

FEB 4 1998

Exigent Diagnostics, Inc.  
Page 12CareSide™ Albumin Premarket Notification  
revised on January 27, 1998

K980041

**V. 510(K) SUMMARY: CARESIDE™ ALBUMIN SAFETY AND EFFECTIVENESS****I. Applicant Information**

A. Applicant Name	Exigent Diagnostics, 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	<a href="mailto:asarchk@worldnet.att.net">asarchk@worldnet.att.net</a>
G. Date 510(k) Summary prepared	January 27, 1998

**II. Device Information**

A. Device Name (Trade)	CareSide™ Albumin
B. Device Name (Classification)	Albumin test system
C. Device Classification	Clinical chemistry panel Albumin test system Regulation Number: 21 CFR 862.1035 Regulatory Class II
D. Device Tier	Tier I
E. 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.

Albumin *in vitro* diagnostic products, in both dry film and other formats, are already on the U.S. market including Albumin products which utilize bromocresol green complexation.

**B. Specific equivalency claim**

This CareSide™ Albumin product is substantially equivalent in principle, intended use, and clinical performance to the currently marketed Vitros slides for the quantitative measurement of albumin on the Vitros DT 60 II.

Name of Predicate Device: Johnson and Johnson's Vitros Albumin Slides (formerly Eastman Kodak, Inc.).

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

Exigent Diagnostics, Inc.  
Page 12a

CareSide™ Albumin Premarket Notification  
revised on January 27, 1998

#### IV. Device Description

CareSide™ Albumin cartridges are used with the Exigent Diagnostics CareSide™ Analyzer to measure albumin concentration in whole blood, plasma or serum specimens. The CareSide™ Albumin 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 albumin concentration. The film cartridge (patent pending) contains all reagents necessary to measure albumin concentration. When used in conjunction with the CareSide™ Total Protein cartridge on the CareSide™ Analyzer, the analyzer calculates globulin (as the difference between the total protein and albumin concentrations) and the albumin/globulin ratio (A/G ratio).

##### A. Explanation of Device Function

Each Exigent Diagnostics CareSide™ Albumin cartridge consists of an albumin-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 Exigent Diagnostics 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. As the cartridge continues to spin, the blood cells are separated from the plasma/serum and the cells accumulate in the separation well. Ten microliters of plasma (or serum, as applicable) remain in the metering passage. Any excess sample flows into an overflow well.

The ten microliters of plasma (or serum, as applicable) is automatically dispensed onto the multi-layer reagent film. The spreading layer distributes the sample evenly on the film, the sample moves through a spreading and substrate layer where a blue dye forms in the presence of albumin, and the blue albumin-BCG complex diffuses through the buffer layer.

##### Test Reaction Sequence:

Albumin + Bromocresol green → Albumin-BCG (Blue)

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 albumin concentration.

##### B. Test Summary

Albumin is the single most abundant protein in normal plasma and usually makes up to two thirds of total plasma protein. Medium to heavy albumin concentration changes in plasma have significant effects on the relative amounts of the bound and free concentration of ligands it carries. As a result, albumin levels can influence the receptor interaction and metabolism of endogenous and exogenous ligands, such as drugs and hormones.

Hyperalbuminemia, an abnormally high plasma albumin level, is found only with dehydration or, artifactually, in a sample taken with prolonged venostasis, and is usually of little clinical importance. Hypoalbuminemia, a low plasma albumin level, may be caused by dilution of an excess protein-free fluid, redistribution of albumin into the interstitial fluid due to a decreased synthesis rate, an increased catabolism rate, or by loss from the body.

The most severe hypoalbuminemia is caused by protein loss by way of urine or feces; when plasma albumin levels are less than 2.0 g/dl, edema is usually present. Normally about 4 percent of the body albumin is replaced each day by hepatic synthesis. Synthesis depends on an adequate dietary supply of amino acids to replace the nitrogen lost, mainly as urinary urea, after protein catabolism.

