# CRESTAT DIAGNOSTICS, INC.

K981276

25549 Adams Avenue
Murrieta, CA 92562

MAY 1 1998

## 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR § 807.92.

The assigned 510(k) number is: _____

Date: April 2, 1998

Submitted by: Colin Getty
KAMIYA BIOMEDICAL COMPANY
910 Industry Drive, Seattle WA 98188
TEL: 206-575-8068; FAX: 206-575-8094

For: Crestat Diagnostics, Inc.
25549 Adams Avenue
Murrieta, CA 92562

Product: N-ASSAY L D-BIL (Direct Bilirubin Assay Reagent)

Serum bilirubin measurement is widely used as a screening test for liver functions. The diazo coupling method and bilirubin oxidase enzymatic method are widely used; however, these methods have disadvantages such as interference by coexistent serum substances and poor reagent stability.

The N-ASSAY L D-BIL reagent is based on a chemical oxidation method, utilizing sodium nitrite as an oxidizing agent, shows good correlation with similar direct bilirubin reagents, practically no interference by coexistent substances, high sensitivity with good reproducibility, wide assay range, and is convenient ready-to-use liquid type reagent.

In this method, a serum sample containing direct bilirubin is mixed with the reagent containing sodium nitrite. Direct bilirubin is oxidized by nitrite at pH 3.7 to produce biliverdin which causes the absorbance at 450 nm (main) and 546 (sub), specific to bilirubin, to decrease. Therefore, the direct bilirubin concentration in the sample can be obtained by measuring the absorbance before and after the sodium nitrite oxidation.

## 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS (Continued)

The safety and effectiveness of the liquid Crestat N-ASSAY L D-BIL Reagent is demonstrated by its substantial equivalence to the WAKO Chemicals Direct Bilirubin liquid reagent (K970986) which is also based on chemical oxidation. Both test systems are intended to quantitatively measure direct bilirubin in human serum.

In comparison studies against the predicate assay, a correlation coefficient of 0.98476 and a regression equation $y = 1.0882 x + 0.1574$ was obtained with serum samples. Precision studies indicate acceptable values can be obtained on a day to day basis. The minimum detectable level of this method is 0.05 mg/dl. The N-ASSAY L D-BIL reagent is linear to 20 mg/dl.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAY 1 1998

Crestat Diagnostics, Inc.
Colin Getty
C/O KAMIYA Biomedical Company
910 Industry Drive
Seattle, Washington 98188

Re: K981276
N-ASSAY L D-BIL (Direct Bilirubin Assay Reagent)
Regulatory Class: II
Product Code: CIG
Dated: April 2, 1998
Received: April 8, 1998

Dear Mr. Getty:

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

# INDICATIONS FOR USE STATEMENT

**510(k) Number (if known):** k981276

**Device Name:** N-ASSAY L D-BIL (Direct Bilirubin Assay Reagent)

**Indications For Use:**

The intended use for the N-ASSAY L D-BIL Reagent is for the quantitative determination of serum direct bilirubin in the diagnosis and treatment of various liver diseases. For in vitro diagnostic use only.

(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 k981276

Prescription Use _____ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

Optional Format 1-2-96)