



GDS@Diagnostics
 Division of GDS Technology, Inc.
 25235 Leer Drive
 P.O. Box 473
 Elkhart, IN 46515

Office: (219) 264-7384
 (800) 545-4GDS
 FAX: (219) 262-0109

SEP 17 1997

Diagnostics

510(k) Summary

Submitter Identification: GDS@ Diagnostics
 A Division of GDS@ Technology, Inc.
 25235 Leer Drive
 Elkhart, IN 46514
 (219) 264-7384
 Fax: (219) 262-0109

Contact: John W. Swatosh
Date: March 27, 1997

Trade Name: GlucoSite® Test System
Common Name: Blood Glucose Test System
Classification Name: Glucose Test System
Comparison Device: YSI 2300 STAT PLUS Analyzer

Device Description:
 This whole blood glucose test system consists of a GlucoSite® Test Card, test card specific Test Module, and a portable, hand held Stat-Site® electronic reflectance photometer (Meter). The test method employs a dry reagent technology based on the glucose oxidase method and is specific for D-Glucose. When a drop of whole blood is applied to the top opening on the test card, the red blood cells are separated allowing only the plasma to pass through. Glucose oxidase catalyzes the oxidation of the glucose in the plasma to produce gluconic acid and hydrogen peroxide in the presence of atmospheric oxygen. The second enzyme peroxidase then catalyzes the reduction of hydrogen peroxide in presence of 4-amino-antipyrine with concomitant oxidation of the chromogen TOOS [N-ethyl-N-(2-hydroxy-3-sulfopropyl)-m-toluidine] to produce a purple color that is measured at 660 nm. The intensity of color developed is correlated with the glucose concentration in the whole blood sample. The Stat-Site® Meter measures the reflectance of the color produced at 660 nm and converts the reflectance reading to corresponding plasma glucose values.

Intended Use:
 The Stat-Site®/GlucoSite® Blood Glucose System is intended for quantitative determination of glucose in whole blood in a point-of-care setting such as a physician's office or hospital point of care sites. The test system provides glucose values equivalent to plasma glucose values. The test is not to be used at home or for neonates or children under the age of six months.

Comparison:

To verify safety and effectiveness of the Stat-Site®/GlucoSite® Glucose Test when used under intended use conditions such as a POL setting, the device was compared with the Hexokinase plasma glucose method and the YSI 2300 STAT PLUS Analyzer. A total of 152 venous whole blood clinical samples and 152 capillary finger stick blood samples were obtained at 3 different physician's office sites. Half of the samples were from diabetic subjects. Ten (10) more venous whole blood samples obtained in house were spiked to 3 different concentrations of glucose and were included in the study to demonstrate maximum reportable range. Whole blood samples were tested on GlucoSite® Test Cards on the Stat-Site® Meter and the results obtained were compared with the glucose values obtained when plasma from the whole blood samples was analyzed on the YSI 2300 STAT PLUS Analyzer and with Hexokinase method on the Olympus Reply Instrument. The following regression parameters were obtained comparing (A) Stat-Site®/GlucoSite Test System (y) with YSI(x) and (B) Stat-Site®/GlucoSite® Test System(y) with Hexokinase results (x).

A. Stat-Site®/GlucoSite® vs. YSI
Slope = 1.008
Intercept = -2.996
Correlation Coefficient (r) = 0.99

B. Stat-Site®/GlucoSite® vs. Hexokinase
Slope = 1.000
Intercept = -11.425
Correlation Coefficient (r) = 0.99

When the glucose data from the finger stick blood on Stat-Site®/GlucoSite® device was compared with plasma glucose values of the same subject obtained from venous blood using YSI, the predicate method, the following regression equation was obtained with 'r' value of 0.965:

$$y = 0.999(x) + 5.473$$

Where y = Stat-Site®/GlucoSite® glucose result and
x = Plasma glucose result from YSI.

A similar regression was obtained when compared with Hexokinase method with 'r' value of 0.965.

Precision evaluation was performed at glucose concentrations of 50, 80, 150 and 350 mg/dL on 3 Stat-Site®/GlucoSite® Test Systems. Total CV's were below 5% demonstrating the performance of the Stat-Site®/GlucoSite® Glucose Test to be comparable to the claimed performance of similar meters currently in commercial distribution.

Conclusion:

The data demonstrated that blood glucose results from Stat-Site®/GlucoSite® Test System, when used in a point of care setting such as a POL or physician's office, compare well to those of laboratory instruments such as YSI and Hexokinase method when determining plasma glucose from normal or diabetic patients.



SEP 17 1997

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Mr. John W. Swatosh
• Regulatory Affairs
GDS Diagnostics
25235 Leer Drive
Elkhart, IN 46515

Re: K971145/S1
GlucoSite® Test System/GlucoSite® Test Cards and Test
Module
Regulatory Class: II
Product Code: CGA
Dated: June 4, 1997
Received: June 10, 1997

Dear Mr. Swatosh:

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 requirement, 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.

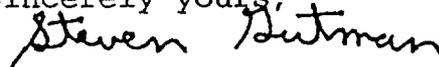
Page 2

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

8.1 Indications for Use Statement

Pursuant to the Notice of 2/6/96 regarding listing of Indications for Use on a separate sheet, the following is provided.

510(k) Number _____ (To be assigned)

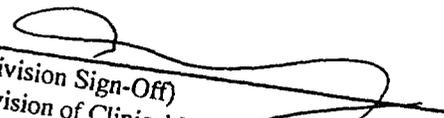
Device Name: GlucoSite® Test System

Indications for Use:

The GDS® GlucoSite® Test System is a device for *in vitro* diagnostic use only. The GDS® GlucoSite® Test Card is intended for the quantitative determination of glucose in whole blood. It is intended for use with the Stat-Site® Meter.

Targeted population: Patients except neonates and children under the age of 6 months.

Environment of Use: Physician's Office or other Professional Point of Care Setting


(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number LC 971145