JUN 23 1998

Attachment 3

(Revised 510(k) Summary)

510(K) SUMMARY: CARESIDE™ TOTAL BILIRUBIN SAFETY AND EFFECTIVENESS

I. Applicant Information

A.	Applicant Name	**CARESIDE, 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	June 11, 1998

II. Device Information

A.	Device Name (Trade)	**CARESIDE™ Total Bilirubin**
B.	Device Name (Classification)	Total Bilirubin test system
C.	Device Classification	Clinical chemistry panel Total Bilirubin test system Regulation Number: 21 CFR 862.1110 Regulatory Class II Classification Number: 75CIG
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.

Total bilirubin *in vitro* diagnostic products, in both dry film and other formats, are already on the U.S. market, including total bilirubin products which utilize diphylline to dissociate conjugated bilirubin and diazonium salts to combine with bilirubin to form an azo dye.

B. Specific equivalency claim

This CARESIDE™ Total Bilirubin test is substantially equivalent in principle, intended use, and clinical performance to the currently marketed Vitros slides for the quantitative measurement of total bilirubin on the Vitros DT 60 II.

Name of Predicate Device:	Johnson and Johnson's (formerly Eastman Kodak, Inc.) Vitros TBIL Slides for Johnson and Johnson's Vitros DT 60 (formerly Eastman Kodak's DT 60 II).
Predicate Device 510K number:	K912844/A
Product Code:	75CIG

IV. Device Description

CARESIDE™ Total Bilirubin cartridges are used with the CARESIDE™ Analyzer to quantitatively measure the total concentration of bilirubin in anti-coagulated whole blood, plasma or serum specimens. The CARESIDE™ Total Bilirubin 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 the total concentration of bilirubin. The film cartridge (patent pending) contains all reagents necessary to measure the total concentration of bilirubin.

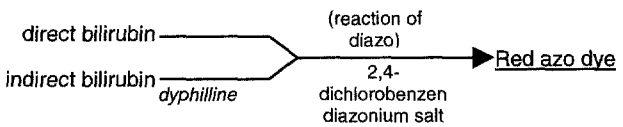
A. Explanation of Device Function

Each CARESIDE™ Total Bilirubin cartridge consists of a bilirubin-specific multi-layer reagent film mounted in a plastic base with a hinged lid. The user introduces the anti-coagulated whole blood, serum, or plasma specimen into the cartridge sample deposition well, closes the lid and inserts the cartridge into the 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. Approximately ten microliters of plasma (or serum, as applicable) remain in the metering passage. Excess sample flows into an overflow well.

The plasma (or serum, as applicable) is automatically dispensed onto the multi-layer reagent film. The spreading and reaction layer distributes the sample evenly on the film and dissociates the unconjugated bilirubin from albumin. Conjugated and unconjugated bilirubin reacts with 2,4-dichlorobenzene diazonium salt to form a red azo dye. The color intensity, as measured by the amount of light reflected at 505 nanometers, directly relates to the total concentration of bilirubin in the specimen.

Test Reaction Sequence:



As the cartridge spins, a photodiodes measures reflectance of light emitted from a wavelength-specific light emitting diode (LED) at a fixed time. The analyzer uses the reflectance measurements and the lot-specific standard curve to calculate the total bilirubin concentration.

B. Test Summary

Bilirubin is formed by the reticuloendothelial system as a by-product of the breakdown of hemoglobin. Bilirubin circulates in multiple forms: (1) unconjugated, also known as indirect, bilirubin which circulates non-covalently bound to albumin, (2) direct or conjugated bilirubin that is covalently bound to glucuronic acid, and (3) covalently protein bonded bilirubin. Conjugated bilirubin, excreted into the bile by the liver, gives the bile its major pigmentation.

In healthy individuals, a small amount of bilirubin is found in the serum. An increase in unconjugated bilirubin is more frequently associated with increased destruction of red blood cells (hemolysis); and an increase in conjugated bilirubin is more likely seen in dysfunction of the liver or bile ducts.

Total bilirubin may be measured as part of a routine examination. A normal level of total bilirubin rules out any significant impairment of the excretory function of the liver or excessive hemolysis of red blood cells. Only when the total bilirubin levels are elevated is it indicated to determine the direct bilirubin level in order to discriminate between the

relative levels of conjugated and unconjugated bilirubin. Total bilirubin levels above 2.5 mg/dL are associated with jaundice.

