

IV. 510(k) Summary: CareSide™ Glucose 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	March 31, 1998

II. Device Information

A. Device Name (Trade)	CareSide™ Glucose
B. Device Name (Classification)	Glucose test system
C. Device Classification	Clinical chemistry panel Glucose test system Regulation Number: 21 CFR 862.1345 Regulatory Class II Classification Number: 75CGA
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.

Glucose *in vitro* diagnostic products, in both dry film and other formats, are already on the U.S. market, including glucose products which utilize glucose oxidase catalyzed generation of hydrogen peroxide which enzymatically reacts with chromogens in a peroxidase catalyzed reaction to form a red dye.

B. Specific equivalency claim

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

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

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

IV. Device Description

CareSide™ Glucose cartridges are used with the Exigent Diagnostics CareSide™ Analyzer to measure glucose concentration in whole blood, plasma or serum specimens. The CareSide™ Glucose 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 glucose concentration. The film cartridge (patent pending) contains all reagents necessary to measure glucose concentration.

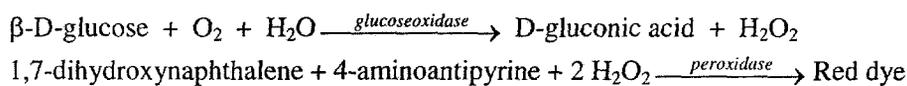
A. Explanation of Device Function

Each Exigent Diagnostics CareSide™ Glucose cartridge consists of a glucose-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, 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 sample evenly on the film. Protein is removed before the glucose solution diffuses through the reflection layer and reaches the reaction layer. In the reaction layer glucose reacts with oxygen via a glucose oxidase-catalyzed reaction to produce hydrogen peroxide which in turn participates in a peroxidase-catalyzed reaction with the substrate to produce a red dye. The color intensity, as measured by the amount of light reflected at 505 nanometers, is directly related to the specimen glucose 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 glucose concentration.

B. Test Summary

Determination of whole blood, serum or plasma glucose levels is important in the diagnosis and control of hypoglycemia, diabetes, nonketotic hyperglycemia, and various endocrine diseases of the pituitary and adrenal glands. Glucose is often measured as a tolerance test after the administration of doses of glucose or insulin. While clinical diagnoses should not be based upon glucose measurements alone, the following criteria for the diagnosis of diabetes mellitus have been proposed by the American Diabetes Association (ADA Glucose Guidelines Diabetes Care, Volume 20, Number 7, p. 1183-1197, July 1997)., including: 126 mg/dL (fasting), 200 mg/mL (non-fasting with symptoms), 200 mg/dL (2-hour oral glucose tolerance).

V. Intended Use

A. Intended Use

The CareSide™ Glucose cartridge is intended for *in vitro* diagnostic use in conjunction with the Exigent Diagnostics CareSide™ Analyzer to quantitatively measure glucose concentration in whole blood, plasma or serum by laboratory professionals. The CareSide™ Glucose test aids in the diagnosis and treatment of glucose regulation disorders such as diabetes.

B. Indications for Use

This product is indicated for use with patients with glucose regulation disorders such as diabetes.

VI. Technological Characteristics

A. Similarities

	CareSide™ Glucose	Vitros Glucose DT Slides
Intended Use	Primarily to aid in the diagnosis and treatment of glucose regulation disorders such as diabetes.	Same
Indications	For <i>in vitro</i> diagnostic use. For laboratory professional use.	For <i>in vitro</i> diagnostic use
Measurement	Quantitative	Same
Method Principle	Dry film based glucose oxidase generation of hydrogen peroxide from glucose. Reaction of chromogen with hydrogen peroxide to form red dye. Dye quantitated by reflectance measurement after fixed time.	Same
Specimen dilution	Not required	Same
Materials Source	Glucose oxidase from <i>Aspergillus niger</i> ; peroxidase from horseradish	Glucose oxidase, peroxidase: sources unknown
Detector	Reflectance (505 nm)	Reflectance (555 nm)
Test time	Approximately 4 minute warm-up (on-board) plus 5 minute test time.	15 minutes slide warm-up (off-line) plus 5 minutes test time.
Reference Method	Hexokinase	Hexokinase
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.	Run Vitros DT II calibrators whenever a new slide lot is used or when necessary.
Quality Control	2 levels	Same
Reporting Units	mg/dL or mmol/L	Same
Reaction Temp.	37 °C	Same

