8/19/99 K983886

510(k) SUMMARY

The assigned 510(k) number is: K983886

Applicant Information:

Date Prepared: February 20, 1999
Submitter's Name: Diagnology Limited
Unit 5 Kennedy Enterprise Center
Blackstaff Road
Belfast, BT11 9DT U.K.

Contact Organization: Schiff & Company, Inc.
Contact Person: Dr. Robert Schiff
Phone Number: 973-227-1830
Fax Number: 973-227-5330

Device Information:

Trade Name: POCkit™ HSV-2 Rapid Test
Common Name: Herpes simplex virus *Type* 2 Antibody Test
Classification Name: *In vitro* Diagnostic to detect antibodies to HSV-2

Equivalent Device Description:

The device was found equivalent to Gull HSV-2 IgG ELISA test. Comparative testing was performed with Western Blot HSV Type 2.

Device Description:

The POCkit™ HSV-2 Rapid Test is a qualitative membrane immunoassay for the detection of IgG antibodies to herpes simplex virus type 2 (HSV-2) in human capillary whole blood and serum.

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Device Intended Use:

The POCkit™ HSV-2 Rapid Test is a single unit, membrane-based immunoassay for the qualitative determination, either in heparinized capillary whole blood taken by fingerstick or in serum, of circulating IgG antibodies specific for herpes simplex virus type 2 (HSV-2), which arise as a result of infection with HSV-2. It is intended for in-vitro diagnostic use by health professionals in Point of Care testing. The presence of antibodies to HSV-2 may be indicative of a previous infection with HSV-2 and may be of value in determination of previous immunological experience and to aid in the diagnosis of HSV associated disease. This assay will not differentiate whether infection is currently in a latent or active state.

PRECAUTION:
The POCkit™ HSV-2 Rapid Test is intended for use in a high prevalence population, e.g. sexually active adults and sexually transmitted disease clinic. If used in a low prevalence population, positive results should be considered presumptive and should be confirmed with an alternate methodology e.g. Western blot. Assay results are not intended for medical/legal use.

The POCkit™ HSV-2 Rapid Test is not recommended as a screening procedure for the general population of for testing in a prenatal, pediatric or neonatal population. Performance characteristics have not been established in a low prevalence population e.g. prenatal patients, on immunocompromised individuals, for prenatal or neonatal screening, on other patients with HSV associated diseases, or for early stages of HSV seroconversion.

Principle of the Procedure:

The POCkit™ HSV-2 Rapid Test consists of a test device that has a solid phase membrane housed in a plastic envelope containing wicking material. The membrane is visible to the user through a test window on the front of the device. The method employs a unique combination of a specific antibody binding protein conjugated to colloidal gold particles and a semi-purified HSV-2 specific antigen (glycoprotein G2, derived from HSV-2 virus). This protein has been bound to the membrane as a TEST spot on the right side of the test window. Human IgG has been bound to the membrane as a CONTROL spot on the left side of the test window.

When a pre-diluted (fingerprick) capillary whole blood sample is allowed to pass through the membrane any anti-HSV-2 antibodies present become bound to the HSV-2 antigen in the TEST spot. Upon addition of the developing reagent, which reacts with human

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IgG antibodies, a pink/red color develops. The developing reagent also reveals the human IgG immobilized in the CONTROL spot, which demonstrates that the test is functioning properly. The test device is designed to absorb the pre-calibrated volume of reagents that are provided in each test kit.

Performance Data:

The POCkit™ HSV-2 Rapid Test was evaluated relative to the HSV-2 Western Blot method. In addition, the CDC serum panel for HSV-2 serology assays was tested with this device.

A total of 1193 whole blood samples and 1220 serum samples were evaluated. These results are shown in the tables 1,2 and 3 below:

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

AUG 19 1999

Diagnology Ltd.
Dr. Robert Schiff
c/o Schiff & Company
1129 Bloomfield Avenue
West Caldwell, New Jersey 07006

Re: K983886
Trade Name: POCkit™ HSV-2 Rapid Test
Regulatory Class: III
Product Code: LGC
Dated: June 4, 1999
Received: June 7, 1999

Dear Dr. Schiff:

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

INDICATIONS FOR USE STATEMENT

510(K) NUMBER: K983886

DEVICE NAME: POCkit™ HSV-2 Rapid Test

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Woody Dubois

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K983886

Prescription Use ____ OR Over-The Counter Use ____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

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