

JAN 28 1998

K980055

Exigent Diagnostics, Inc.
Page 10aCareSide™ Globulin and A/G Ratio Premarket Notification
revised on January 26, 1998**V. 510(k) Summary: CareSide™ Globulin and A/G Ratio
Calculation 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 26, 1998

II. Device Information

A. Device Name (Trade)	CareSide™ Globulin and Albumin/Globulin (A/G) Ratio
B. Device Name (Classification)	Globulin test system
C. Device Classification	Clinical chemistry panel Globulin test system Regulation Number: 21 CFR 862.1330 Regulatory Class I
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. Historically, globulin has been measured directly in a variety of ways, including electrophoretically, nephelometrically, turbidimetrically, and colorimetrically. However, direct measurement is no longer in common use. Rather, commercial *in vitro* diagnostic systems and clinical laboratories have, for many years, provided clinically useful results by calculating globulin results from albumin and total protein. Calculations of globulin from these dry film and other formats are similarly widely recognized.

Globulin *in vitro* diagnostic products are already on the U.S. market. These products utilize dry film and other formats. These products utilize the biuret reaction (reaction of protein peptide bonds with cupric ion in alkaline environment).

B. Specific equivalency claim

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

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

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

IV. Device Description

The CareSide™ Analyzer uses the Total Protein and Albumin cartridge test results from a single patient sample to determine the globulin concentration and A/G Ratio. Globulin is calculated as the difference between the total protein and albumin concentrations.

A. Explanation of Device Function

The CareSide™ Globulin is a calculated test based upon whole blood, plasma or serum results from CareSide™ Total Protein and Albumin cartridges using only the CareSide™ Analyzer [510(k) pending]. The CareSide™ Globulin is an *in vitro* diagnostic product intended for the calculation of globulin in human serum, plasma, and whole blood. The principle of the calculation relies upon the following CareSide™ Total Protein and CareSide™ Albumin cartridges test reactions.

Test Reaction Sequences:

Total Protein

Protein + Cupric ion → purple dye

Albumin

Albumin + Bromocresol green → Albumin-BCG (Blue)

B. Test Summary

Globulin is a term for a subset of serum proteins distinguished from the major plasma protein, serum albumin, by their electrophoretic properties. Most globulins have major carbohydrate components. Globulins are categorized by their electrophoretic properties as, α , β , and γ -globulins. α -Globulins include α_1 -globulin and α_2 -globulin (α_2 -glycoprotein, ceruloplasmin, and prothrombin). β -globulins consist of β_1 -lipoproteins, transferrin, and plasminogen. γ -globulins, which have molecular weights approximately 150,000, function as antibodies and occur in a very large number of different types. The quantitation of globulin (either indirect calculation or less commonly, direct measurement) is used to aid in the diagnosis of many disease states.

Globulins are elevated in chronic infections, most acute and chronic liver diseases, collagen disorders such as rheumatoid arthritis and lupus erythematosus, and neoplastic diseases such as multiple myeloma, macroglobulinemia, and leukemia.

Although it is recommended that clinicians evaluate the level of globulin and albumin individually, many physicians additionally request the calculated ratio of albumin to globulin concentration for evaluation.

V. Intended Use

A. Intended Use

The CareSide™ Globulin product is intended for *in vitro* diagnostic use when used in conjunction with the Exigent Diagnostics CareSide™ Analyzer to calculate globulin and albumin/globulin ratio from albumin and total protein results. When a CareSide™ Analyzer operator performs both a total protein test (Product Code: TP) and an albumin test (Product Code: ALB) on a single patient sample, the CareSide™ Analyzer automatically calculates the Globulin measurement and the Albumin to Globulin ratio (A/G Ratio). Both calculations aid in the diagnosis and treatment of patients with numerous illnesses including severe liver and renal disease, multiple myeloma, and other disorders of blood globulins.

B. Indications for Use

This product is indicated for use with patients with numerous illnesses including severe liver and renal disease, multiple myeloma, and other disorders of blood globulins.

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VI. Expected Values (Reference Interval)

To determine the following central 95% interval, an on-site investigator used CareSide™ Total Protein and CareSide™ Albumin test cartridges on the CareSide™ Analyzer to test specimens from a population of 68 ambulatory, healthy adult workers (males, n=27, mean age 38; females, n= 41, mean age 38):

Globulin 2.7 to 4.2 g/dL
A/G Ratio 0.9 to 1.6

This reference interval is similar to the globulin reference interval (2.8 to 3.8 g/dL) published by Lehninger, 1975. (Lehninger, A.L., Biochemistry, Worth Publishers, p. 831; 1975)



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JAN 28 1998

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

Re: K980055
CareSide™ Globulin
Regulatory Class: I
Product Code: JGE
Dated: December 30, 1997
Received: January 6, 1997

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.

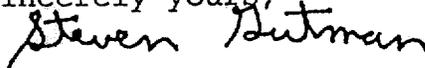
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Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

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/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

510(k) Number (if known): K980055

Device Name: _____

Indications For Use:

VII. Indications for Use

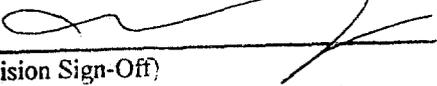
510(k) Number: To be assigned

Device Name: CareSide Globulin

Indications for use: For *in vitro* diagnostic use with Exigent Diagnostics CareSide Analyzer to calculate globulin and albumin/globulin ratio from albumin and globulin results generated on the CareSide Analyzer by professionals to aid in the diagnosis and treatment of patients with numerous illnesses including severe liver and renal disease, multiple myeloma, and other disorders of blood globulins.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Clinical Laboratory Devices

510(k) Number K980055

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)