K990141

OCT 19 1999

510(k) Summary

Submitter: *Light Diagnostics*
28835 Single Oak Drive
Temecula, CA 92590
Tel: 909/676-8080
Fax: 909/676-9209

Contact Person: Cindy Penny

Product Name:

Trade Name: ***Light Diagnostics*** **SimulFluor™ HSV/VZV**
Common Name: Immunofluorescence Assay
Classification Name: Herpes simplex virus and varicella-zoster virus
Classification Number: 866.3305-83LKC and 866.3900-83GQX

Intended Use:

Light Diagnostics **SimulFluor™ HSV/VZV** Immunofluorescence Assay is a direct immunofluorescence test intended for the simultaneous detection and identification of HSV 1 and 2 and varicella-zoster virus (VZV) from patients with vesicular, oral, genital, or skin lesions, and following amplification of virus in culture. Specimens found to be negative on direct specimen examination should be tested by cell culture.

Predicate Devices:

1. Bartels HSV Fluorescent Monoclonal Antibody Test
   The Bartels HSV reagent is a direct immunofluorescence test intended for the detection of HSV type 1 and HSV type 2 viruses in direct specimen and for culture confirmation.
   For *in vitro* diagnostic use.

2. Meridian Merifluor™ VZV
   The Meridian VZV reagent is a direct immunofluorescence test for the detection of varicella-zoster virus in direct specimens and for culture confirmation.
   For *in vitro* diagnostic use.

3. DPC PathoDx® Herpes Typing Kit
   The DPC HSV typing kit is a direct immunofluorescence test containing two reagents for the detection of HSV type 1 or HSV type 2 in direct specimens and for culture confirmation.
   For *in vitro* diagnostic use.

4. ***Light Diagnostics*** Varicella-zoster virus DFA
   The Light Diagnostic VZV reagent is a direct immunofluorescence test for the detection of VZV in direct specimens and for culture confirmation.
   For *in vitro* diagnostic use.

Device description:

Light Diagnostics **SimulFluor™ HSV/VZV Immunofluorescence Assay** utilizes a single reagent for the simultaneous detection and identification of HSV and VZV. The primary component, specific for both HSV 1 and 2 will bind to 155kD major capsid protein in HSV-infected cells. The secondary component, specific for VZV, will bind to glycoprotein gp I and the immediate early antigen in VZV-infected cells. Unbound reagent is removed by rinsing with phosphate-buffered saline (PBS). Illumination with ultraviolet light allows visualization of the antigen-antibody complexes by fluorescence microscopy. When a FITC filter set is used, the HSV antigen-antibody complex will exhibit an apple green fluorescence and the VZV antigen-antibody complex will fluoresce yellow-gold. Uninfected cells stain a dull red due to the presence of Evans blue in the reagent.

A blend of monoclonal antibodies directed against HSV and VZV is used in the ***Light Diagnostics*** **SimulFluor™ HSV/VZV** reagent. The use of monoclonal antibodies ensures increased specificity of the reagent and reduces the risk of non-specific background or interference.

Technological Comparison of Methods:

The ***Light Diagnostics*** SimulFluor™ HSV/VZV Immunofluorescence Assay is substantially equivalent to Bartels HSV Fluorescent Monoclonal Antibody Test, DPC PathoDx® Herpes Typing Kit, Meridian Merifluor™ VZV, and the ***Light Diagnostics*** VZV DFA:

A. Three methods are intended for use in the detection of HSV antigens in patient specimens and infected cells.

B. Three methods are intended for use in the detection of VZV antigens in patient specimens and infected cells.

C. All five methods are *in vitro* test methods.

D. All five methods use a direct immunofluorescence assay procedure for staining of slides using FITC filter sets.

The methods differ in that:

A. The ***Light Diagnostics*** **SimulFluor™ HSV/VZV** Immunofluorescence Assay consists of only one reagent that contains specific monoclonal antibodies labeled with two different fluorescent labels. This allows visualization of both viruses in one well. The Bartels reagent contains FITC-labeled monoclonal antibodies directed against HSV type 1 and type 2, the DPC kit consists of two FITC-labeled monoclonal antibodies directed against HSV type 1 or HSV type 2, and the Meridian reagent and the ***Light Diagnostics*** reagent each contains FITC-labeled monoclonal antibodies directed against VZV. Two or three completely separate tests are necessary to detect both viruses in one sample.

Performance Data for *Light Diagnostics* SimulFluor™ HSV/VZV Immunofluorescence Assay:

1. Non-clinical evaluation:

   The monoclonal antibodies directed against VZV used in the ***Light Diagnostics*** **SimulFluor™ HSV/VZV** reagent are identical to those used in the ***Light Diagnostics*** **VZV DFA**, cleared for *in vitro* diagnostic use (K951799).