V. Intended Use

A. Intended Use

The CARESIDE™ Total Bilirubin cartridge is intended for *in vitro* diagnostic use in conjunction with the CARESIDE™ Analyzer to quantitatively measure the total concentration of bilirubin in anti-coagulated whole blood, plasma or serum. The CARESIDE™ Total Bilirubin test aids in the diagnosis and treatment of patients with liver, hemolytic, hematological, and metabolic disorders, including hepatitis and gall bladder blockage.

B. Indications for Use

This product is for in vitro diagnostic use with the CARESIDE™ Analyzer to quantitatively measure total bilirubin concentration in anti-coagulated whole blood, plasma or serum specimens to aid in the diagnosis and treatment of patients with liver, hemolytic, hematological, and metabolic disorders, including hepatitis and gall bladder blockage. It is intended for professional laboratory use: not for point of care use or physician office laboratory use.

VI. Technological Characteristics

A. Similarities

	CARESIDE™ Total Bilirubin	**Vitros TBIL DT Slides**
Intended Use	Primarily to aid in the diagnosis and treatment of patients with liver, hemolytic, hematological and metabolic disorders.	Same
Indications	For *in vitro* diagnostic use. For professional laboratory use: not for point of care or physician office laboratory use.	For in vitro diagnostic use
Measurement	Quantitative	Same
Method Principle	Dry film based diazo reaction.	Same
Specimen dilution	Not required	Same
Materials	Dyphilline 2,4-*dichlorobenzene* diazonium salt	Dyphilline [4-(N-carboxymethylsulfamyl)-benzene diazonium hexafluorophosphate]
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	Diazotized sulfanilic acid reaction in presence of caffeine-benzoate-acetate (candidate ref. method for serum total bilirubin determination)	Unknown
Sample Type	Serum, plasma, anti-coagulated 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™ Total Bilirubin	**Vitros TBIL DT Slides**
Direct blood specimen	Yes, whole blood	No, requires separation of whole blood prior to sample application
Reportable range	0.2 to 24 mg/dL	0.1 to 20 mg/dL
Accurate pipetting	Not required	Required
Reagent pre-warming	Not required	Required

C. Comparative Performance Characteristics

	CARESIDE™ Total Bilirubin	**Vitros TBIL DT Slides**
Detection limit	0.2 mg/dL	Not provided
Reportable range	0.2 to 24 mg/dL	0.1 to 20 mg/dL
Accuracy	Mean recovery 96%	Not provided
Precision	Total CV, 1.1 mg/dL, 12%	Total CV, 1.2 mg/dL, 6%
Method comparison	CARESIDE™ = 1.04 (Vitros TBIL DT) + 1.0 mg/dL, r = 0.96	
Linearity	Linearity by mixing and by dilution yielded results within acceptable limits	Not provided
Interference	No significant interference observed at tested concentration of interferent: Ascorbic Acid, 20 mg/dL Hemoglobin, 100 mg/dL Protein, 9 mg/dL	Not provided
Specimen Types & Anticoagulants	No clinically significant difference between anti-coagulated whole blood, serum, sodium heparin plasma, and EDTA plasma.	No clinically significant difference between serum, heparin plasma, or EDTA plasma. Whole blood is unsuitable.
Expected Values	0.2 to 1.3 mg/dL Central 95% interval	0.1 –1.4 mg/dL (male) Central 95% interval

D. Conclusion

The nonclinical and clinical data provided demonstrate that the CARESIDE™ Total Bilirubin 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

JUN 23 1998

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

Re: K981588
CareSide™ Total Bilirubin
Regulatory Class: II
Product Code: CIG
Dated: April 30, 1998
Received: May 4, 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

VI. INDICATIONS FOR USE

510(k) Number: K981588

Device Name: CARESIDE™ Total Bilirbuin

Indications for use: This product is for *in vitro* diagnostic use with the CARESIDE™ Analyzer to quantitatively measure total bilirubin concentration in anti-coagulated whole blood, plasma or serum specimens to aid in the diagnosis and treatment of patients with liver, hemolytic, hematological, and metabolic disorders, including hepatitis and gall bladder blockage. It is intended for professional laboratory use: not for point of care use or physician office laboratory use.

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K981588

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

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)