B. Differences

	CareSide™ Glucose	Vitros Glucose DT Slides
Direct blood specimen	Yes, whole blood	No, requires separation of whole blood prior to sample application
Reportable range	20 to 600 mg/dL	20 to 450 mg/dL
Accurate pipetting	Not required	Required
Reagent pre-warming	Not required	Required

C. Comparative Performance Characteristics

	CareSide™ Glucose	Vitros Glucose DT Slides
Detection limit	20 mg/dL	20 mg/dL
Reportable range	20 to 600 mg/dL	20 to 450 mg/dL
Accuracy	Mean recovery 98%	Not provided
Precision	Total CV, 94 mg/dL, 5.8%	Total CV, 117 mg/dL, 1.4%
Method comparison	CareSide™ = 1.04 (Vitros Glucose DT) - 7.0 mg/dL, r = 1.00	
Linearity	Mean deviation approx 99%, r = 1.00	Not provided
Interference	No significant interference observed at tested concentration of interferent: Ascorbic Acid, 20 mg/dL Bilirubin, 20 mg/dL Creatinine 40 mg/dL Hemoglobin, 500 mg/dL Protein 3.5 - 9.5 g/dL Triglycerides 3000 mg/dL Uric Acid 20 mg/dL	Interference observed for: Ascorbic acid Hemoglobin @ 250 mg/dL Protein < 5 g/dL Protein > 10 g/dL
Specimen Types & Anticoagulants	No clinically significant difference between heparinized whole blood, serum, heparin plasma, and EDTA plasma.	No clinically significant difference between serum, heparin plasma, or EDTA plasma. Whole blood is unsuitable.
Expected Values	68 to 101 mg/dL (fasting) Central 95% interval	65 - 110 mg/dL (fasting) Central 95% interval

D. Conclusion

The nonclinical and clinical data provided demonstrate that the CareSide™ Glucose 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

MAY 7 1998

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

Re: K981183
CareSide™ Glucose
Regulatory Class: II
Product Code: CGA
Dated: March 31, 1998
Received: April 1, 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.

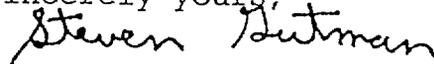
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Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

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

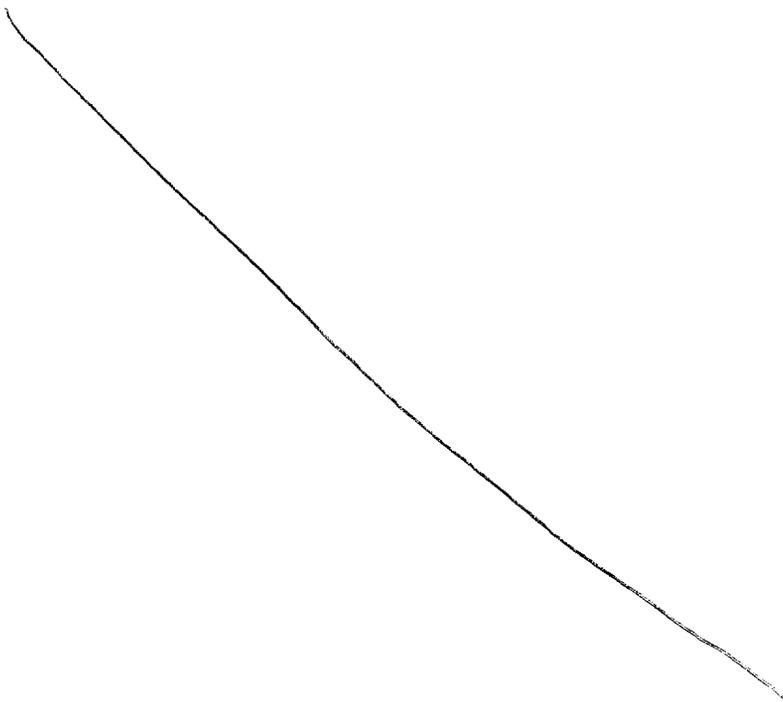
Enclosure

Indications for Use

510(k) Number:

Device Name: CareSide™ Glucose

Indications for use: For *in vitro* diagnostic use with Exigent Diagnostics' CareSide™ Analyzer to measure glucose from anti-coagulated whole blood, plasma or serum specimens to aid in the diagnosis and management of disorders of blood glucose regulation such as diabetes.



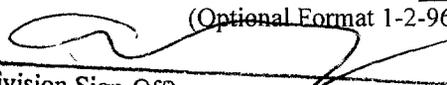
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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use
(Per 21 CFR 801.109)

OR

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



(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number 62981153