SEP 24 1999

K991683

XI. SUMMARY OF SAFETY AND EFFECTIVENESS

The following information as presented in the Premarket Notification [510(k)] for the QuickVue Influenza A/B Test constitutes data supporting a substantially equivalent determination.

Product:
QuickVue® Influenza A/B Test

Manufacturer:
QUIDEL Corporation
10165 McKellar Court
San Diego, California 92121

Device Classification:
The device, 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 is intended for the rapid, qualitative detection of influenza Types A and B antigen directly from nasal swab, nasal wash and/or nasal aspirate specimens. The test is intended for use as an aid in the rapid diagnosis of acute influenza virus infection. The test is intended for professional and laboratory use.

Physiologic Basis for 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.

Principle of the Test:
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.

Safety and Effectiveness:
Substantial equivalence has been demonstrated between the QuickVue Influenza A/B 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 comparison of the QuickVue Influenza A/B Test to viral culture was conducted in a multi-clinical field study.

Physician's Office Laboratory studies were also conducted to show that doctors' office personnel with diverse educational backgrounds and work experience can perform the test accurately and reproducibly. Testing was performed at three geographically distinct sites in the United States. The results obtained at each site agreed >99% with the expected results.

Conclusion:
These studies demonstrated the substantial equivalence of the QuickVue Influenza A/B Test to existing products already marketed. They 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

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

SEP 24 1999

Ms. Mary De Armond
Regulatory Compliance Manager
Quidel Corporation
10165 McKellar Court
San Diego, California 92121

Re: K991633
Trade Name: QuickVue® Influenza A/B Test
Regulatory Class: I
Product Code: GNX
Dated: August 10, 1999
Received: August 17, 1999

Dear Ms. De Armond:

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

QUIDEL

XIII. Indications for Use (Separate Page)

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510(k) Number (if known): K991633

Device Name: **QuickVue® Influenza A/B Test**

Indications for Use:

The QuickVue Influenza A/B Test is intended for the qualitative detection of influenza Type A and Type B antigens directly from nasal swab, nasal wash and nasal aspirate specimens. The QuickVue Influenza A/B Test is intended for laboratory and professional use.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Woody Dutcher

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K991633

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

Quidel Corporation
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(619) 552-1100 • FAX (619) 453-4338