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K020484

510(K) SUMMARY: CARESIDE *LDH* 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	Renate A. MacLaren, Ph.D.
E.	FAX Number	310-670-6986
F.	e-Mail Address	rmaclaren@CARESIDE.com
G.	Date 510(k) Summary prepared	May 14, 2002

II. Device Information

A.	Device Name (Trade)	CARESIDE *LDH*
B.	Device Name (Classification)	LDH test system
C.	Device Classification	Clinical chemistry panel LDH test system Regulation Number: 21 CFR 862.1440 Regulatory Class II Classification Number: 75CFH
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.

LDH *in vitro* diagnostic products, in both dry film and other formats, are legally marketed in the United States.

B. Specific equivalency claim

The CARESIDE *LDH* test is substantially equivalent in principle, intended use, and clinical performance to the currently marketed Vitros slides for the quantitative measurement of LDH on the Vitros DT 60 II.

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

IV. Device Description

CARESIDE *LDH* cartridges are used with the CARESIDE, Inc. CARESIDE *Analyzer* to measure LDH activity in anti-coagulated whole blood, serum or plasma specimens. The CARESIDE *LDH* cartridge, a single use disposable *in vitro* diagnostic test cartridge, delivers a measured volume of serum or plasma to a dry film to initiate the measurement of LDH activity. The patented film cartridge contains all reagents necessary to measure LDH activity.

A. Explanation of Device Function

The activity of the CARESIDE *LDH* test measures LDH activity in the direction of the conversion of lactate to pyruvate. Some other LDH tests measure the activity of the enzyme in the direction of the conversion of pyruvate to lactate. The two different methods yield clinically equivalent results when interpreted with respect to their own reference ranges although the results are different quantitatively.

Each CARESIDE *LDH* cartridge consists of an LDH-specific multi-layer reagent film mounted in a plastic base with a hinged lid. The user introduces the 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. Approximately 8.5 microliters of sample remains in the metering passage. Any excess sample flows into an overflow well.

The sample is automatically dispensed onto the multi-layer reagent film. The spreading and substrate layer distributes the LDH containing specimen uniformly. The sample moves through a reagent layer where the NADH formed in the LDH catalyzed reaction of lactate and NAD^+ reacts with nitrotetrazolium blue (NTB) in a diaphorase catalyzed reaction to produce a bluish formazan dye. The rate of change of the dye's color intensity, as measured by the amount of reflected light at 570 nanometers, directly relates to the specimen LDH activity.

Test Reaction Sequence:

$$\textbf{L-Lactate + NAD}^+ \xrightarrow{LDH} \textbf{Pyruvic acid + NADH + H}^+$$

$$\textbf{NTB + NADH} \xrightarrow{Diaphorase} \textbf{Formazan Dye + NAD}^+$$

As the cartridges spin, a photodiode measures reflectance of light emitted by a wavelength-specific light emitting diode (LED) over a fixed time period. The instrument uses the reflectance measurements and the lot-specific standard curve to calculate LDH activity.

B. Test Summary

Lactate dehydrogenase (LDH) is distributed very widely in the body and is found in the in very high activities in the cytoplasm of cells in the heart, liver, kidney, and skeletal muscle, and in lesser amounts in lung, smooth muscle, erythrocytes, brain and pancreas. Because activities of LDH are much higher in tissues than in plasma, injury to tissue, with accompanying leakage of the cytoplasm into the peripheral blood, can increase the blood LDH dramatically. At least five forms of LDH are separable by electrophoresis. The predominant form in the blood varies with the tissue of origin, and therefore, LDH sub-typing may have diagnostic value.

Above-normal LDH activities in blood (> 220 U/L) are seen in several hematologic, neoplastic, cardiac, hepatic, skeletomuscular, and renal diseases. Very high elevations (> 500 U/L) of LDH activity have been seen in megaloblastic anemia, extensive carcinomatosis, viral hepatitis, shock, hypoxia, and extreme hyperthermia. Somewhat lower elevations (>300 U/L) occur after myocardial or pulmonary infarction, leukemia, and hemolytic anemia. Moderate elevations occur in cirrhosis, obstructive jaundice, and neoplastic diseases. Thus, an elevated LDH activity is only a nonspecific finding.

