

CRESTAT DIAGNOSTICS, INC.**25549 Adams Avenue
Murrieta, CA 92562****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: March 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 Glu-UL (Glucose Assay Reagent)

Blood glucose determinations are one of the most frequently performed clinical chemistry laboratory procedures and are commonly used as an aid in the diagnosis and treatment of diabetes. Early methods were based on the reducing properties of glucose; however, these methods are susceptible to positive errors caused by nonglucose-reducing substances present in normal blood. Chemical methods using o-toluidine offered improved specificity, but other sugars not normally present in serum can also react with o-toluidine and be a potential source of error. Enzymatic methods using purified enzymes which act on glucose provided greater specificity.

The N-ASSAY Glu-UL reagent is based on an enzymatic hexokinase/glucose-6-phosphate dehydrogenase method, shows good correlation with similar glucose reagents, practically no interference by coexistent substances, high sensitivity with good reproducibility, wide assay range, and is a convenient ready-to-use liquid type reagent.

In this method, serum D-glucose is phosphorylated by hexokinase (HK) in the presence of adenosine triphosphate (ATP) to produce glucose-6-phosphate (G-6-P) and adenosine diphosphate (ADP). Glucose-6-phosphate dehydrogenase (G-6-PDH) specifically oxidizes G-6-P to 6-Phosphogluconate with the concurrent reduction of nicotinamide adenine dinucleotide phosphate (NADP) to nicotinamide adenine dinucleotide phosphate reduced (NADPH). The NADPH produced absorbs light at 340 nm (main) and 405 nm (sub) and can be detected spectrophotometrically. The increase in absorbance measured at 340 nm (main) and 405 (sub), due to the formation of the NADPH, is directly proportional to the glucose concentration in the sample.

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

The safety and effectiveness of the liquid Crestat N-ASSAY Glu-UL Reagent is demonstrated by its substantial equivalence to the Medical Analysis Systems Glucose liquid reagent (K853464) which is also based on an enzymatic hexokinase/glucose-6-phosphate dehydrogenase method. Both test systems are intended to quantitatively measure glucose in human serum.

In comparison studies against the predicate assay, a correlation coefficient of 0.99587 and a regression equation $y = 0.8861x + 4.7012$ 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 1 mg/dl. The N-ASSAY Glu UL reagent is linear to 1,000 mg/dl.

For urine and CSF samples, the liquid Crestat N-ASSAY Glu-UL Reagent was compared to the Boehringer Mannheim Glucose assay (K812303) which is also based on an enzymatic hexokinase method. Using urine samples, a correlation coefficient of 0.9989 and a regression equation $y = 1.038x + 1.528$ was obtained. Using CSF samples, a correlation coefficient of 0.9923 and a regression equation of $y = 1.080x + -1.233$ was obtained. The limit of quantitation is 0.3 mg/dl.



SEP 3 1998

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

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

Re: K980883
N-ASSAY Glu-UL
Regulatory Class: II
Product Code: CFR
Dated: June 30, 1998
Received: July 2, 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 (Pre-market 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 pre-market 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.

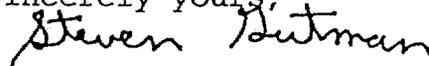
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Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

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 STATEMENT

510(k) Number (if known): K980883

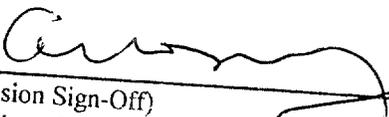
Device Name: N-ASSAY Glu-UL (Glucose Assay Reagent)

Indications For Use:

The intended use for the N-ASSAY Glu-UL Reagent is for the quantitative determination of glucose in serum, plasma, urine, and cerebrospinal fluid in the diagnosis and treatment of diabetes mellitus, neonatal hypoglycemia and idiopathic hypoglycemia, and of pancreatic islet cell carcinoma. 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 K980883

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

Optional Format 1-2-96)