

DEC - 2 1999

K993634

IV. 510(K) SUMMARY: CARESIDE™ 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 | October 25, 1999 |

II. Device Information

- | | |
|---|--|
| A. Device Name (Trade) | CARESIDE Analyzer |
| B. Device Name (Classification) | Microchemistry instrument for clinical use |
| C. Device Classification | Clinical Chemistry Panel
Microchemistry instrument for clinical use
Regulation Number: 21 CFR 862.2170
Regulatory Class 2
Classification Number: 75JFF, CDQ, CEK,
CIX, JGS, CEM, CGZ, JJE |
| D. Special controls and performance standards | Not applicable |

III. Substantial Equivalence Claim

A. General equivalency claim

The CARESIDE Analyzer is an *in vitro* diagnostic instrument intended for the measurement of various clinical chemistry analytes in human whole blood, plasma, and serum. The instrument utilizes reflectance photometry and differential potentiometry measurement for analyte quantitation. Together, the device and the test cartridge perform most of the pre-analytical, analytical, and post-analytical test steps. The CARESIDE Analyzer reads calibration information from the bar code on the cartridge label, warms the cartridge and sample, separates the blood cells if the sample is not pre-processed, meters the sample, dispenses the metered volume, and reads the signal.

For film chemistry cartridges, the diffuse reflectance is read off of the reagent film using light emitting diode/photodiode sets spaced radially under the reagent film. Reflectance is read at defined times during the reaction period. The analyte concentration is proportional to the concentration of dye on the film.

For electrochemistry cartridges voltage differences are measured. The analyte concentration is proportional to the voltage difference between the sample electrode and the reference solution electrode.

The ability to monitor analyte-specific biochemical reactions in dry film by reflectance and via ion-selective electrodes are widely recognized and have gained widespread acceptance for use in chemistry assays. Microchemistry instruments are already on the U.S. market. These products utilize reflectance photometry from dry film and ion-selective electrodes. For example,

- Vitros DT 60/DTSC/DTE II Module (formerly Kodak Ektachem DT 60/DTSC/DTE II), Johnson & Johnson Clinical Diagnostics (Operator's Manual available upon request)

B. Specific equivalency claim

The CARESIDE Analyzer is substantially equivalent in principle, intended use, and clinical performance to itself and to the currently marketed Vitros DT 60/DTSC/DTE II Module.

- | | | |
|----|--|--|
| 1. | <u>Name of Predicate Device 1:</u>

Predicate Device 510K number:
Product Code: | Johnson and Johnson's DT
60/DTSC/DTE II(formerly Kodak
Ektachem DT 60/DTSC/DTE II
System)
K 912844/A
75JJE, JJF, others |
| 2. | <u>Name of Predicate Device 2:</u>
Predicate Device 510K number:
Product Code: | CARESIDE Analyzer (for lab use)
K 980056
JJF, CDQ, CEK, CIX |

IV. **Device Description**

A. Explanation of Device Function

1. Instrument

The CARESIDE Analyzer is a compact chemistry instrument that performs multiple discrete analyses on human whole blood, plasma, or serum samples. The CARESIDE Analyzer is semi-automated: the only operator steps are the addition of the sample to the test cartridge and the insertion of the dosed cartridge into the instrument. The CARESIDE Analyzer automatically warms, separates, meters, dispenses, and incubates the sample before reading the signal and calculating results. The CARESIDE Analyzer is intended only for use with CARESIDE test cartridges.

The instrument is controlled through a touch-screen interface. Results are displayed on the interface screen. Results can also be downloaded on to a 3-1/2 inch diskette or to a computer via a RS-232 port.

The CARESIDE Analyzer accepts up to 6 test cartridges from a single patient at the same time.

The user enters the patient identification and test(s) to be performed via the touch screen by following a series of menus and prompts. Next, the user obtains the required test cartridge(s) from refrigerated storage and removes the cartridge from its individual hermetically sealed package. Each CARESIDE test cartridge contains both human readable and barcode labeling. Test specific requirements, such as specimen type, sample storage, and reagent storage are provided in test-specific package inserts. See CARESIDE package inserts and CARESIDE Analyzer Operator's Manual (Appendix 2 and 3).

