K971432

APR - 8 1998

510(k) Notification for ***Light Diagnostics*** SimulFluor™ Flu A/Flu B Immunofluorescence Assay

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™ Flu A/Flu B
Common Name: Immunofluorescence Assay
Classification Name: Influenza virus
Classification Number: 866.3330

Intended Use:

The ***Light Diagnostics*** **SimulFluor™ Flu A/Flu B Immunofluorescence Assay** is intended for the detection and identification of influenza A and influenza B in respiratory specimens such as throat, nasal and nasopharyngeal swabs, nasopharyngeal aspirates, broncho-alveolar lavages from patients with febrile respiratory illness and following amplification of virus in cell culture. Specimens found to be negative on direct specimen examination must be confirmed with culture.
For *in vitro* diagnostic use.

Predicate Devices:

1) BARTELS Influenza A and B Reagents

The Bartels Influenza A and B reagents are part of the Viral Respiratory Screening and Identificaton Kit. The reagents are intended for the detection of influenza A and B viruses in direct specimen and for culture confirmation.
For *in vitro* diagnostic use.

2) DAKO IMAGEN™ Influenza Virus A and B

The IMAGEN™ Influenza virus A and B test is a qualitative direct immunofluorescence test for the detection and differentiation of Influenza A virus and Influenza B virus in clinical samples or for the confirmation and differentiation of Influenza virus A and B in cell cultures.
For *in vitro* diagnostic use.

510(k) Notification for ***Light Diagnostics*** SimulFluor™ Flu A/Flu B Immunofluorescence Assay

Device description:

Light Diagnostics **SimulFluor™ Flu A/Flu B Immunofluorescence Assay** utilizes a single reagent for the simultaneous detection and identification of influenza A and influenza B. The primary component, specific for influenza A, will bind to influenza A nucleoprotein in influenza A-infected cells. The secondary component, specific for influenza B, will bind to influenza B nucleoprotein in influenza B-infected cells. Unbound reagent is removed by rinsing with phosphate-buffered saline (PBS). The complexes are visualized with a fluorescence microscope. The influenza A antigen-antibody complex will exhibit an apple-green fluorescence and the influenza B antigen-antibody complex will be yellow-gold. Uninfected cells stain a dull red due to the presence of Evans blue in the reagent.
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™ Flu A/Flu B Immunofluorescence Assay is substantially equivalent to DAKO IMAGEN Influenza Virus A and B and Bartels Influenza A and B reagents:

A. All three methods are intended for use in the detection of influenza A and influenza B antigens in patient specimens and infected cells.

B. All three methods are *in vitro* test methods.

C. All three methods use a direct immunofluorescence assay procedure for staining of slides.

The methods differ in that:

A. The ***Light Diagnostics*** SimulFluor™ Flu A/Flu B Immunofluorescence Assay contains only one reagent which contains specific monoclonal antibodies labeled with two different fluorescent labels. This allows visualization of both viruses in one well, whereas both DAKO and BARTELS kits contain two separate reagents, each of which contains FITC-labeled monoclonal antibodies directed against either influenza A or B. Two separate wells are necessary to detect both viruses in one sample.

Performance Data for Light Diagnostics SimulFluor™ Flu A/Flu B Immunofluorescence Assay:

1. Non-clinical evaluation:

With the exception of one monoclonal antibody to influenza B (clone 22D), the monoclonal antibodies used in this reagent are identical to those used in the Influenza A and Influenza B reagents that are part of the ***Light Diagnostics*** Respiratory Virus Panel I IFA, cleared for *in vitro* diagnostic use.

The conjugated monoclonal antibodies used in the SimulFluor™ Flu A/Flu B reagent were tested against a variety of viruses and bacteria found in the respiratory tract, and cell lines commonly used to isolate influenza A and B viruses. The results are indicated in the table below.

Microorganisms	**SimulFluor ™ Flu A/B**
Viruses	
Adenovirus: AD-75 CDC V5-002	-
Coxsackievirus A9; ATCC VR-186	-
Coxsackievirus B1; NIH	-
Cytomegalovirus; clinical isolate	-
Enterovirus 70; ATCC VR-836	-
Enterovirus 71; ATCC VR-784	-
Echovirus 4; ATCC VR-34	-
Echovirus 6; ATCC VR-36	-
Echovirus, 9; ATCC VR-39	-
Echovirus 11; ATCC VR-41	-
Echovirus 30; ATCC VR-322	-
Herpes simplex virus type 1; clinical isolate	-
Herpes simplex virus type 2; clinical isolate	
Influenza A: H1N1: 6 strains H2N2: 1 strain H3N2: 8 strains	 + + +
Influenza B; 6 strains	+
Mumps;	-
Measles	-
Parainfluenza 1; CDC V6-004	-
Parainfluenza 2; CDC V7-003	-
Parainfluenza 3; CDC V5-003	-
Parainfluenza 4A; VR1378 Strain M-25	-
Respiratory syncytial virus; clinical isolate	-
Pneumocystis carinii, rat lung	-
Varicella zoster virus; clinical isolate	-

