DEC 17 1998

K983789

Attachment 3: Revised 510(k) Summary

510(K) SUMMARY: CARESIDE™ CALCIUM 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 11, 1998

II. Device Information

A.	Device Name (Trade)	**CARESIDE™ Calcium**
B.	Device Name (Classification)	Calcium test system
C.	Device Classification	Clinical chemistry panel Calcium test system Regulation Number: 21 CFR 862.1145 Regulatory Class II Classification Number: 75CJY
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.

Calcium *in vitro* diagnostic products, in both dry film and other formats, are already on the U.S. market, including calcium products that utilize azo dye reactions.

B. Specific equivalency claim

This CARESIDE™ Calcium test is substantially equivalent in principle, intended use, and clinical performance to the currently marketed Vitros slides for the quantitative measurement of calcium on the Vitros DTSC II.

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

IV. Device Description

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

A. Explanation of Device Function

Each CARESIDE™ Calcium cartridge consists of a calcium-specific multi-layer reagent film mounted in a plastic base with a hinged lid. The user introduces the specimen into the cartridge sample deposition 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 deposition well into the cartridge channels and chambers. 8.5µL of sample remains in the metering passage. Any excess sample flows into an overflow well.

The plasma (or serum, as applicable) is automatically dispensed onto the multi-layer reagent film. The spreading layer distributes the sample evenly on the film, and the sample moves through a reagent layer and a detection layer where a dye complex forms in the presence of calcium. The color intensity of the resulting blue dye, as measured by the amount of reflected light at 615 nanometers directly relates to the calcium concentration of the specimen.

Test Reaction Sequence:

$$Ca^{+2} + \text{Bound-Ca} \rightarrow Ca^{+2}$$

$$Ca^{+2} + \text{chlorophosphonazo (III)} \rightarrow \text{Ca-chlorophosphonazo (III)}$$

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

B. Test Summary

Calcium is an element found in fairly fixed proportions in the mineral phase of the human hard tissues (bone, dentine, and enamel) as well as in dynamic exchange with the intracellular and extracellular tissue fluids. Over 95% of the body calcium store is in the skeleton and teeth. Of the blood calcium, 45-50% is ionized, 40-45% is protein-bound and about 10% is chelated with ligands like citrate, lactate, phosphate and bicarbonates[1].

Intracellularly, calcium (Ca^{+2}) is a prime inorganic messenger for cell function regulation. Extracellular Ca^{+2} at the cell surface controls secretions from several endocrine glands including the parathyroid and pancreas. Calcium also plays a key role in blood coagulation.

The three main regulators of calcium homeostasis are parathyroid hormone, vitamin D, and calcitonin. Disorders involving these regulators directly impact calcium levels. Calcium level determination in human body fluids is used to measure parathyroid function, to assess vitamin D status; to evaluate calcium metabolism; to diagnose Addison's disease and to investigate malignancies[2]. Increased calcium levels are seen in cases of hyperparathyroidism and malignancy. Reduced levels are commonly seen in cases of hypoalbuminemia[3]

V. Intended Use

A. Intended Use

The CARESIDE™ Calcium cartridge is intended for *in vitro* diagnostic use in conjunction with the CARESIDE *Analyzer*™ to quantitatively measure calcium concentration in heparinized whole blood, heparin plasma, or serum.

B. Indications for Use

For in vitro diagnostic use with the CARESIDE *Analyzer*™ to quantitatively measure total calcium from heparinized whole blood, heparin plasma or serum specimens to aid in diagnosis and treatment of patients with parathyroid disease, a variety of bone diseases, chronic renal disease, and tetany. It is intended for professional laboratory use: not for point of care or physician office laboratory use.

VI. Technological Characteristics

A. Similarities

	CARESIDE™ Calcium	Vitros CA DT Slides
Intended Use	Primarily to aid in the diagnosis and treatment of patients with parathyroid disease, a variety of bone diseases, chronic renal disease, and tetany (intermittent muscular contractions or spasms).	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	Dry film based already on the U.S. market, including calcium products that utilize azo dye reactions.	Same
Specimen	Not required	Same
Materials	Chlorophosphonazo (III)	Arsenazo (III) dye
Detector	Reflectance (615)	Reflectance (680 nm)
Test time	Approx. 4-minute warm-up (on-board) plus 4 minute test time.	15 minutes slide warm-up (off-line) plus 5 minutes test time.
Reference Method	2-cresolphthalein complexone colorimetric	Atomic Absorption Spectrophotometry
Sample Type	Heparinized whole blood, heparin plasma or serum	Same
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 DTSC II calibrators whenever a new slide lot is used or when necessary.
Quality Control	2 levels	Same
Reporting Units	mg/dL or mmol/L	Same
Reaction Temp.	37 °C	Same

B. Differences

	CARESIDE™ Calcium	Vitros CA DT Slides
Specimen pre-treatment	Required	Required
Reportable range	4.2 to 14 mg/dL	3 to 14 mg/dL
Accurate pipetting	Not required	Required
Reagent pre-warming	Not required	Required

C. Comparative Performance Characteristics

	CARESIDE™ Calcium	Vitros Ca DT Slides
Detection limit	4.2 mg/dL	3 mg/dL
Reportable range	4.2 to 14 mg/dL	3 to 14 mg/dL
Accuracy	Mean recovery 98%	Not provided
Precision	Total CV at 6.5mg/dL, 7.8%	Total CV at 11.9 mg/dL = 1.6%
Method comparison	CARESIDE™ = 0.90 (Reference Method) + 1.09 mg/dL, 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, 10 mg/dL Bilirubin, 10 mg/dL Hemoglobin, 250 mg/dL Magnesium 2.5 mmol/L Triglycerides 600 mg/dL	Not provided

D. Conclusion

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC 17 1998

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

Re: K983789
Trade Name: CARESIDE™ Calcium for use on the CARESIDE *Analyzer*™
Regulatory Class: II
Product Code: CJY
Dated: October 26, 1998
Received: October 27, 1998

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.

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: K983789

Device Name: CARESIDE™ Calcium

Indications for use: For *in vitro* diagnostic use with the CARESIDE *Analyzer*™ to measure total calcium from heparinized whole blood, heparin plasma or serum specimens to aid in the diagnosis and treatment of patients with parathyroid disease, a variety of bone diseases, chronic renal disease, and tetany. It is intended for professional laboratory use: not for point of care or physician office laboratory use.

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K983789

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use ___
(Per 21 CFR 801.109) (Optional Format 1-2-96)