The user doses the cartridge by lifting the cartridge lid, filling the cartridge Sample Well with sample via a dropper or pipette, and closing the cartridge lid. The user inserts the cartridge into the instrument when prompted. During the subsequent operations, the cartridge is held securely on a circular platter, which is automatically weight balanced. The cartridge is rotated beneath a bar code reader which reads the cartridge name, lot identification, calibration data, and expiration date from the barcode located on the top surface of the disposable cartridge. The cartridge chamber is heated and the cartridges are equilibrated at 37 °C. The cartridges are spun to initially transfer the sample from the Sample Well to the Separation Well, metering passages, and overflow well and then to separate the blood cells (if present) from the sample. After spinning, 8.5 µl of sample is automatically dispensed onto the analytical element of the cartridge by two plungers, one of which seals the cartridge vent hole and other which depresses the membrane that covers the Sample Well. After dispensing, the instrument takes any differential potentiometry readings via pins that move into

contact with the electrodes on the slide of any CARESIDE ELECTROLYTE (NA+K+CL) cartridge present. Next, the instrument begins taking reflectance readings while spinning. Light emitting diodes (LEDs) are arranged radially beneath the film reading position. The reflected light is detected by photodiodes that convert the light energy to electrical signals. Reflectance is measured from the center of the bottom surface of the reagent film through the optically clear plastic transparent support and also from white and black standards that are present on the cartridge platter for continuous reference measurements. After all readings are taken, the spinning cartridges are stopped and the cartridges are ejected into a removable waste bin.

The reflectance readings are taken at a fixed angle from the incident light at a regular interval. Multiple readings at each time point are taken across the film. From each series of readings a single digital signal is stored for final data reduction. From the signals corresponding to the desired time point(s), the reflectance is calculated based on the signals obtained from the film and the white and black standards. Test specific algorithms are used to calculate results from the reflectance.

2. Test Cartridges

The CARESIDE Analyzer utilizes CARESIDE film chemistry and electrochemistry cartridges. The CARESIDE cartridges for individual chemistry tests were the subject of separate past 510(k) submissions as well as future 510(k) submissions. These cartridges consist of a pre-analytical element and an analytical element.

For electrochemistry cartridge, the pre-analytical element consists of a plastic cartridge consisting of 4 parts which holds an electrochemical slide in a plastic housing.

For the film chemistry cartridge, the pre-analytical element consists of a plastic cartridge consisting of 5 parts which holds a rectangular piece of dry reagent film. A top and bottom housing form a series of channel and wells in the cartridge base. On top of the cartridge base is a hinged lid with a vent hole and a plastic membrane to cover the Sample Well when the lid is closed. Whole blood, plasma or is introduced into the Sample Well of the cartridge. During centrifugation within the instrument, the force of centrifugation moves the sample to the Separation Well, to the various channels and chambers of the test cartridge and separates the blood cells from the plasma. Next, the flow of the plasma or serum (if applicable) from the metering channel is initiated when the Sample Well is pressurized by deformation of its plastic membrane by a plunger within the instrument while the vent hole is sealed by another plunger. The pressure forces the plasma or serum out of the sample delivery passage onto the analytical element.

The analytical elements consist of a test-specific multi-layer film or ion-selective electrode slide. Films consist of a combination of layers. A typical film consists of 3 to 6 layers and ranges from about 0.5 to 0.7 mm in thickness. Films are approximately 1 x 1 cm.

The CARESIDE test cartridges are individually bar coded and packaged. The test cartridge package is hermetically sealed to assure stability over the shelf-life of the cartridge. The following are film layers used for various test cartridges.

- Spreading layer - distributes the sample evenly on the film
- Substrate layer - provides substrates for enzymatic reactions
- Reaction layer - provides an environment and time for a reaction to proceed
- Reflection layer - provides a background upon which the formed dye or colored substance is irradiated with light of a specific wavelength.
- Detection layer - provides a layer in which the biochemical reaction is coupled to a detectable chromogen
- Suction layer - provides a layer to draw fluid

- Absorbing layer – provides a layer in which a molecule of interest is absorbed
- Porous layer – provides a layer to allow gas to permeate while retaining other substances
- Buffer layer – provides a medium with a defined stable pH for a reaction to proceed
- Interference elimination layer – provides a reaction to eliminate a potential interferent
- Transparent support – a transparent material, typically mylar, used to support the other layers and allow the incident and reflected light to pass.

3. Calibration

Similar to other automated instruments in commercial distribution, the CARESIDE Analyzer and reagent cartridges are factory-calibrated. The user does not perform calibration.

The user receives CARESIDE cartridges that are labeled with a barcode. This barcode contains lot-specific coefficients for a polynomial equation and is scanned by the CARESIDE Analyzer. The observed reflectance (ODr) is adjusted by inputting it into the equation. The patient result is calculated from the adjusted ODr using the polynomial describing the master dose – response curve.