Exigent Diagnostics, Inc.  
Page 12b

CareSide™ Albumin Premarket Notification  
revised on January 27, 1998

V. Intended Use

A. Intended Use

The CareSide™ Albumin product is intended for *in vitro* diagnostic use when used with the Exigent Diagnostics CareSide™ Analyzer to measure albumin concentration in whole blood, plasma or serum specimens. When used in conjunction with the Exigent Diagnostics CareSide™ Total Protein cartridge on the CareSide™ Analyzer, the albumin device may be used to calculate globulin concentration and albumin/globulin ratio from albumin and total protein results. The CareSide™ Albumin test aids in the diagnosis and treatment of numerous diseases involving mainly the liver or kidneys.

B. Indications for Use

This product is indicated for use with patients with numerous diseases involving mainly the liver or kidneys.

VI. Technological Characteristics

A. Similarities

	CareSide™ Albumin	Vitros ALB DT Slides
Intended Use	Primarily to aid in the diagnosis and treatment of numerous diseases mainly involving the liver or kidneys.	Same
Indications	For <i>in vitro</i> diagnostic use. For professional use only.	For <i>in vitro</i> diagnostic use.
Measurement	Quantitative	Same
Reportable range	1.0 to 6.0 g/dL	1.0 to 6.0 g/dL
Method Principle	Dry film based complexation with bromocresol green	Same
Specimen dilution	Not required	Same
Detector	Reflectance (615 nm)	Reflectance (630 nm)
Test time	Approximately 4 minute warm-up (on-board) plus 6 minute test time.	15 minutes slide warm-up (off-line) plus 3 minutes test time.
Reference Method	Bromocresol green (wet)	Bromocresol green (dry film)
Sample Type	Serum, plasma, whole blood (wb) [wb applied sample, plasma test sample]	serum, plasma
Specimen volume	10 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.	
Quality Control	2 levels	Same
Reporting Units	g/dL or µmol/L	g/dL or g/L
Reaction temperature	37 °C	Same

Exigent Diagnostics, Inc.  
Page 12c

CareSide™ Albumin Premarket Notification  
revised on January 27, 1998

B. Differences

	CareSide™ Albumin	Vitros ALB DT Slides
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

	CareSide™ Albumin	Vitros Albumin DT Slides
Detection limit	1 g/dL	1 g/dL
Reportable range	1.0 to 6.0 g/dL	1.0 to 6.0 g/dL
Accuracy	Mean recovery 107%	Not provided
Precision	Total CV, 4.3 g/dL 5.3%	Total CV, 4.2 g/dL 2.1%
Method comparison	CareSide™ = 0.95 (Vitros Albumin DT) + 0.14, r=0.96	
Linearity	Mean deviation approx 5%, r>0.99	Not provided
Interference	No significant interference observed at tested concentration of interferent: Ascorbic Acid, 20 mg/dL Bilirubin, 20 mg/dL Hemoglobin, 250 mg/dL Triglycerides 3000 mg/dL	Not provided
Specimen Types & Anticoagulants	No clinically significant difference between heparinized whole blood, serum, heparin plasma, and EDTA plasma.	No clinically significant difference between serum and heparin plasma. Whole blood is unsuitable.
Expected Values	3.6 to 4.5 g/dL. (combined male and female) Central 95% interval	3.5 to 5.0 g/dL referenced from literature

D. Conclusion

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



Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

FEB 4 1998

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

Re: K980041  
CareSide™ Albumin  
Regulatory Class: II  
Product Code: CIX  
Dated: December 30, 1997  
Received: January 6, 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 (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 have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

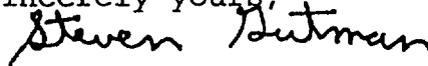
Page 2

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

### VII. Indications for Use

510(k) Number: ~~To be assigned~~ K98064  
Device Name: CareSide™ Albumin  
Indications for use: For *in vitro* diagnostic use with Exigent Diagnostics CareSide Analyzer to measure albumin from whole blood, plasma or serum specimens by professionals to aid in the diagnosis and treatment of a variety of numerous diseases involving mainly the liver or kidneys.

Alper  
(Division Sign-Off)  
Division of Clinical Laboratory Devices  
510(k) Number K980041

✓ prescription use

awm 1-29-98