SEP 11 2003

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Assigned 510(k) Number: K031899

Submitted By:

Quidel Corporation
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Submission Contact: Robin Weiner

Date Prepared: June 27, 2003

Device Trade Name: QuickVue® Influenza A + B test

Predicate Devices:

Quidel QuickVue® Influenza test (K991633)
BD Directigen™ Flu A+B test (K001364)
BioStar® AB Flu OIA® test (K023556)

Device Classification:

21 CFR 866.3330
The device, the QuickVue Influenza A + B test, is similar to other FDA-cleared devices used for the qualitative detection of influenza type A and B directly from clinical specimens. These tests are used to aid in the diagnosis of disease cause by influenza viruses A and B and provide epidemiological information on these diseases (21CFR 866.3330).

The Food and Drug Administration has proposed that serological test systems for the detection of influenza virus be classified as Class I.

Intended Use:

The QuickVue Influenza A + B test allows for the rapid, qualitative detection of influenza type A and type B antigens directly from nasal swab, nasal wash and nasal aspirate specimens. The test is intended for use as an aid in the rapid differential diagnosis of acute influenza type A and type B viral infections. The test is not intended to detect influenza C antigens. The test is intended for professional and laboratory use.

Physiologic Basis of the Test: Influenza is a highly contagious, acute, viral infection of the respiratory tract. The causative agents of the disease are immunologically diverse, single-strand RNA viruses known as Influenza Viruses. There are three types of influenza viruses: A, B, and C. Type A viruses are the most prevalent and are associated with the most serious epidemics. Type B produces a disease that is generally milder than that caused by Type A. Type C has never been connected with a large epidemic of human disease. Both Type A and B viruses can circulate simultaneously, but usually one type is dominant during a given season.

Influenza antigens may be detected in clinical specimens by immunoassay. The QuickVue Influenza A + B test is a lateral-flow immunoassay using highly sensitive monoclonal antibodies that are specific for influenza antigens. The test is specific to influenza Types A and B antigen with no know cross-reactivity to normal flora or other known respiratory pathogens.

Device Description: The QuickVue Influenza A + B test, the successor product to the QuickVue Influenza test, has two Test Line indicators – one for type A and one for type B. The two Test Line indicators allow for the separate identification of type A and type B viral antigens from the same specimen. If either Test Line turns pink-to-red, the test is positive for influenza.

Nasal swabs, nasal wash and/or nasal aspirates serve as specimens for this test. The patient specimen is placed in a tube containing Extraction Reagent, during which time the virus particles in the specimen are disrupted, exposing internal viral antigens. After extraction, the Test Strip is placed in the Extraction Tube for 10 minutes. During this time, the extracted specimen will react with the reagents in the Test Strip.

If the extracted specimen contains influenza Type A and/or B antigens, a pink-to-red Test Line along with a blue procedural Control Line will appear on the Test Strip. If influenza Type A and B viral antigens are not present, or present at very low levels, only a blue procedural Control Line will appear. If no blue procedural Control Line develops, the result is considered invalid.

Device Comparison:

Features	QuickVue® Influenza A+B test	QuickVue® Influenza test	BD Directigen™ Flu A+B	BioStar® AB Flu OIA® test
Intended Use	Differential detection of influenza A and B viral antigen	Detection of influenza A and B viral antigen	Direct and qualitative detection of influenza A and B viral antigen	Qualitative, rapid detection of influenza A and B viral antigen (nucleoprotein)
Specimen Types	Nasal Swab Nasal Wash Nasal Aspirate	Nasal Swab Nasal Wash Nasal Aspirate	Nasopharyngeal Washes Nasopharyngeal Swabs Nasopharyngeal Aspirates Throat Swabs Lower Nasal Swabs Bronchoalveolar Lavages	Nasal Aspirates Nasopharyngeal Swabs Throat Swabs Sputum
Technology	Lateral-flow immunoassay	Lateral-flow immunoassay	Enzyme immunoassay	Optical sandwich immunoassay
Detection of Influenza Virus	Detection of Influenza type A and type B	Differentiated detection of Influenza type A and type B	Differentiated detection of Influenza type A and type B	Differentiated detection of Influenza type A and type B
Extraction	1 step; buffer and detergent	1 step; buffer and detergent	1 step; detergent	2 steps; detergent and reducing agent

Summary of Performance Data:

Clinical Studies

Substantial equivalence has been demonstrated between the QuickVue test and viral culture for the qualitative detection of influenza Type A and B antigens. Using clinical specimens obtained from patients symptomatic for upper respiratory infection, a retrospective comparison of the QuickVue Influenza A + B test to viral culture was conducted in a multi-clinical field study.

Analytical Studies

Analytical testing, including analytical sensitivity, specificity, cross-reactivity and interference were conducted. These studies further demonstrated the suitability of the product for laboratory and professional use. Such studies are a critical element in establishing the fundamental safety and effectiveness of the product and its appropriateness for commercial distribution.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

SEP 11 2003

Ms. Robin Weiner
Vice President, Clinical and Regulatory Affairs
Quidel Corporation
10165 McKellar Court
San Diego, CA 92121

Re: k031899
Trade/Device Name: QuickVue® Influenza A+B Test
Regulation Number: 21 CFR 866.3330
Regulation Name: Influenza Virus Serological Reagents
Regulatory Class: Class I
Product Code: GNX
Dated: June 3, 2003
Received: June 25, 2003

Dear Ms. Weiner:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 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 information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer 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 Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

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510(k) Number (if known): K031899

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

9/11/03

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

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Prescription Use ✓ OR Over-The Counter Use

(Per 21 CFR 801.109)