

JUN 25 1998

510(K) SUMMARY

CARESIDE™ URIC ACID 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@worldnet.att.net
G. Date 510(k) Summary prepared	April 27, 1998

II. Device Information

A. Device Name (Trade)	CARESIDE™ Uric Acid
B. Device Name (Classification)	Uric acid test system
C. Device Classification	Clinical chemistry panel Uric acid test system Regulation Number: 21 CFR 862.1775 Regulatory Class I Classification Number: 75JHB
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.

Uric acid *in vitro* diagnostic products, in both dry film and other formats, are already on the U.S. market, including uric acid products which utilize uricase catalyzed generation of hydrogen peroxide which reacts with chromogens in a peroxidase catalyzed reaction to form a blue dye.

B. Specific equivalency claim

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

Name of Predicate Device: Johnson and Johnson's (formerly Eastman Kodak, Inc.) **Vitros URIC Slides** for Johnson and Johnson's **Vitros DT 60** (formerly Eastman Kodak's DT 60 II).

Predicate Device 510K number: **K912844/A**
Product Code: **75JHB**

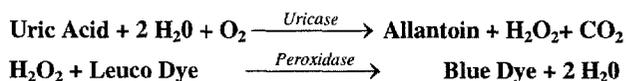
IV. Device Description

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

A. Explanation of Device Function

Each CARESIDE™ Uric Acid cartridge consists of a uric acid-specific multi-layer reagent film mounted in a plastic base with a hinged lid. The user introduces the whole blood, serum, or plasma 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, spins the cartridge to move the sample from the sample deposition well into the cartridge channels and chambers, and brings the cartridge and the contained specimen to 37°C. As the cartridge continues to spin, the blood cells are separated from the plasma/serum and the cells accumulate in the separation well. Approximately ten microliters of plasma (or serum, as applicable) remain 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 uric acid containing specimen uniformly and removes large molecular weight components, such as protein, as the specimen moves into the underlying reaction layer. Uric acid is hydrolyzed by uricase to generate hydrogen peroxide which in turn oxidizes the leuco dye in a peroxidase catalyzed reaction. The color intensity of the resulting blue dye, as measured by the amount of reflected light at 655 nanometers, is directly related to the specimen uric acid concentration.

Test Reaction Sequence:



As the cartridges spin, photodiodes measure reflectance of light emitted by wavelength-specific light emitting diodes (LEDs) at a fixed time. The analyzer uses the reflectance measurements and the lot-specific standard curve to calculate uric acid concentration.

B. Test Summary

Uric acid is the major product of the catabolism of purine nucleosides, adenosine and guanosine. Purines from catabolism of dietary nucleic acid are converted to uric acid directly. Approximately 75 percent of uric acid excreted is lost in the urine. Most of the remainder is secreted into the gastrointestinal tract, where it is degraded to allantoin and other compounds by bacterial enzymes¹. Hyperuricemia is caused when serum or plasma uric acid concentration levels rise above 7 mg/dL in men and 6 mg/dL in women³. Disorders of hyperuricemia can be divided into those due to increased intake, decreased intake excretion, and increased production². Hyperuricemia can result from uric acid overproduction or under excretion, renal retention due to renal failure, drug or chemical toxicity, hypothyroidism, hyperparathyroidism, increased turnover of nucleic acid due to myeloproliferative syndromes or cancer chemotherapy, or specific enzyme deficiencies such as hypoxanthine-guanine phosphoribosyl transferase or phosphoribosyl pyrophosphate synthetase.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

JUN 25 1998

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

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

Re: K981604
CareSide™ Uric Acid
Regulatory Class: I
Product Code: JHB
Dated: April 27, 1998
Received: April 28, 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 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.

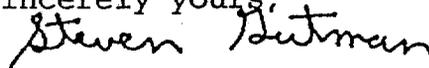
Page 2

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/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

VI. INDICATIONS FOR USE

510(k) Number: K981604

Device Name: CARESIDE™ Uric Acid

Indications for use: For *in vitro* diagnostic use with the CARESIDE™ Analyzer to quantitatively measure uric acid from whole blood, plasma or serum specimens to aid in the diagnosis and treatment of patients with numerous renal and metabolic disorders including renal failure, gout, leukemia, psoriasis, starvation or wasting conditions, and of patients receiving cytotoxic drugs. 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: K981604

(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)