Quidel Corporation
Jennifer Rial
Director, Regulatory Affairs
10165 McKellar Court
San Diego, California 92121

February 13, 2018

Re: K180288
Trade/Device Name: QuickVue Influenza A+B
Regulation Number: 21 CFR 866.3328
Regulation Name: Influenza virus antigen detection test systems
Regulatory Class: Class II
Product Code: PSZ
Dated: January 31, 2018
Received: February 2, 2018

Dear Jennifer Rial:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Uwe Scherf -S

Uwe Scherf, MSc., Ph.D.
Director
Division of Microbiology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K180288

Device Name
QuickVue Influenza A+B Test

Indications for Use *(Describe)*
The QuickVue Influenza A+B Test allows for the rapid, qualitative detection of influenza type A and type B antigens directly in nasal swab and nasopharyngeal swab specimens from symptomatic patients. 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. A negative test is presumptive, and it is recommended these results be confirmed by viral culture or an FDA-cleared influenza A and B molecular assay. Negative results do not preclude influenza virus infections and should not be used as the sole basis for treatment or other patient management decisions. The test is intended for professional and laboratory use.

Performance characteristics for influenza A were established during the 2017/2018 influenza seasons when influenza A/H3N2 and A/H1N1 pandemic were the predominant influenza A viruses in circulation. When other influenza A viruses are emerging, performance characteristics may vary.

If infection with a novel influenza A virus is suspected based on current clinical and epidemiological screening criteria recommended by public health authorities, specimens should be collected with appropriate infection control precautions for novel virulent Influenza viruses and sent to state or local health department for testing. Viral culture should not be attempted in these cases unless a BSL 3+ facility is available to receive and culture specimens.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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7. SPECIAL 510(K) SUMMARY

Submitted By:	Quidel Corporation 10165 McKellar Court San Diego, California 92121 Telephone: 858-552-7910 Fax: 858-646-8045
Submission Contact:	Jennifer S. Rial, Director, Regulatory Affairs
Date Prepared:	January 25, 2018
Device Trade Name:	QuickVue® Influenza A+B Test
Common Name:	Influenza A+B immunological test
Predicate Devices:	Sofia Influenza A+B FIA, K162438
Device Classification/Name:	21 CFR 866.3328 / Class II / Influenza virus antigen detection system

An influenza virus antigen detection test system is a device intended for the qualitative detection of influenza viral antigens directly from clinical specimens in patients with signs and symptoms of respiratory infection. The test aids in the diagnosis of influenza infection and provides epidemiological information on influenza. Due to the propensity of the virus to mutate, new strains emerge over time which may potentially affect the performance of these devices. Because influenza is highly contagious and may lead to an acute respiratory tract infection causing severe illness and even death, the accuracy of these devices has serious public health implications.

Intended Use:

The QuickVue Influenza A+B Test allows for the rapid, qualitative detection of influenza type A and type B antigens directly in nasal swab and nasopharyngeal swab specimens from symptomatic patients. 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. A negative test is presumptive, and it is recommended these results be confirmed by viral culture or an FDA-cleared influenza A and B molecular assay. Negative results do not preclude influenza virus infections and should not be used as the sole basis for treatment or other patient management decisions. The test is intended for professional and laboratory use.

Performance characteristics for influenza A were established during the 2017/2018 influenza seasons when influenza A/H3N2 and A/H1N1 pandemic were the predominant influenza A viruses in circulation. When other influenza A viruses are emerging, performance characteristics may vary.

If infection with a novel influenza A virus is suspected based on current clinical and epidemiological screening criteria recommended by public health authorities, specimens should be collected with appropriate infection control precautions for novel virulent Influenza viruses and sent to state or local health department for testing. Viral culture should not be attempted in these cases unless a BSL 3+ facility is available to receive and culture specimens.

Physiologic Basis of the Test:

Influenza viruses are causative agents of highly contagious, acute, viral infections of the respiratory tract.

Influenza viruses are immunologically diverse, single-stranded RNA viruses. There are three types of influenza viruses: A, B, and C. Type A viruses are the most prevalent and are associated with most serious epidemics. Type B viruses produce a disease that is generally milder than that caused by type A. Type C viruses have never been associated 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.

Every year in the United States, on average 5% to 20% of the population contract influenza; more than 200,000 people are hospitalized from influenza complications; and, about 36,000 people die from influenza-related causes. Some people, such as older people, young children, and people with certain health conditions, are at high risk for serious influenza complications.

Device Description:

The QuickVue Influenza A+B Test involves the extraction of influenza A and B viral antigens. The patient specimen is placed in the Extraction Reagent Tube, during which time the virus particles in the specimen are disrupted, exposing internal viral nucleoproteins. After extraction, the Test Strip is placed in the Extraction Reagent Tube where nucleoproteins in the specimen will react with the reagents in the Test Strip.

