



Food and Drug Administration
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Quidel Corporation
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January 12, 2016

Re: K153012
Trade/Device Name: Sofia[®] Influenza A+B FIA
Regulation Number: 21 CFR 866.3330
Regulation Name: Influenza virus serological reagents
Regulatory Class: I
Product Code: GNX
Dated: October 13, 2015
Received: October 14, 2015

Dear Dr. Brehm:

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 Parts 801 and 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.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Tamara V. Feldblyum -S for

Uwe Scherf
Director
Division of Microbiology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K153012

Device Name
Sofia® Influenza A+B FIA

Indications for Use (Describe)

The Sofia Influenza A +B FIA employs immunofluorescence to detect influenza A and influenza B viral nucleoprotein antigens in nasal swab, nasopharyngeal swab, and nasopharyngeal aspirate/wash in fresh or transport media specimens 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 virus 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 management decisions. The test is intended for professional and laboratory use.

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, specimens should be collected with appropriate infection control precautions for novel virulent influenza viruses and sent to state or local health department for testing. Virus 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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5. 510(K) SUMMARY

5.1. Submitted By:

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5.2. Submission Contact:

Edward C. Brehm, Ph.D.

5.3. Date Prepared

October 13, 2015

5.4. Device Trade Name:

Sofia[®] Influenza A+B FIA

5.5. Common Name:

Influenza A+B immunological test system

5.6. Predicate Device:

Sofia Influenza A+B FIA (K112177 and K131606)

5.7. Device Classification/Name:

21 CFR 866.3330 / Influenza virus serological reagents

Influenza virus serological reagents are devices that consist of antigens and antisera used in serological tests to identify antibodies to influenza in serum. The identification aids in the diagnosis of influenza (flu) and provides epidemiological information on influenza. Influenza is an acute respiratory tract disease, which is often epidemic.

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



5.8. Intended Use:

The Sofia Influenza A+B FIA employs immunofluorescence to detect influenza A and influenza B viral nucleoprotein antigens in nasal swab, nasopharyngeal swab, and nasopharyngeal aspirate/wash in fresh or transport media specimens 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 cell 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 management decisions. The test is intended for professional and laboratory use.

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, specimens should be collected with appropriate infection control precautions for novel virulent influenza viruses and sent to state or local health department for testing. Virus culture should not be attempted in these cases unless a BSL 3+ facility is available to receive and culture specimens.

5.9. 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 adults 65 years of age and older, young children, and people with certain health conditions, are at high risk for serious influenza complications.



5.10. Device Description:

The Sofia Influenza A+B FIA employs immunofluorescence technology that is used with Sofia to detect influenza virus nucleoproteins. This test allows for the differential detection of influenza A and influenza B antigens.

The Sofia Influenza A+B FIA is a lateral-flow immunoassay that uses monoclonal antibodies that are specific for influenza antigens and have no known cross-reactivity to normal flora or other known respiratory pathogens.

Nasal swab, nasopharyngeal swab, and nasopharyngeal aspirate/wash specimens (both fresh and in VTM) are used for this test. The patient specimen is placed in the Reagent Tube, during which time the virus particles in the specimen are disrupted, exposing internal viral nucleoproteins. After disruption, the specimen is dispensed into the cassette sample well. From the sample well, the specimen migrates through a test strip containing various unique chemical environments. If influenza viral antigen is present, they will be trapped in a specific location.

Note: Depending upon the user's choice, the cassette is either placed inside Sofia for automatically timed development (Walk Away Mode) or placed on the counter or bench top for a manually timed development and then placed into Sofia to be scanned (Read Now Mode).

Sofia will scan the test strip and measure the fluorescent signal by processing the results using method-specific algorithms. Sofia will display the test results (Positive, Negative, or Invalid) on the screen. The results can also be automatically printed on an integrated printer if this option is selected.



5.11. Device Comparison:

Item	Proposed Device	Predicate Device
Features	Sofia Influenza A+B FIA	Sofia Influenza A+B FIA
Intended Use	The Sofia Influenza A+B FIA employs immunofluorescence to detect influenza A and influenza B viral nucleoprotein antigens in nasal swab, nasopharyngeal swab, and nasopharyngeal aspirate/wash in fresh or transport media specimens from symptomatic patients. The 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 cell 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 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 nasal swab, nasopharyngeal swab, and nasopharyngeal aspirate/wash specimens taken directly from symptomatic patients. The 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 cell 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 management decisions. The test is intended for professional and laboratory use.
Specimen Types	Nasal swab, Nasopharyngeal swab, and nasopharyngeal aspirate/wash specimens both direct and in VTM	Direct Nasal swab, Nasopharyngeal swab, and nasopharyngeal aspirate/wash specimens
Clinical Performance Data	Fresh and with Viral Transport Media	Fresh only
Read Results	Same	Read results on instrument screen or print with optional printer
Instrument	Same	Sofia Analyzer
Calibrator	Same	Yes; a Calibration Cassette and QC Card are provided
Read Result Time	Same	15 Minutes



Item	Proposed Device	Predicate Device
Features	Sofia Influenza A+B FIA	Sofia Influenza A+B FIA
External Controls	Same	Test kit contains Positive and Negative Control swabs

5.12. Summary of Performance Data

Studies were undertaken to document the performance characteristics and the substantial equivalence of the test to the predicate devices. These studies included the following:

- An analytical study to determine the Limit of Detection (LoD) using two (2) strains of Influenza A and two (2) strains of Influenza B viruses in negative clinical nasal matrix from virus transport mediums.
- A multi-center field clinical study was performed, and the data was submitted to verify the performance of specimens in Viral Transport Media.

5.13. Conclusion

These studies demonstrate the substantial equivalence of the Sofia Influenza A+B FIA to the existing product already marketed. They further demonstrate the suitability of the product for use with Viral Transport Media. Such studies are a critical element in establishing the fundamental safety and effectiveness of the product and its appropriateness for commercial distribution.