   The monoclonal antibodies directed against HSV used in the ***Light Diagnostics*** **SimulFluor™ HSV/VZV** reagent were characterized for their ability to detect HSV types 1 and 2. These antibodies reacted concordantly when tested with reference viral strains and clinical isolates. The conjugated monoclonal antibodies were also evaluated for cross reactivity to a variety of viruses and bacteria, and cell lines commonly used to isolate HSV. No reactivity was observed.

2. Clinical evaluation:

   The ***Light Diagnostics*** **SimulFluor™ HSV/VZV** Immunofluorescence Assay was compared in clinical evaluation to culture confirmation for the detection and identification of HSV and VZV in patient specimens at 2 separate sites, the northeast (Site 1), and the west coast (Site 2). The ***Light Diagnostics*** **SimulFluor™ HSV/VZV** reagent was compared to the Bartels HSV reagent, the DPC PathoDx® Herpes Typing, the Meridian Merifluor™ VZV reagent, and the ***Light Diagnostics*** VZV reagent for the detection and identification of HSV and VZV in direct specimens and following isolation in culture.

At Site 1, 203 specimens were tested for the presence of HSV or VZV. Site 1 is a hospital laboratory in the northeast region of the US which also acts as a regional reference lab. On patient specimens the ***Light Diagnostics*** **SimulFluor™ HSV/VZV** reagent had a sensitivity of 64.7% (95% Confidence Interval of 50.1% to 77.62%) and a specificity of 97.5% (95% Confidence Interval of 91.3% to 99.7%) compared to culture for the identification of HSV, and a sensitivity of 100% (95% Confidence Interval of 83.2% to 100%) and a specificity of 85.7% (95% Confidence Interval of 79.2% to 92.2%) compared to culture for the identification of VZV. After amplification in culture the ***Light Diagnostics*** **SimulFluor™ HSV/VZV** reagent had a relative sensitivity of 100% (95% Confidence Interval of 93.8% to 100%) and a relative specificity of 100% (95% Confidence Interval of 97.1% to 100%) compared to the predicate device for detection of HSV, and a relative sensitivity of 95.2% (95% Confidence Interval of 76.2% to 99.9%) and a relative specificity of 100% (95% Confidence Interval of 97% to 100%) compared to the predicate device for detection of VZV.

At Site 2, 283 specimens were submitted to a hospital laboratory for HSV and / or VZV testing. Of these, 236 specimens were tested for the presence of HSV and VZV in direct specimens. Site 2 is a hospital laboratory on the west coast. Direct specimen slides were stained with the ***Light Diagnostics*** **SimulFluor™ HSV/VZV** reagent and the results compared to culture. The SimulFluor™ HSV/VZV reagent had a sensitivity of 82.4% (95% Confidence Interval of 56.6% - 96.2%) and specificity of 99.5% (95% Confidence Interval 97.5% – 100%) for the detection of HSV in direct specimens compared to culture. For the detection of VZV in patient specimens, the ***Light Diagnostics*** **SimulFluor™ HSV/VZV** had a sensitivity of 100% (95% Confidence Interval 71.5% - 100%) and a specificity of 99.1% 95% (Confidence Interval 96.9% – 99.9%) when compared to culture.

3. Conclusions drawn from evaluations:

Light Diagnostics **SimulFluor™ HSV/VZV** uses a standard direct immunofluorescence assay procedure for the detection of HSV and VZV in patient specimens and in cell culture. The monoclonal antibodies used in the reagent have been characterized to ensure specificity and reliability of the product. In clinical evaluations, the performance characteristics of the reagent was shown to be substantially equivalent to those of Bartels HSV reagent, DPC's HSV typing kit, Meridians Merifluor™ VZV reagent, and ***Light Diagnostics*** VZV reagent.

The characterization and clinical evaluation of the ***Light*** *Diagnostics* SimulFluor™ HSV/VZV Immunofluorescence Assay demonstrates the safety and effectiveness of this product when used as intended as described in the product insert.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

OCT 19 1999

Ms. Cindy Penny
Manager, Quality Assurance
Light Diagnostics
28835 Single Oak Drive
Temecula, California 92590

Re: K990141
Trade Name: Light Diagnostics SimulFluor™ HSV/VZV Immunofluorescence Assay
Regulatory Class: II, III
Product Code: GQW, GQN
Dated: July 20, 1999
Received: July 22, 1999

Dear Ms. Penny:

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

510(k) Number (if known):

Device Name: Light Diagnostics Simulfluor™ HSV / VZV Immunofluorescence Assay

Indications For Use: *Light Diagnostics* SimulFluor™ HSV/VZV Immunofluorescence Assay is a direct immunofluorescence test intended for the simultaneous detection and identification of HSV 1 and 2 and varicella-zoster virus (VZV) from patients with vesicular, oral, genital, or skin lesions, and following amplification of virus in culture. Specimens found to be negative on direct specimen examination should be tested by cell culture.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Woody Dubois

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K990141

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

(Optional Format 1-2-96)