K992132

GDS® Technology, Inc.
25235 Leer Drive
P.O. Box 473
Elkhart, IN 46515

Office: (219) 264-7384
FAX: (219) 262-0109

AUG 20 1999

510(k) SUMMARY

Submitter Identification:	GDS® Technology, Inc. 25235 Leer Dr. Elkhart, IN 46514 Phone: (219) 264-7384 Fax: (219) 266-0062
Contact:	Keith Crawford
Date:	June 18, 1999
Trade Name:	CholeSite® Test System
Common Name:	Whole Blood Cholesterol Test System
Classification Name:	Whole Blood Total Cholesterol Determination
Comparison Device:	Abell-Kendall Reference Standard Methodology

DEVICE DESCRIPTION

This whole blood cholesterol test system consists of a CholeSite® Test Card, Test Card specific Test Module, and the hand-held Stat-Site® electronic reflectance photometer (Meter). The test methodology employs a dry reagent technology based on the cholesterol esterase method. When a drop of whole blood is applied to the top opening on the Test Card. The cholesterol esters present in the patient's blood sample are hydrolyzed by cholesterol esterase. The free cholesterol is then oxidized by cholesterol oxidase, producing hydrogen peroxide, which substantially reacts with TOOS in a reaction catalyzed by peroxidase to produce a colored compound on the bottom of the Test Card. The Stat-Site® Meter, using reflectance at 660 nm, measures the color characteristics produced and converts the reflectance reading to a correlated cholesterol concentration value.

INTENDED USE

The CholeSite® Test System is a blood cholesterol screening device used for the quantitative determination of total cholesterol in whole blood and, thereby, producing a plasma equivalent result. This test system is to be utilized in a point-of-care setting such as a physician's office or hospital point-of-care site.

COMPARISON

To verify safety and effectiveness of the CholeSite® Test System when used under intended POL use conditions, the device was compared to the Abell-Kendall industry "gold standard" cholesterol test reference method. A total of 148 venous whole blood clinical samples and 148 capillary whole blood clinical samples were obtained at 3 different physician's office sites. Additionally, in-house testing was performed using 40 venous whole blood samples and 40 capillary whole blood samples

and then tested against the GDS® reference method (COBAS) using plasma from the same blood samples. The following regression parameters were obtained:

- CholeSite® Test System .vs. Abell-Kendall (clinical)
  Slope= 1.192
  Intercept= 27.94
  Correlation Coefficient (R)= 0.96

- CholeSite® Test System .vs. COBAS Bio Reference (in-house)
  Slope= 1.000
  Intercept= 0.91
  Correlation Coefficient (R)= 0.9437

A precision evaluation was performed at cholesterol concentrations of 135 and 300 mg/dL on three Stat-Site® Meters. Total CV^S were below 5.4%, with no single Meter having CV^S above 4.2%; therefore, demonstrating comparable performance of the CholeSite® Test System against the COBAS analyzer used as an in-house reference.

CONCLUSION
The data demonstrated that whole blood cholesterol results using the CholeSite® Test System, when used in a POC setting such as a POL or physician's office, compare acceptably with the Abell-Kendall and Follas reference methods. Likewise, reference whole blood samples compared acceptably with standard, in-house testing reference equipment (COBAS).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

AUG 20 1999

Mr. Keith Crawford
Director, Regulatory Affairs / Quality Assurance
GDS Technology, Inc.
25235 Leer Drive
P.O. Box 473
Elkhart, Indiana 46515

Re: K992132
Trade Name: CholSite® Test System
Regulatory Class: I reserved
Product Code: CHH
Dated: June 18, 1999
Received: June 23, 1999

Dear Mr. Crawford:

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 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). 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/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 Statement

510(k) Number _____

Device Name:
CholeSite® Test System

Indications for Use:
The GDS® CholeSite® Test System is an *in vitro* diagnostic product for the quantitative determination of total cholesterol in whole blood. It is intended for the sole use with the GDS® Stat-Site® Meter.

Targeted Population:
The targeted population for the CholeSite® Test System is adults.

Environment of Use:
The environment of use are Physician Office Laboratories and other Professional Point of Care settings.

Acting Branch Chief for Dr Coppe
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K992132