Microorganisms	SimulFluor™ Flu A/B
Parainfluenza 1: CDC V6-004	-
Parainfluenza 2; CDC V7-003	-
Parainfluenza 3; CDC VS-003	-
Parainfluenza 4A; VR1378 Strain M-25	-
Respiratory syncytial virus: clinical isolate*	-
PCP; rat derived	-
Varicella zoster virus; clinical isolate*	-
Bacteria	
Bordetella bronchiseptica; ATCC 10580	-
Bordetella pertussis; ATCC 9340	-
Branhamella catarrhalis; ATCC 25238	-
Chlamydia trachomatis; ATCC	-
Chlamydia pneumoniae	-
Corynebacterium diptheriae; ATCC 13812	-
Legionella micdadei; ATCC 33204	-
Legionella pneumophila; ATCC 33156	-
Mycobacterium tuberculosis; ATCC 25177	-
Mycoplasma hominis; ATCC 23114	-
Mycoplasma pneumoniae; ATCC 15531	-
Neisseria meningitidis; ATCC 13077	-
Cell Lines	
RMK	-
MRC5	-
A549	-
Vero	-
LLC-MK2	-

* Slides obtained from Bion: for *in vitro* diagnostic use for serological assays

2. Clinical evaluation:

The ***Light Diagnostics*** SimulFluor™ Flu A/Flu B Immunofluorescence Assay was compared in clinical evaluation to culture confirmation for the detection and identification of influenza A and B viruses and patient specimens. The SimulFluor™ Flu A/Flu B was compared to the Bartels Influenza A and Influenza B reagents, and the Dako IMAGEN Influenza Virus A and B reagents for the detection and identification of influenza A and B viruses following isolation in culture.

One hundred and forty-seven specimens were evaluated at Site 1. On patient specimens the SimulFluor™ Flu A/Flu B reagent had a sensitivity of 80.0% (95% Confidence Interval of 61.4% to 92.3%) and a specificity of 98.6% (95% Confidence Interval of 93.6% to 100%) compared to culture for the identification

of influenza A and a sensitivity of 50.0% (95% Confidence Interval of 15.7% to 84.3%) and a specificity of 100% (95% Confidence Interval of 96.7% to 100%) compared to culture for the identification of influenza B.

When compared to Bartels Influenza A and B reagents for culture confirmation, the ***Light Diagnostics*** SimulFluor™ Flu A/Flu B Immunofluorescence Assay had a sensitivity of 97.8% (95% Confidence Interval of 93.8% to 100%) and a specificity of 100% (95% Confidence Interval of 96.4% to 100%) for influenza A and a sensitivity of 100% (95% Confidence Interval of 75.3% to 100%) and a specificity of 100% (95% Confidence Interval of 97.3% to 100%) for influenza B.

Two hundred and fifty-two specimens were evaluated at Site 2. On patient specimens the SimulFluor™ Flu A/Flu B reagent had a sensitivity of 58.8% (95% Confidence Interval of 32.9% to 81.6%) and a specificity of 98.3% (95% Confidence Interval of 95.7% to 99.5%) compared to culture for the identification of influenza A and a sensitivity of 43.2% (95% Confidence Interval of 28.4% to 59.0%) and a specificity of 98.1% (95% Confidence Interval of 95.1% to 99.5%) compared to culture for the identification of influenza B.

When compared to Bartels Influenza A and B reagents for culture confirmation, the ***Light Diagnostics*** SimulFluor™ Flu A/Flu B Immunofluorescence Assay had a sensitivity of 100% (95% Confidence Interval of 79.4% to 100%) and a specificity of 100% (95% Confidence Interval of 98.4% to 100%) for influenza A and a sensitivity of 100% (95% Confidence Interval of 92.6% to 100%) and a specificity of 100% (95% Confidence Interval of 98.2% to 100%) for influenza B.

3. Conclusions drawn from evaluations:

Light Diagnostics SimulFluor™ Flu A/Flu B Immunofluorescence Assay uses a standard direct immunofluorescence assay procedure for the detection of influenza A and B viruses in patient specimens and in cell culture. The monoclonal antibodies used in the reagent have been characterized so as 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 Influenza A and Influenza B reagents and Dako IMAGEN Influenza Virus A and B.

The characterization and clinical evaluation of the ***Light Diagnostics*** SimulFluor™ Flu A/Flu B 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

Public Health Service

APR - 8 1998

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

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

Re: K974302
Trade Name: Light Diagnostics SimulFluor Flu A / Flu B
Regulatory Class: I
Product Code: GNW
Dated: February 4, 1998
Received: February 5, 1998

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): K974302

Device Name: *Light Diagnostics* SimulFluor™ Flu A/Flu B Immunofluorescence Assay

Indications For Use: The *Light Diagnostics* SimulFluor™ Flu A/Flu B Immunofluorescence Assay is intended for the detection and identification of influenza A and influenza B in respiratory specimens such as throat, nasal and nasopharyngeal swabs, nasopharyngeal aspirates, broncho-alveolar lavages from patients with febrile respiratory illness and following amplification of virus in cell culture. Specimens found to be negative on direct specimen examination must be confirmed with culture.
For *in vitro* diagnostic use.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K974302