AUG 11 1999

K991717

IV. 510(K) SUMMARY: CARESIDE™ MG 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	May 19, 1999

II. Device Information

A.	Device Name (Trade)	**CARESIDE™ Mg**
B.	Device Name (Classification)	Magnesium test system
C.	Device Classification	Clinical chemistry panel Mg test system Regulation Number: 21 CFR 862.1495 Regulatory Class I Classification Number: 75JGJ
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 clinical chemistry assays.

Magnesium *in vitro* diagnostic products, in both dry film and other formats, are already on the U.S. market. In vitro diagnostic products in dry film format also employ enzymatic coupling to indirectly measure the analyte of interest.

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

This CARESIDE™ Mg test is substantially equivalent in principle, intended use, and clinical performance to the currently marketed Vitros slides for the quantitative measurement of magnesium for use on the Vitros DT 60 II system.

Name of Predicate Device:	Johnson and Johnson's (formerly Eastman Kodak, Inc.) **Vitros Mg DT Slides** for use on the **Vitros DT 60 II** system (formerly Eastman Kodak's DT 60 II).
Predicate Device 510K number:	**K912844/A**
Product Code:	75JGJ

IV. Device Description

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

A. Explanation of Device Function

Each CARESIDE™ Mg cartridge consists of a magnesium-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 μL microliters of sample remains in the metering passage. Any excess sample flows into the Overflow Well.

The sample is automatically dispensed onto the multi-layer film. The spreading layer distributes the sample evenly on the film before it moves onto a reaction layer where magnesium in the sample complexes with ATP to serve as a substrate in the glycerol kinase (GK) catalyzed reaction with glycerol to form L-α-glycerol-3-phosphate. Hydrogen peroxide (H_2O_2) and dihydroxyacetone phosphate (DAP) is formed in a glycerol phosphate oxidase (GPO) catalyzed reaction of L-α-glycerol-3-phosphate (L-α-GP) with oxygen. The H_2O_2 produced reacts with a leuco dye in a peroxidase (POD) catalyzed reaction to form a green dye. The rate of change of the color intensity of the dye, as measured by the time course of reflected light at 655 nanometers, and directly relates to the magnesium concentration of the specimen.

Test Reaction Sequence:

$$\text{Mg•ATP + Glycerol} \xrightarrow{\text{GK}} \text{L-α-GP + Mg•ADP}$$

$$\text{L-α-GP + } O_2 \xrightarrow{\text{GPO}} H_2O_2 + \text{DAP}$$

$$H_2O_2 + \text{Leuco Dye} \xrightarrow{\text{POD}} \text{Green Dye} + 2\,H_2O$$

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 the magnesium concentration.

B. Test Summary

Magnesium has essential functions intracellularly, extracellularly, and in the skeleton in the human body. Intracellularly, magnesium is a cofactor for more than 300 enzymes. Magnesium is needed for the physiological processes of oxidative phosphorylation, glycolysis, cell replication, nucleotide metabolism, and protein biosynthesis. Extracellularly, magnesium is involved in the regulation of nerve conduction and neuromuscular transmission. Magnesium is incorporated into the mineral lattice of the skeleton. About one-third of the skeletal magnesium is exchangeable with the extracellular fluid which in turn serves as a source for maintaining intracellular magnesium.

Magnesium deficiency is a very common sign in a variety of diseases. Causes of hypomagnesemia include gastrointestinal disorders, renal disease, alcohol and other drugs, metabolic acidosis, diabetes mellitus, increased sodium or calcium excretion, and phosphate depletion. Hypomagnesemia most commonly presents with neuromuscular hyperexcitability, although the features of the primary disease process causing the magnesium deficiency may mask the signs and symptoms.

Hypermagnesemia is encountered less commonly than hypomagnesemia. Causes of hypermagnesemia include excessive magnesium intake, renal failure, familial hypocalciuric hypercalcemia, and lithium ingestion. Hypermagnesemia most commonly presents with neuromuscular symptoms, such as the disappearance of the deep tendon reflex.

V. Intended Use

A. Intended Use

The CARESIDE™ Mg cartridge is intended for *in vitro* diagnostic use in conjunction with the CARESIDE *Analyzer*™ to quantitatively measure magnesium concentration in anti-coagulated whole blood, plasma or serum.

B. Indications for Use

For *in vitro* diagnostic use with the CARESIDE *Analyzer*™ to quantitatively measure magnesium from anti-coagulated whole blood, plasma, or serum specimens to aid in the diagnosis and treatment of patients with hypomagnesemia or hypermagnesmia. It is intended professional laboratory use: not for point of care or physician office laboratory use.

VI. Technological Characteristics

A. Similarities

	CARESIDE™ Mg	Vitros Mg DT Slides
Intended Use	Primarily to aid in the diagnosis and treatment of patients with with hypomagnesemia or hypermagnesmia.	Same.
Indications	For *in vitro* diagnostic use. For professional laboratory: not for point of care or physician office laboratory use.	For *in vitro* diagnostic use
Measurement	Quantitative	Same
Method Principle	Reflectometry of enzymatically coupled production of dye from magnesium reaction product.	Complexation of magnesium with formazan dye to form a colored complex.
Specimen dilution	Not required	Same
Materials	Glycerol, glycerol kinase, glycerol kinase oxidase, and leuco dye.	Formazan dye
Detector	Reflectance (655 nm)	Reflectance (660 nm)
Test time	4 minute warm-up (on-board) plus 4.5 minute test time.	15 minutes slide warm-up (off-line) plus 5 minutes test time.
Sample Type	Anti-coagulated whole blood, plasma, or serum	Plasma or serum
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	mg/dL	Same
Reaction Temp.	37°C	Same

B. Differences

	CARESIDE™ Mg	Vitros Mg DT Slides
Accurate pipetting	Not required	Required
Reagent pre-warming	Not required	Required

C. Comparative Performance Characteristics

	CARESIDE™ Mg	Vitros Mg DT Slides
Detection limit	0.2 mg/dL	0.2 mg/dL
Reportable range	0.2 to 7.0 mg/dL	0.2 to 7.0 mg/dL
Accuracy	Mean recovery 97%	Not provided
Precision	Total CV, 1.2 mg/dL , 4.3%	Total CV, 1.1 mg/dL, 3.6%
Method comparison	CARESIDE™ Mg = 0.98 (Hitachi 902/BMD) – 0.086 mg/dL, r = 0.99 CARESIDE™ Mg = 0.82 (Vitros DT 60 II) + 0.31 mg/dL, 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, 10 mg/dL Bilirubin, 60 mg/dL Calcium, 20 mg/dL Inorg. Phosphorus, 9 mg/dL Total Protein, 9 g/dL Triglycerides, 2000 mg/dL	Calcium 20 mg/dL Inorg. Phosphorus 9 mg/dL

D. Conclusion

The nonclinical and clinical data provided demonstrate that the CARESIDE™ Mg 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 10 1999

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

Re: K991717
Trade Name: CARESIDE™ Magnesium (Mg)
Regulatory Class: II
Product Code: JGJ
Dated: May 19, 1999
Received: May 20, 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: K991717

Device Name: CARESIDE™ Mg

Indications for use: For *in vitro* diagnostic use with the CARESIDE *Analyzer*™ to quantitatively measure magnesium from anti-coagulated whole blood, plasma, or serum specimens to aid in the diagnosis and treatment of patients with hypomagnesemia or hypermagnesmia. It is intended 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 K991717

(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)