510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY

A. 510(k) Number:
k031899

B. Analyte:
influenza type A and type B antigens

C. Type of Test:
Lateral-flow immunoassay

D. Applicant:
Quidel, Inc.

E. Proprietary and Established Names:
QuickVue® Influenza A+B Test

F. Regulatory Information:

1. Regulation section:
21 CFR 866.3330; Influenza virus serological reagents

2. Classification:
Class I

3. Product Code:
GNX; Antigens, CF, Influenza Virus A, B, C.

4. Panel:
Microbiology (83)

G. Intended Use:

1. Intended use(s):
The QuickVue® Influenza A+B Test allows for the rapid, qualitative determination of influenza type A and type B antigens directly from nasal swab, nasal wash and/or 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 virus infection. The test is not intended to detect influenza C antigens. Negative test results should be confirmed by cell culture.

2. Indication(s) for use:
The QuickVue® Influenza A+B test allows for the rapid, qualitative determination 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.

3. Special condition for use statement(s):
Not applicable

4. Special instrument Requirements:
Not applicable

H. 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.

After extraction of the specimen, 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.

I. Substantial Equivalence Information:

1. Predicate device name(s):
BD Directigen™ Flu A+B test
2. Predicate K number(s):
k001364
3. Comparison with predicate:

Similarities		
Item	**Device**	**Predicate**
Procedure	Qualitative; Influenza A and B viral antigens with differentiation.	Qualitative; Influenza A and B viral antigens with differentiation.
Differences		
Item	**Device**	**Predicate**
Assay	Lateral-flow immunoassay	Enzyme Immunoassay (EIA) membrane assay
Specimen Type	Nasal Swab, Nasal Wash, and Nasal Aspirate	Nasopharyngeal wash, nasopharyngeal aspirate, nasopharyngeal swab, lower nasal swab, throat swab and bronchoalveolar lavage specimens

J. Standard/Guidance Document Referenced (if applicable):
Not applicable

K. Test Principle:
Immunochromatographic Test

L. Performance Characteristics (if/when applicable):

1. Analytical performance:
    a. Precision/Reproducibility:

The total, within-run, and between run performance of the test was evaluated with weak positive and strong positive antigens for precision. The testing was repeated 5 times on three different days. One hundred per cent (100%) reproducibility was obtained for all specimens tested.

b. Linearity/assay reportable range:
Not applicable

c. Traceability (controls, calibrators, or method):
Not applicable

d. Detection limit:
Analytical sensitivity was established using a total of 50 human epidemic strains of influenza viruses: 37 influenza A and 13 influenza B. The results are presented in the product labeling.

e. Analytical specificity:
A representative panel of known bacteria and viral pathogens, which may be encountered as pathogens or normal flora in a clinical nasal swab or nasal wash/aspirate specimen were tested. None of the microorganisms tested at the levels indicated showed any sign of cross-reactivity in the test.

f. Assay cut-off:
Not applicable

2. Comparison studies:

a. Method comparison with predicate device:

Performance characteristics of the QuickVue® Influenza A+B test were established on specimens collected during the 1998-1999 influenza season in North America. A multi-center clinical study was conducted in pediatric, adult and geriatric patient populations from physician offices located in the Northwest, Midwest, Northeast, Mid-Atlantic, Southeast and Western regions of the U.S. In this multi-center, point-of-care (POC) field trial, a combination of nasal swabs, nasal wash and nasal aspirate specimens (275) were compared to cell culture.

Sample types

Nasal Wash/Aspirate Vs. Culture

Influenza A	Influenza B
Sensitivity 77% (10/13)	Sensitivity 73% (9/11)
Specificity 99% (68/ 69)	Specificity 99% (68/ 69)
Accuracy 95% (78/ 82)	Accuracy 96% (77/ 80)

Nasal Swab Vs. Culture

Influenza A	Influenza B
Sensitivity 72% (46/64)	Sensitivity 73% (29/40)

Specificity	96% (159/166)	Specificity	96% (159/166)
Accuracy	89% (205/230)	Accuracy	91% (188/206)

Physician Office Laboratory (POL) Studies: An evaluation of the QuickVue® Influenza A+B Test was conducted at three Physicians' Offices using a panel of 180 coded specimens. The panel contained negative, low positive, and moderately positive specimens. Each specimen level was tested at each site in replicates of at least six over a period of three days. The results obtained at each site agreed >99% with the expected results. No significant differences were observed within run (6 replicates), between runs (3 different days) or between sites (3 POL sites).

b. Matrix comparison:
Not applicable

3. Clinical studies:
   a. Clinical sensitivity:
   Not applicable
   b. Clinical specificity:
   Not applicable
   c. Other clinical supportive data (when a and b are not applicable):

4. Clinical cut-off:
   Not applicable
5. Expected values/Reference range:
   Not applicable

M. Conclusion:

The Performance characteristics reported here for the device indicate that it is comparable to other such test kits currently in the market.