The instrument is calibrated during each test by automatically reading a black and white reflectance standard and making adjustments if necessary.

The user performs periodic quality control and calibration verification to confirm maintenance of calibration over time.

B. Test Summary

Measurement of each analyte from blood using the CARESIDE Analyzer is useful in the diagnosis and treatment of patients with a variety of diseases as described in each test cartridge package insert.

V. Intended Use

A. Intended Use

The CARESIDE Analyzer is an *in vitro* diagnostic instrument intended for the measurement of various clinical chemistry analytes in human whole blood, plasma, or serum.

B. Indications for Use

For *in vitro* diagnostic use. For point of care use.

VI. Technological Characteristics

A. Similarities

	CARESIDE Analyzer	Vitros DT 60/DTSC/DTE II System
Intended Use	Intended for the measurement of various analytes	Same
Indications	For <i>in vitro</i> diagnostic use For point of care use	Same
Type	Quantitative	Same
Principle of method	Chemistry - Dry film based. Chromogen quantitated by reflectance measurement at single and multiple reaction times for end-point and rate measurements. Electrochemistry – ion-selective electrodes and differential potentiometry	Same
Compatible reagents	CARESIDE cartridges	Vitros DT Slides
Menu	Currently 32 direct and calculated tests	Approx 37 direct and calculated tests
Specimen dilution	Not required	Not required
Detector	Reflectance and differential potentiometry	Reflectance and differential potentiometry
Test time	Approx 4 minutes warm-up (on-board) plus up to 6 minutes test time.	15 minutes warm-up (off-line) plus 5 minutes test time.
Throughput (approximate)	24 test/hours (no centrifugation required)	10 minute centrifugation (typical) required for sample preparation (quoted throughput is without centrifugation) DT60 II 65 DTSC II 15 DTE 15
Sample Type	Whole blood, plasma and serum (for whole blood applied sample plasma is test sample except for hemoglobin and Na, K, Cl) Tests for urine not available.	serum, plasma whole blood not acceptable except for hemoglobin Urine for some tests
Specimen volume	90 ± 10 µl applied volume, 8.5 µl test volume	10 µl
Calibration	Calibration information bar coded on each cartridge. Calibration information may change with each lot.	Run Kodak Ektachem DT II calibrators whenever a new slide lot is used or when necessary
Quality Control	External Wet Internal and External Dry.	External Wet
Incubation Temperature	37 °C	37 °C

B. Differences

	CARESIDE Analyzer	DT 60/DTSC/DTE II
Access	Single patient per platter run	Single or multiple patient
Queuing	6 cartridges	Multiple slides
Module	Single	Multiple
Software updating	3-1/2 inch floppy	EPROM (CDM, CLM)
Direct blood specimen	Yes, whole blood	No, requires separation of whole blood prior to sample application
Accurate pipetting	Not required	Required
Reagent pre-warming	Not required	Required

C. Comparative Performance Characteristics
Comparative Performance Characteristics (see individual test 510k submissions)

D. Conclusion
The clinical data provided demonstrate that the CARESIDE Analyzer, like other microchemistry instruments, is safe and effective for point of care as well as laboratory use, and performs equivalently or better than the other legally marketed predicate device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC - 2 1999

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

Re: K993634
Trade Name: CARESIDE™ Analyzer System for Point of Care Use
Regulatory Class: I
Product Code: JJF
Regulatory Class: II
Product Codes: CGA, CHH, JGS, CEM, CGZ, CDQ, JFY
Dated: October 25, 1999
Received: October 27, 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 (Pre-market 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

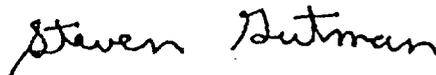
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Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

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

INDICATIONS FOR USE

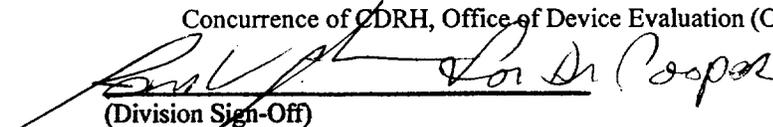
510(k) Number: K 993634

Device Name: CARESIDE™ Sytem

Indications for use: The CARESIDE *Analyzer* is an *in vitro* diagnostic instrument intended for the measurement of various clinical chemistry analytes in whole blood, plasma, and serum. It is intended for in vitro diagnostic use and is intended for point of care use.

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

Concurrence of CDRL, Office of Device Evaluation (ODE)



(Division Sign-Off)

Division of Clinical Laboratory Devices

510(k) Number K993634

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____
(Optional Format 1-2-96)