FEB 4 1998

K980042

V. 510(K) SUMMARY: CARESIDE™ TOTAL PROTEIN 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	asarchk@worldnet.att.net
G.	Date 510(k) Summary prepared	January 30, 1998

II. Device Information

A.	Device Name (Trade)	**CareSide™ Total Protein**
B.	Device Name (Classification)	Total Protein test system
C.	Device Classification	Clinical chemistry panel Total Protein test system Regulation Number: 21 CFR 862.1635 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.

Total Protein *in vitro* diagnostic products, in both dry film and other formats, are already on the U.S. market including total protein products which utilize the biuret reaction (reaction of protein peptide bonds with cupric ion in alkaline environment).

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 total protein on the Vitros DT 60 II.

Name of Predicate Device:	Johnson and Johnson's Vitros Total Protein Slides (formerly Eastman Kodak, Inc.).
Predicate Device 510K number:	**K912844/A**
Product Code:	75CEK

IV. Device Description

CareSide™ Total Protein cartridges are used with the Exigent Diagnostics CareSide™ Analyzer to measure total protein concentration in whole blood, plasma or serum specimens. The CareSide™ Total Protein 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 total protein concentration. The film cartridge (patent pending) contains all reagents necessary to measure total protein concentration. When used in conjunction with the CareSide™ Albumin 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™ Total Protein cartridge consists of a total protein - 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 and substrate layer distributes the sample evenly on the film and diffuses into the reagent layer where protein in the specimen reacts with copper ion in an alkaline environment to form a purple dye.

Test Reaction Sequence:

Protein + Cupric ion → purple dye

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 total protein concentration.

B. Test Summary

The majority of proteins found in the blood, except for immunoglobulins and protein hormones, are synthesized in the liver by hepatocytes and enter the bloodstream through the hepatic sinusoids. Functions of protein in the blood include maintenance of osmotic pressure, transport, defense, coagulation, fibrinolysis, buffering, and other special functions. The amount and proportions of blood proteins can be altered in some diseases.

Severe hypoproteinemia (primarily albumin), <6.0 g/dL, can be seen in dietary insufficiency, maldigestion, or malabsorption. Severe liver and renal disease such as glomerular nephritis, nephrotic syndrome, and severe proximal tubular disease can also cause decreased total protein levels. Edema can result in a fall in serum or plasma protein levels (<4.0 g/dL). Hyperproteinemia (10 to 15% increase) can be a symptom in monoclonal gammopathies as well as in dehydration.

V. Intended Use

A. Intended Use

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

B. Indications for Use

This product is indicated for use with patients with a variety of diseases involving liver, kidney, or bone marrow as well as various metabolic or nutritional disorders.

VI. Technological Characteristics

A. Similarities

	CareSide™ Total Protein	Vitros TP DT Slides
Intended Use	Primarily to aid in the diagnosis and treatment of a variety of diseases involving liver, kidney, or bone marrow as well as various metabolic or nutritional disorders.	Same
Indications	For *in vitro* diagnostic use. For professional use only.	Same
Measurement	Quantitative	Same
Reportable range	2.0 to 11 g/dL	2.0 to 11 g/dL
Method Principle	Dry film based reaction of protein with cupric ion in an alkaline environment	Same
Specimen dilution	Not required	Same
Materials Source	Cupric sulfate (synthetic)	Cupric tartrate (synthetic)
Detector	Reflectance (570 nm)	Reflectance (555 nm)
Test time	Approximately 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	Biuret	Same
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 g/L	Same
Reaction temperature	37 °C	Same

B. Differences

	CareSide™ Total Protein	Vitros TP 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™ Total Protein	Vitros TP DT Slides
Detection limit	2 g/dL	2 g/dL
Reportable range	2.0 to 11 g/dL	2.0 to 11 g/dL
Accuracy	Mean recovery 105%	Not provided
Precision	Total CV, 6.0 g/dL 7.2%	Total CV, 4.5 g/dL 2.5%
Method comparison	CareSide™ = 0.9 (Vitros Total Protein DT) + 0.56, r=0.93	
Linearity	Mean deviation approx 1%, $r^2 \geq 0.99$	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 1500 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 and heparin plasma. Whole blood is unsuitable.
Expected Values	6.3 to 8.4 g/dL (combined male and female) Central 95% interval	6.3 to 8.2 g/dL (combined male and female) Central 95% interval

D. Conclusion

The nonclinical and clinical data provided demonstrate that the CareSide™ Total Protein 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

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

Re: K980042
CareSide™ Total Protein
Regulatory Class: II
Product Code: CEK
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 (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/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

VII. INDICATIONS FOR USE

510(k) Number: To be assigned

Device Name: CareSide Total Protein

Indications for use: For *in vitro* diagnostic use with Exigent Diagnostics CareSide™ Analyzer to measure total protein from whole blood, heparinized plasma or serum specimens by professionals to aid in the diagnosis and treatment of a variety of diseases involving the liver, kidney, or bone marrow as well as other metabolic or nutritional disorders.

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number k980042