V. Intended Use

A. Intended Use

The CARESIDE *LDH* cartridge is intended for *in vitro* diagnostic use in conjunction with the CARESIDE *Analyzer* to quantitatively measure LDH activity in anti-coagulated whole blood, serum or plasma.

B. Indications for Use

For *in vitro* diagnostic use with the CARESIDE *Analyzer* to measure LDH activity from anti-coagulated whole blood, serum or plasma specimens to aid in the diagnosis and treatment of patients with certain liver diseases, heart diseases, and tumors of the lung, kidneys, and liver.

VI. Technological Characteristics

A. Similarities

	CARESIDE *LDH*	**Vitros LDH DT Slides**
Intended Use	For *in vitro* diagnostic use	Same
Indications	Primarily to aid in the diagnosis and treatment of patients with certain liver diseases, heart disease, and tumors of the lung, kidneys, and liver.	Same
Measurement	Quantitative	Quantitative
Method Principle	Dry film based reflectance measurement of NAD reduction to NADH consequent to conversion of lactate to pyruvate.	Dry film based reflectance measurement of NADH oxidation to NAD consequent to conversion of pyruvate to lactate.
Specimen Dilution	Not required	Not required
Materials	Lithium lactate, NAD^+, nitrotetrazolium blue, and diaphorase	NADH and sodium pyruvate
Detector	Reflectance (570 nm)	Reflectance (340 nm)
Test time	Approx. 4-minute warm-up (on-board) plus 4 minute test time.	15 minutes slide warm-up (off-line) plus 5 minutes test time.
Sample Type	Anti-coagulated whole blood, serum or plasma	Serum or plasma
Specimen Volume	8.5 µl test volume (90 ± 10 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	2 levels
Reporting Units	U/L	U/L
Reaction Temp.	37 °C	37 °C

B. Differences

	CARESIDE *LDH*	**Vitros LDH DT Slides**
Specimen Pre-treatment	Not Required	Not Required
Reportable Range	50 to 650 U/L	100 to 1750 U/L
Accurate pipetting	Not required	Required
Reagent pre-warming	Not required	Required

C. Comparative Performance Characteristics

	CARESIDE *LDH*	**Vitros LDH DT Slides**
Detection limit	50 U/L	100 U/L
Reportable range	50 – 650 U/L	100 – 1750 U/L
Recovery (Mean)	103%	Not available
Linearity	Linearity by dilution yielded slope and correlation coefficient within acceptable limits	
Interference	No significant interference observed at tested concentration of interferent: Ascorbic Acid, 20 mg/dL Bilirubin, 20 mg/dL Triglycerides 3000 mg/dL	
Precision	Total CV, 335 U/L, 7.2%	Total CV, 649 U/L, 2.9%
Rel. Accuracy	Careside = 0.97 (BM/Hitachi 902) + 9.1 U/L r = 0.99	

D. Conclusion

The nonclinical and clinical data provided demonstrate that the CARESIDE *LDH* product is substantially equivalent to the legally marketed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUL 3 2002

Renate A. MacLauren, Ph.D.
Clinical Affairs Manager
Careside, Inc.
6100 Bristol Parkway
Culver City, CA 90230

Re: k020484
Trade/Device Name: Careside LDH
Regulation Number: 21 CFR 862.1440
Regulation Name: Lactate dehydrogenase test system
Regulatory Class: Class II
Product Code: CFH
Dated: May 15, 2002
Received: May 16, 2002

Dear Dr. MacLauren:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/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

INDICATIONS FOR USE

510(k) Number: K020484

Device Name: CARESIDE *LDH*

Indications for use: For *in vitro* diagnostic use with the CARESIDE *Analyzer* to measure LDH activity from anti-coagulated whole blood, serum or plasma specimens to aid in the diagnosis and treatment of patients with certain liver diseases, heart diseases, and tumors of the lung, kidneys, and liver.

Jean Cooper

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K020484

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use ___
(Per 21 CFR 801.109) (Optional Format 1-2-96)