

K973649

AUG 31 1998

## HemoSite® Test System 510k Summary

**Submitter Identification:**

GDS® Diagnostics  
25235 Leer Drive  
Elkhart, IN 46514  
Phone: (800) 545-4437  
Fax: (219) 262-0109

**Contact:**

Jonathan Kovach

**Date:**

June 4, 1998

**Trade Name:**

HemoSite® Test System

**Common Name:**

Whole Blood Hemoglobin Test

**Classification Name:**

Whole Blood Hemoglobin Determination

**Comparison Device:**

Coulter® JT (K896873)

**Device Description:**

The HemoSite® Test Cards are dry-chemistry Test Cards that contain chemicals which react and produce color when hemoglobin is present. The Stat-Site® Meter is a reflectance colorimeter that reads color intensity. A Test Module is provided with each box of Test Cards. The Test-Module contains all current calibration information for the specific lot of reagent. The Test Module and Test Cards are coded to each other, and the Stat-Site® Meter will only operate if they are properly matched. HemoSite® Test Cards are dry reagent cards based on the azidemethemoglobin method. When a drop of whole blood is applied to the top of the Test Card, hemolysis occurs, with the release of hemoglobin. Sodium nitrite converts the hemoglobin to methemoglobin. Sodium azide converts methemoglobin to azidemethemoglobin to produce a brown color that is measured at 580 nm using the Stat-Site® Meter. The Stat-Site® Meter measures the color intensity and calculates the hemoglobin concentration.

**Intended Use:**

The GDS® 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.

**Comparison:**

To verify safety and effectiveness of the Stat-Site®/HemoSite® Hemoglobin Test when used under intended use conditions such as a POL setting, the device was compared with the Coulter® JT hematology analyzer. A total of 212 venous and capillary blood samples were obtained internally and at three different physician's office sites.

HemoSite® Test System results were compared to the venous blood results from the Coulter® JT reference method. The following regression statistics were obtained:

Venous Blood:  $Y = 0.90x + 1.3$ ,  $r=0.8878$

Capillary Blood:  $Y = 1.0x - 0.18$ ,  $r=0.8358$

Precision evaluation was performed with whole blood hemoglobin concentrations of 8.7, 13.8 and 18.9 g/dL. All whole blood within-run precision estimates were below 4 %CV. Total precision estimates ranged from 3.0-3.5 %CV at high hemoglobin levels, 5.7-5.9 %CV at normal levels, and 5.9-7.2 %CV at low hemoglobin levels.

**Conclusion:**

The data demonstrates that blood hemoglobin results from the Stat-Site®/HemoSite® 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 the Coulter® JT when determining blood hemoglobin concentrations.



AUG 31 1998

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

Linda Williams  
Manager of Quality Assurance, Regulatory Affairs  
GDS TECHNOLOGY, INC.  
25235 Leer Drive  
Elkhart, IN 46514

Re: K973649  
Trade Name: HemoSite® Test System  
Regulatory Class: II  
Product Code: KHG  
Dated: June 4, 1998  
Received: June 9, 1998

Dear Ms. Williams:

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.

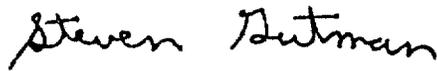
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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.

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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 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

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:** K973649

**Device Name:** HemoSite® Test System

**Indications for Use:** The GDS® 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.

**Targeted population:** HemoSite has been evaluated with adults. No samples from neonates, children, or infants were tested at this time.

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



**(Division Sign-Off)**  
**Division of Clinical Laboratory Devices**  
**510(k) Number** K973649