

V. 510(k) Summary: CareSide™ Analyzer Safety and Effectiveness

MAR - 6 1998

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 | February 23, 1998 |

II. Device Information

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|---|---|
| A. Device Name (Trade) | CareSide™ Analyzer |
| B. Device Name (Classification) | Micro chemistry analyzer for clinical use |
| C. Device Classification | Clinical chemistry panel
Micro chemistry analyzer for clinical use
Regulation Number: 21 CFR 862.2170
Regulatory Class I
Classification Number: 75JJF |
| 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 by reflectance and other techniques is widely recognized and has gained widespread acceptance for use in chemistry assays. Micro chemistry analyzers are already on the U.S. market. These products utilize dry film and other formats, and use reflectance and other types of signals. For example,

Vitros DT 60 II Johnson & Johnson Clinical Diagnostics, formerly Kodak Ektachem DT 60 II (analyzer using reflectance photometry and electrochemical measurement for signal detection)

Seralyzer Reflectance Photometer formerly Miles/Ames (analyzer using reflectance photometry for signal detection)

B. Specific equivalency claim

The CareSide™ Analyzer is substantially equivalent in principle, intended use, and clinical performance to the currently marketed Vitros DT 60 II/DTSC II Module.

Name of Predicate Device: Johnson and Johnson's Vitros DT 60 II/DTSC II/ (formerly Kodak Ektachem DT 60 II System)

Predicate Device 510K number: K 912844/A

Product Code: 75JJE

IV. Device Description

A. CareSide™ System Overview

The Exigent Diagnostics CareSide™ System utilizes individual (analyte specific) test cartridges to perform a variety of clinical blood tests. 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. The Exigent Diagnostics CareSide™ Analyzer automatically performs up to 6 quantitative test results in approximately ten minutes using approximately 85 microliters of human blood per test. Results are provided on-screen, and may be transferred to a floppy disk for subsequent uploading to a laboratory information system. The Exigent Diagnostics CareSide™ System components include:

- CareSide™ Analyzer
- Analyte-specific Cartridge(s)

B. CareSide Cartridge™ Description

The CareSide™ Test Cartridge, a single use analyte-specific cartridge, performs the following functions: reagent and specimen temperature equilibration, sample separation, sample metering, sample dispensing, test incubation, and colorimetric detection. Each cartridge (patents pending) contains all reagents necessary to perform an analyte measurement.

The CareSide™ test cartridges are individually bar coded and packaged, containing both human readable and barcode labeling. The test cartridge package is hermetically sealed to assure stability over the shelf-life of the cartridge. Test specific requirements are provided in test specific package inserts. These cartridges consist of a pre-analytical element and an analytical element.

1. **Pre-analytical Element** The pre-analytical element consists of a plastic cartridge consisting of a series of channel and wells. On top of the cartridge is a hinged lid and a plastic membrane covered opening. The assembled cartridge contains various channels and chambers which, upon centrifugation within the Analyzer, separates the blood cells from the plasma or serum. The plasma or serum flow from the metering channel is initiated when the specimen deposition well is pressurized by deformation of its plastic cover within the analyzer. The pressure forces the plasma or serum out of the sample delivery passage onto the analytical element.
2. **Analytical Element** The analytical elements consist of a multi-layer film. Each different chemistry cartridge differs only with respect to the multi-layer film which is described in the analyte-specific test cartridge package insert.

C. CareSide™ Analyzer Description and explanation of Device Function

The CareSide™ Analyzer is a compact tabletop chemistry analyzer that performs multiple discrete analyses on human whole blood, plasma, or serum specimens. The CareSide™ analyzer is semi-automated: the only operator intervention is the addition of the specimen to the test cartridge and the insertion of the dosed cartridge into the analyzer. The CareSide™ Analyzer automatically warms, separates, meters, dispenses, and incubates the specimen before reading the signal and calculating results. The CareSide™ Analyzer is intended only for use with Exigent Diagnostics CareSide™ test cartridges.

The user enters the patient identification and test(s) to be performed via the touch screen by following a series of menus and prompts. The CareSide™ Analyzer accepts up to 6 test cartridges from a single patient at the same time. Next, the user obtains the required test cartridge(s) from refrigerated storage and removes the cartridge from its individual hermetically sealed package.

Once loaded, the analyzer spins the cartridge(s) to heat the cartridge(s) and the contained specimen(s) to the reaction temperature and to move the sample from the sample deposition well into the cartridge channels and chambers. As the cartridge spins, the cells accumulate in the separation well. A defined volume of plasma (or serum, as applicable) remain in the metering passage. Any excess sample flows into an overflow well. To dispense the metered volume of sample onto the film, a plunger displaces a flexible seal that covers the sample deposition well. As the flexible seal is displaced, air is forced through the metering passage, forcing the sample out and onto the reagent film. As the cartridges spin, the film passes by one of 6 LED/photodiode pairs. The LED/photodiodes perform reflectance measurements at a specified time(s). The analyzer uses the reflectance measurements and a chemistry-specific standard curve to calculate the concentration.

