K070747

APR 23 2007

510(k) SUMMARY

Submitted By:

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Submission Contact: Jennifer Hankard

Date Prepared: March 16, 2007

Device Trade Name: QuickVue® RSV test

Common Name: Respiratory Syncytial Virus (RSV) Test

Predicate Device: QuickVue® RSV test (K061008)

Device Classification/Name: 21 CFR 866.3480 / Respiratory syncytial virus serological reagents

These tests are used to aid in the diagnosis of disease caused by respiratory syncytial viruses and provides epidemiological information on these diseases (21 CFR 866.3480). The Food and Drug Administration has classified serological test systems for the detection of respiratory syncytial virus as Class I.

Intended Use: The QuickVue RSV test is a dipstick immunoassay which allows for the rapid, qualitative detection of respiratory syncytial virus (RSV) antigen (viral fusion protein) directly from nasopharyngeal swab, nasopharyngeal aspirate, or nasal/nasopharyngeal wash specimens for symptomatic pediatric patients (eighteen years of age and younger). The test is intended for use as an aid in the diagnosis of acute respiratory syncytial viral infections. It is recommended that negative test results be confirmed by cell culture. Negative results do not preclude RSV infection and it is recommended that they not be used as the sole basis for treatment or other management decisions. The test is intended for professional and laboratory use.

Physiologic Basis of the Test:

Respiratory syncytial virus (RSV) is a single stranded (negative strand) RNA virus of the Paramyxoviridae family. It is the causative agent of a highly contagious, acute, viral infection of the respiratory tract. Nearly half of all children become infected by their first year of life. It is also the major viral cause of nosocomial illness in children already hospitalized for other reasons. In the United States, RSV is estimated to be responsible for 73,400 to 126,300 hospitalizations annually for bronchiolitis and pneumonia alone among children younger than 1 year. In children hospitalized with RSV infection, it is believed to be the most common viral cause of death in children younger than 5 years, particularly in children younger than one year. Among children hospitalized with RSV infection, the mortality rate is estimated to be as low as 0.3% to 1.0% of hospitalized children and in the range of 2.5% to 4.0% for hospitalized children with underlying cardiac or pulmonary disease.

The QuickVue® RSV test is a lateral-flow immunoassay using highly sensitive monoclonal antibodies that are specific for RSV antigens. The test is specific to RSV antigen with no known cross-reactivity to normal flora or other known respiratory pathogens.

Device Description:

Nasopharyngeal swabs, nasopharyngeal aspirate, and nasal/nasopharyngeal wash 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 15 minutes. During this time, the extracted specimen will react with the reagents in the Test Strip.

If the extracted specimen contains RSV antigens, a pink-to-red Test Line along with a blue procedural Control Line will appear on the Test Strip. If RSV 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® RSV test (Proposed)	QuickVue® RSV test (K061008)
Intended Use	The QuickVue RSV test is a dipstick immunoassay which allows for the rapid, qualitative detection of respiratory syncytial virus (RSV) antigen (viral fusion protein) directly from nasopharyngeal swab, nasopharyngeal aspirate, or nasal/nasopharyngeal wash specimens for symptomatic pediatric patients (eighteen years of age and younger). The test is intended for use as an aid in the diagnosis of acute respiratory syncytial viral infections. It is recommended that negative test results be confirmed by cell culture. Negative results do not preclude RSV infection and it is recommended that they not be used as the sole basis for treatment or other management decisions. The test is intended for professional and laboratory use.	The QuickVue RSV test is a dipstick immunoassay which allows for the rapid, qualitative detection of respiratory syncytial virus (RSV) antigen (viral fusion protein) directly from nasopharyngeal swab or nasopharyngeal aspirate specimens for symptomatic pediatric patients (eighteen years of age and younger). The test is intended for use as an aid in the diagnosis of acute respiratory syncytial viral infections. It is recommended that negative test results be confirmed by cell culture. Negative results do not preclude RSV infection and it is recommended that they not be used as the sole basis for treatment or other management decisions. The test is intended for professional and laboratory use.
Specimen Types	Nasopharyngeal swab, Nasopharyngeal aspirate, and Nasal/nasopharyngeal wash	Nasopharyngeal swab and Nasopharyngeal aspirate
Extract / Elute	Extraction reagent used for swab/aspirate/wash	Extraction reagent used for swab/aspirate
Read Result Time	15 Minutes	15 Minutes
Format	Lateral-flow immunoassay dipstick	Lateral-flow immunoassay dipstick
Control Features	Procedural Control Line Clearing of background	Procedural Control Line Clearing of background
External Controls	Positive RSV swab RSV negative swab coated with Streptococcus C antigen	Positive RSV swab RSV negative swab coated with Streptococcus C antigen

Summary of Performance Data:

A multi-center field clinical study was undertaken to document the performance characteristics of the test. Sensitivity, specificity and overall accuracy were calculated using nasal/nasopharyngeal wash specimens compared to viral culture.

Conclusion:

This study demonstrated the substantial equivalence of the QuickVue® RSV test with the addition of the nasal/nasopharyngeal wash specimen type to existing products already marketed. This study further demonstrated the suitability of the product for professional and laboratory use. Clinical 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

Jennifer Hankard
Regulatory Affairs Manager
Quidel Corporation
10165 McKellar Court
San Diego, CA 92121

APR 23 2007

Re: k070747
Trade/Device Name: QuickVue® RSV Test
Regulation Number: 21CFR 866.3480
Regulation Name: Respiratory syncytial virus serological reagents
Regulatory Class: Class I
Product Code: GQG
Dated: March 16, 2007
Received: March 19, 2007

Dear Ms. Hankard:

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.

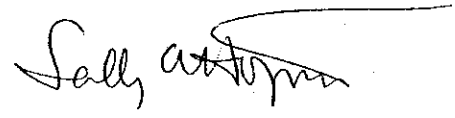
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 (240)276-0450. 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,



Sally A. Hojvat, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K070747

Device Name: **QuickVue® RSV test**

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Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

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