whole blood, serum or plasma specimens. The CARESIDE™ CO_2 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 total CO_2. The film cartridge (patent pending) contains all reagents necessary to measure total CO_2.

A. Explanation of Device Function

Each CARESIDE™ CO_2 cartridge consists of a CO_2-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 where separation of cells, if present, occurs. 8.5 microliters of sample remains in the metering channel. 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. The color intensity of the resulting yellow dye, as measured by the amount of reflected light at 425 nanometers, directly relates to the total CO_2 concentration of the specimen.

Test Reaction Sequence:

Carbon dioxide in the form of bicarbonate ion combines with phosphoenolpyruvate in a reaction catalyzed by PEP-carboxylase (PEPC) to form oxaloacetate (OAC) and inorganic phosphate (PO_4^{-3}) as shown below. Oxaloacetate reacts with thio-NADH (t-NADH) and hydrogen ion (H^+) in a malate dehydrogenase (MDH) catalyzed reaction to form L-malate and thio-NAD^+ (t-NAD^+).

$$HCO_3^- + PEP \xrightarrow{PEPC \quad Mg^{+2}} OAC + PO_4^{-3}$$

$$OAC + t\text{-}NADH + H^+ \xrightarrow{MDH} L\text{-}Malate + t\text{-}NAD^+$$

As the cartridges spin, a photodiode measures reflectance of light emitted by a wavelength-specific light emitting diode (LED) over a fixed time. The analyzer uses the reflectance measurements and the lot-specific standard curve to calculate total carbon dioxide concentration.

B. Test Summary

Carbon dioxide is a gas, and as such occurs in very low concentrations in this form in the blood. Bicarbonate ion (HCO_3^-) as well as other ions are in equilibrium with CO_2 in the blood. At physiological pH, CO_2 occurs in the largest concentration while carbonate and carbamino compounds are present in such low quantities that they are generally not considered separately. The bicarbonate ion concentration in blood is related to the total carbon dioxide concentration and the pH according to the Henderson-Hasselbach equation.

The bicarbonate ion/carbonic acid pair represents the most important buffer system of plasma. Clinical conditions characterized as metabolic disturbances of acid-base balance are classified as primary disturbances in HCO_3^- ion concentration. Primary disturbances in the total dissolved CO_2 are characterized as respiratory disturbances. Changes in the bicarbonate ion, dissolved CO_2 concentration, or both occur as a result of various compensatory mechanisms attempting to re-establish the normal ratio of bicarbonate ion to total dissolved CO_2.

V. Intended Use

A. Intended Use

The CARESIDE™ CO_2 cartridge is intended for *in vitro* diagnostic use in conjunction with the CARESIDE *Analyzer*™ to quantitatively measure total CO_2 in whole blood, serum or plasma.

B. Indications for Use

This product is indicated for use in the diagnosis and treatment of patients with respiratory and metabolic disorders associated with acid-base imbalance.

VI. Technological Characteristics

A. Similarities

	CARESIDE™ CO_2	Vitros CO_2 DT Slides
Intended Use	Primarily to aid in the diagnosis and treatment of patients with respiratory and metabolic disorders associated with acid-base imbalance	Primarily to aid in the evaluation of acid-base status.
Indications	For *in vitro* diagnostic use. For professional laboratory use: not for point of care or physician office laboratory use.	For *in vitro* diagnostic use
Measurement	Quantitative	Same
Method Principle	Dry film, reflectance photometry	Differential potentiometry
Specimen dilution	Not required	Same
Materials	PEP, PEP carboxylase, thio-NADH, and malate dehydrogenase.	Silver, silver chloride, sodium chloride, potassium chloride, trioctylpropylammonium chloride, and decyltrifluoroacetophenone
Detector	Photodiode (425 nm)	Ion-selective electrode
Test time	Approx. 4 minute warm-up (on-board) plus 5 minute test time.	15 minutes slide warm-up (off-line) plus 3 minutes test time.
Sample Type	Anti-coagulated whole blood, heparinized plasma, or serum.	Serum or 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	mmol/L	Same
Reaction Temp.	37 °C	Same

B. Differences

	CARESIDE™ CO_2	Vitros CO_2 DT Slides
Specimen Processing	Not required	Required
Accurate pipetting	Not required	Required
Reagent pre-warming	Not required	Required

C. Comparative Performance Characteristics

	CARESIDE™ CO_2	Vitros CO_2 DT Slides
Detection limit	5 mmol/L	5 mmol/L
Reportable range	5 to 40 mmol/L	5 to 50 mmol/L
Accuracy	Mean recovery 101%	Not provided
Precision	Total CV, 19 mmol/L, 6.6%	Total CV, 22 mmol/L, 6.6%
Method comparison	CARESIDE™ = 1.06 (Vitros CO_2 DT) – 1.94 mmol/L, r = 0.97	
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 Bilirubin, ...15 mg/dL Hemoglobin,.....300 mg/dL Total Protein,.....15 g/dL Triglycerides .....3000 mg/dL	Bromide, iodide, nitrate, diatrizoate may cause positive interference.

D. Conclusion

The nonclinical and clinical data provided demonstrate that the CARESIDE™ CO_2 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

SEP 15 1999

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

Re: K992475
Trade Name: CARESIDE™ CO_2 Total for use on the Careside Analyzer™
Regulatory Class: II
Product Code: KHS
Dated: July 23, 1999
Received: July 26, 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.

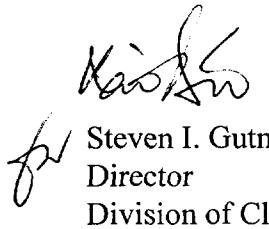
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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 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: K992475

Device Name: CARESIDE™ CO_2

Indications for use: For *in vitro* diagnostic use with the CARESIDE *Analyzer*™ to measure total CO_2 from anticoagulated whole blood, serum or plasma specimens to aid in the diagnosis and treatment of patients with respiratory and metabolic disorders associated with acid-base imbalance.

Dean Cooper
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K992475

(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)