K981306

SEP 29 1998

510(k) Summary

This 510(k) summary is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K981306

Applicant Information:

Date Prepared:	September 28, 1998
Submitter's Name:	Diamedix Corporation
Address:	2140 N. Miami Avenue Miami, FL 33127
Contact Person:	Dr. Lynne Stirling
Phone Number:	305-324-2354
Fax Number:	305-324-2585

Device Information:

Trade Name:	Is-HSV 1 & 2 IgG Test System
Common Name:	HSV EIA Test
Classification Name:	Enzyme linked immunosorbent assay, herpes simplex virus

Equivalent Device Description:
Incstar HSV I/II IgG "fast" ELISA Kit
The Incstar Herpes Simplex Virus I/II IgG "fast" ELISA kit contains instructions and materials for the qualitiative and semi-quantitative detection of IgG antibodies to herpes simplex virus type 1 and/or type 2 in human serum by indirect ELISA.

Device Description: The Is-HSV 1 & 2 IgG Test System is an enzyme-linked immunosorbent assay (ELISA) for the detection and semi-quantitation of IgG to HSV 1 and/or HSV 2 antigens in human serum

Device Intended Use: This device is intended for the qualitative and semi-quantitative detection of IgG antibodies to herpes simplex virus (HSV) type 1 and/or type 2 in human serum. This test is useful for indicating a past infection with HSV in a single specimen, including females of child-bearing age. The evaluation of acute and convalescent specimens, by demonstrating seroconversion or a significant increase in antibody level, can aid in the diagnosis of primary infection with HSV. These reagents can be used either manually or in conjunction with the MAGO Plus Automated Processor.

Principle of the Procedure:

The Is-HSV 1 & 2 IgG Test System is an enzyme-linked immunosorbent assay to detect IgG to HSV1 and/or HSV 2 in human serum. Purified HSV 1 and 2 antigens are attached to a solid phase microtiter well. Diluted test sera are added to each well. If antibodies which recognize the HSV antigens are present in the patient sample they will bind to the antigens on the well. After incubation, the wells are washed to remove unbound antibody. An enzyme

labeled anti-human immunoglobulin (conjugate) is added to each test well. If antibody is present the enzyme-linked antibody will bind to it. After incubation, the wells are washed to remove unbound conjugate. A substrate solution is then added to each well. If enzyme is present from the prior step, the reaction is stopped and the color intensity is measured photometrically producing an indirect measure of the specific antibody present in the patient sample.

The Is-HSV 1 & 2 IgG Test System and the Incstar HSV I/II IgG "fast" ELISA are substantially equivalent in that :

1. Both are in vitro immunologic methods
2. Both are intended for use in the detection of IgG antibody to herpes simplex virus type 1 and/or type 2 in human serum.
3. Both are based on the formation of a complex between HSV antigens and antibody
4. Both use antigen coated microtiter plates
5. Both are qualitative/semi-quantitative assays
6. Both use goat anti-human IgG conjugated to horseradish peroxidase
7. Both use TMB as the enzyme substrate.

A detailed comparison between the proposed device and the predicate device is shown in Table 1.

Performance Data : The Is-HSV 1 & 2 IgG Test System was evaluated relative to the predicate device and to other legally maketed devices at 3 different test sites. In addition, the CDC serum panel for HSV serology assays was tested with this device.

A total of 645 different patient sera were evaluated. Thes results of these comparisons are shown below :

	# of Sera	*Relative Sensitivity (%)*	*Relative Specificity (%)*	*Overall Agreement* (%)*
Site 1	200	100.0 (97.7-100.0)	92.7 (80.1-98.5)	98.5 (95.6-99.7)
Site 2	178	99.2 (95.4-100.0)	94.7 (85.4-98.9)	97.7 (94.3-99.4)
Site 3 (manual)	267	100.0 (98.3-100.0)	100.0 (93.4-100.0)	100.0 (98.6-100.0)
Site 3 (automated)	259	99.5 (97.4-100.0)	97.8 (88.5-99.9)	99.2 (97.2-99.9)

* equivocal samples were not included in calculations
( ) 95% confidence interval

The precision of the Is-HSV1 & 2 IgG Test Sytem was determined at 3 testing sites by testing several sera in two different runs per day for threee days. Intra-assay CVs for positive samples ranged from 1.4 to 18.7%. Interassay CVs for positive samples ranged from 3.5 to 15.5%.

Studies were also conducted to show the correlation between manual and autmated methods for samples within the assay's critical range (20-100 EU/ml).

The titration of strongly positive sampes demonstrate a linear relationship between the Is-HSV 1 & 2 IgG EU/ml values and the log of the serum dilution.

Studies undertaken to determine cross-reactivity of the Is-HSV 1 & 2 IgG Test System demonstrated no detectable cross-reactivity to varicella zoster virus, cytomegalovirus, Epstein Barr virus, measles virus, rubella virus or Toxoplasma.

Conclusions : The Diamedix Is-HSV 1 & 2 IgG is substantially equivalent to the Incstar HSV I/II "fast" ELISA for the detection of IgG antibodies to herpes simplex virus in human serum to aid in the indication of a past infection or, in the case of paired samples, as an aid in the diagnosis of a primary infection. The device is as safe, as effective and performs as well as the legally marketed device described.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

SEP 29 1998

Lynne Stirling, Ph.D.
Vice President, Regulatory Affairs
Diamedix Corporation
2140 N. Miami Ave.
Miami, FL 33127

Re: K981306
Trade Name: Is-HSV 1 & 2 IgG Test System
Regulatory Class: III
Product Code: LGC
Dated: July 14, 1998
Received: July 17, 1998

Dear Dr. Stirling:

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 at (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/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

ATTACHMENT 1

Appendix G Rev. Indications for Use Statement

INDICATIONS FOR USE STATEMENT

510(K) NUMBER : K981306

DEVICE NAME : Is-HSV 1 & 2 IgG Test System

Indications for Use : The Diamedix Is-HSV 1 & 2 IgG is an indirect Enzyme Immunoassay (EIA) for the qualitative and semi-quantitative determination of IgG antibodies to herpes simplex virus (HSV) type 1 and/ or type 2 in human serum. This test is useful for indicating a past infection with HSV in a single specimen, including females of child-bearing age. The evaluation of acute and convalescent specimens, by demonstrating seroconversion or a significant increase in antibody level, can aid in the diagnosis of primary infection with HSV. These reagents can be used either manually or in conjunction with the MAGO® Plus Automated EIA Processor.

Woody Dubois

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K981306