

JAN 14 2000

510(k) SUMMARY

Submitter Identification:	GDS® Technology, Inc. 25235 Leer Dr. Elkhart, IN 46514 Phone: (219) 264-7384 Fax: (219) 262-0109
Contact:	Keith Crawford Director, Quality Assurance / Regulatory Affairs
Date:	November 30, 1999
Trade Name:	HemoSite® Test System
Common Name:	Whole Blood Hemoglobin Test
Classification Name:	Whole Blood Hemoglobin Determination
Comparison Device:	

DEVICE DESCRIPTION

The HemoSite® Test System is a whole blood hemoglobin measurement device which consists of the Stat-Site® Meter (K911801), HemoSite® Test Card and {lot-specific} HemoSite® Test Module. The test employs dry reagent technology based on the azidemethemoglobin method. The blood sample is applied to one side of the HemoSite® Test Card and the color develops on the opposite side. The color produced is directly proportional to the concentration of hemoglobin in the sample and is read using light reflectance at a specific wavelength; the reflectance reading is performed and reported by the Stat-Site® meter.

INTENDED USE

The HemoSite® Test System is a device for *in vitro* diagnostic use only. The GDS® HemoSite® Test Card is intended for the quantitative determination of hemoglobin in whole blood. It is intended for use with the Stat-Site® Meter in a point-of-care setting such as a physician's office or hospital.

COMPARISON

To verify the safety and effectiveness of the HemoSite® Test System with infants and children, when used under intended POL use conditions, a total of 151 whole blood clinical samples were obtained at 3 independent physician's office sites. The samples were tested against a certified reference

HemoSite® Test System

Premarket Notification 510(k)

standard to determine test performance accuracy. The following combined data regression parameters were obtained:

◆ HemoSite® Test System .vs. Reference

Slope= 0.9717

Intercept= 0.0397

Correlation Coefficient= 0.91

Since there are no differences in the product relative to the HemoSite® Test System (K973649), no other product evaluations were required.

CONCLUSION

The clinical data demonstrated that whole blood HemoSite® results with infants and children, when used in a POC setting such as a POL or physician's office, compare acceptably with the reference methods and with the prior Premarket Notification for HemoSite® Hemoglobin Test System, K973649.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JAN 14 2000

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

Re: K994073
Trade Name: Hemosite[®] Test System
Regulatory Class: II
Product Code: KHG
Dated: November 30, 1999
Received: December 2, 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.

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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 at (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

510(k) Number (if known): K994073

Device Name: Hemosite® Test System

Indications For Use:

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

Target Population:

HemoSite® has been evaluated with adults, children and infants.

Environment of Use:

Physician's Office or other Professional Point of Care setting.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Peter E. Madoni

(Division Sign-Off)

Division of Clinical Laboratory Devices

510(k) Number

K994073

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)