The analyte concentration is proportional to the concentration of dye on the film. The amount of dye is quantitated by the measurement of the reflected light from the reagent film using a light emitting diode/photodiode set under the reagent film. Reflectance is read at defined times during the reaction period.

D. Analyzer Software

The CareSide™ Analyzer is software controlled. The software system utilizes a Real-Time Processor (RTP) and a User Interface Processor (UIP). New software will be provided and installed in the field to add additional tests as they are developed and receive U.S. FDA marketing clearance. The Analyzer is controlled through a touch-screen interface. Results are displayed on the interface screen. Results can also be down-loaded on to a 3-1/2 " diskette or on to a computer via a RS-232 port.

E. System Calibration

Similar to other automated analyzers in commercial distribution, such as the Abaxis Picollo, the CareSide™ Analyzer is factory calibrated. The user is not expected to perform calibration. The Analyzer is calibrated during each test by automatically reading a black and white reflectance standard and making adjustments if necessary.

Each CareSide™ Cartridge bar-code label contains lot-specific coefficients for a polynomial and is scanned by the CareSide™ Analyzer. The observed reflectance is adjusted by inputting it into the polynomial. The patient result is then calculated from the adjusted reflectance using the polynomial describing the master dose – response curve.

The user performs periodic calibration verification and quality control to confirm that the analyzer maintains its calibration over time.

V. **Intended Use**

A. Intended Use

This product is intended for use with Exigent Diagnostics Cartridges when used by laboratory professionals for the *in vitro* measurement of various clinical chemistry analytes in human blood.

B. Indications for Use

This product is indicated for *in vitro* measurement of various clinical chemistry analytes in human blood.

VI. Technological Characteristics

A. Similarities

	CareSide™ Analyzer	Vitros DT 60 II System
Intended Use	Intended for the measurement of various analytes using reflectance photometry measurements	Same
Indications	For <i>in vitro</i> diagnostic use by professional laboratory personnel	Same
Type	Quantitative	Same
Principle of method	Dry film based: chromogen quantitated by reflectance measurement	Same
Compatible reagents	CareSide™ Cartridges	Vitros DT Slides
Menu	7 direct and calculated tests (submitted)	37 direct and calculated tests (cleared)
Specimen dilution	Not required	Not required
Detector	Reflectance	Reflectance
Test time	4 minutes warm-up (on-board) plus up to 6 minutes test time.	15 minutes warm-up (off-line) plus 5 minutes test time.
Sample Type	serum, plasma, whole blood (whole blood. applied sample, plasma test sample) Tests for urine not currently available	serum, plasma whole blood not acceptable except for hemoglobin Urine for some tests
Specimen volume	85 µl (applied volume)	10 µl
Calibration	Calibration information bar coded on each cartridge. Calibration information may change with each lot.	Run Kodak Ektachem DT II calibrators whenever a new slide lot is used or when necessary

B. Differences

	CareSide™ Analyzer	DT 60 II
Access	Single patient per platter run	Single or multiple patient
Queuing	6 cartridges	Multiple slides
Module	Single	Multiple
Software updating	3-1/2 floppy	EPROM (CDM, CLM)
Direct blood specimen	Yes, whole blood	No, requires separation of whole blood prior to sample application
Pipetting	Not required	Required
Accurate pipetting	Not required	Required
Reagent pre-warming	Not required	Required

C. Comparative Performance Characteristics

	CareSide™	DT 60 II
Precision	Typical total CV 3.1% to 8.5% (4 tests evaluated)	Typical total CV 1.5% to 5.2% (4 tests evaluated)
Relative Accuracy	Mean difference [Vitros – CareSide™] from method comparison means is test specific (3% for 4 tests evaluated)	
Linearity	Correlation coefficient ≥ 0.95	Not provided
Interference	Susceptibility to interference is test specific.	Not provided
Detection limit	Test specific.	Not provided

D. Conclusion

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

MAR - 6 1998

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

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

Re: K980056
CareSide™ Analyzer
Regulatory Class: II
Product Code: JJF, CDQ, CEK, 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 (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.

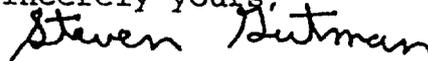
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Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

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

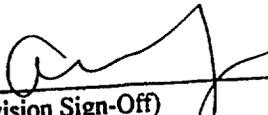
Indications for Use

510(k) Number:
Device Name:
Indications for use:

To be assigned K980056
CareSide Analyzer
For *in vitro* diagnostic use by professionals with Exigent
Diagnostics Cartridges for the *in vitro* measurement of
various clinical chemistry analytes in human blood.

(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 K980056

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)