If the extracted specimen contains influenza A or B antigens, a pink-to-red Test Line along with a blue procedural Control Line will appear on the Test Strip indicating a positive result. The Test Line for influenza A or B will develop at separate specified locations on the same Test Strip. If influenza A or B antigens are not present, or are present at very low levels, only the blue procedural Control Line will appear.

Device Comparison

Item	Proposed Device	Previously Cleared Device	Predicate Device
Features	**QuickVue Influenza A+B Test**	**QuickVue Influenza A+B Test**	**Sofia Influenza A+B FIA**
Intended Use	The QuickVue Influenza A+B Test allows for the rapid, qualitative detection of influenza type A and type B antigens directly in nasal swab and nasopharyngeal swab specimens from symptomatic patients. 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. A negative test is presumptive, and it is recommended these results be confirmed by viral culture or an FDA-cleared influenza A and B molecular assay. Negative results do not preclude influenza virus infections and should not be used as the sole basis for treatment or other patient management decisions. The test is intended for professional and laboratory 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, nasopharyngeal swab, nasal aspirate, and nasal wash 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. Negative results should be confirmed by cell culture; they do not preclude influenza virus infection and should not be used as the sole basis for treatment or other management decisions. The test is intended for professional and laboratory use.	The Sofia Influenza A+B FIA employs immunofluorescence to detect influenza A and influenza B viral nucleoprotein antigens in direct nasal swab, nasopharyngeal swab, and nasopharyngeal aspirate/wash specimens and nasopharyngeal swab and nasopharyngeal aspirate/wash specimens in transport media from symptomatic patients. This qualitative test is intended for use as an aid in the rapid differential diagnosis of acute influenza A and influenza B viral infections. The test is not intended to detect influenza C antigens. A negative test is presumptive and it is recommended these results be confirmed by viral culture or an FDA-cleared influenza A and B molecular assay. Negative results do not preclude influenza virus infections and should not be used as the sole basis for treatment or other patient management decisions. This test is intended for professional and laboratory use.

Item	Proposed Device	Previously Cleared Device	Predicate Device
Features	**QuickVue Influenza A+B Test**	**QuickVue Influenza A+B Test**	**Sofia Influenza A+B FIA**
Intended Use (cont.)	Performance characteristics for influenza A were established during the 2017/2018 influenza seasons when influenza A/H3N2 and A/H1N1 pandemic were the predominant influenza A viruses in circulation. When other influenza A viruses are emerging, performance characteristics may vary. If infection with a novel influenza A virus is suspected based on current clinical and epidemiological screening criteria recommended by public health authorities, specimens should be collected with appropriate infection control precautions for novel virulent Influenza viruses and sent to state or local health department for testing. Viral culture should not be attempted in these cases unless a BSL 3+ facility is available to receive and culture specimens.	---	The Sofia Influenza A+B FIA may be used with Sofia or Sofia 2. Performance characteristics for influenza A and B were established during February through March 2011 when influenza viruses A/California/7/2009 (2009 H1N1), A/Perth/16/2009 (H3N2), and B/Brisbane/60/2008 (Victoria-Like) were the predominant influenza viruses in circulation according to the Morbidity and Mortality Weekly Report from the CDC entitled "Update: Influenza Activity--United States, 2010-2011 Season, and Composition of the 2011-2012 Influenza Vaccine." Performance characteristics may vary against other emerging influenza viruses. If infection with a novel influenza virus is suspected based on current clinical and epidemiological screening criteria recommended by public health authorities, samples should be collected with appropriate infection control precautions for novel virulent influenza viruses and sent to state or local health department for testing. Viral culture should not be attempted in these cases unless a BSL 3+ facility is available to receive and culture samples.

Item	Proposed Device	Previously Cleared Device	Predicate Device
Features	**QuickVue Influenza A+B Test**	**QuickVue Influenza A+B Test**	**Sofia Influenza A+B FIA**
Read Results	Visual	Visual	Reader
Specimen Types	Nasal swab, nasopharyngeal swab	Nasal swab, nasopharyngeal swab, nasal aspirate, and nasal wash	Direct nasal swab, nasopharyngeal swab, and nasopharyngeal aspirate/wash specimens and nasopharyngeal swab and nasopharyngeal aspirate/wash specimens in transport media
Read Result Time	10 minutes	10 minutes	15 minutes
External Controls	Test kit contains Positive and Negative Control swabs	Test kit contains Positive and Negative Control swabs	Test kit contains Positive and Negative Control swabs

7.1. Summary of Performance Data

Additional Clinical Studies were performed using the QuickVue Influenza A+B Test to confirm the device meets the performance characteristics detailed in 21 CFR 866.3328 for Class II influenza virus antigen detection test systems.

7.2. Conclusion

The results of this study demonstrate that the QuickVue Influenza A+B Test meets the performance requirements according to FDA's reclassification of rapid Influenza assays. The QuickVue Influenza A+B test is substantially equivalent with the predicate device, Sofia Influenza A+B FIA.