K131606

510(k) SUMMARY

JUL 05 2013

Submitted By:

Quidel Corporation
10165 McKellar Court
San Diego, California 92121
Telephone: 858-552-7908
Fax: 858-646-8045

Submission Contact:

John D. Tamerius, Ph.D.

Date Prepared:

May 30, 2013

Device Trade Name:

Sofia® Influenza A+B FIA

Common Name:

Influenza A+B immunological test

Predicate Devices:

Sofia Influenza A+B FIA

Device Classification/Name:

21 CFR 866.3330 / Influenza virus serological reagents

These tests are used to aid in the diagnosis of influenza and provide epidemiological information on influenza (21 CFR 866.3330). The Food and Drug Administration has classified serological test systems for the detection of influenza virus as Class I.

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 specimens taken directly 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 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.

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 Sofia Influenza A+B FIA employs immunofluorescence technology that is used with the Sofia Analyzer to detect influenza virus nucleoproteins.

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 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 of the Sofia Analyzer for automatically timed development (Walk Away Mode) or placed on the counter or bench top for a manually timed development and then placed into the Sofia Analyzer to be scanned (Read Now Mode).

The Sofia Analyzer will scan the test strip and measure the fluorescent signal by processing the results using method-specific algorithms. The Sofia Analyzer 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.

Device Comparison:

Item	Proposed Device	Proposed 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 specimens taken directly 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 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.	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. 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 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.

Item	Proposed Device	Proposed Device
Features	**Sofia Influenza A+B FIA**	**Sofia Influenza A+B FIA**
Read Results	Read results on instrument screen or print with optional printer	Read results on instrument screen or print with optional printer
Instrument	Sofia Analyzer	Sofia Analyzer
Calibrator	Yes – Calibration Cassette and QC Card provided	Yes – Calibration Cassette and QC Card provided
Specimen Types	nasal swab, nasopharyngeal swab, and nasopharyngeal aspirate/wash	nasal swab, nasopharyngeal swab, and nasopharyngeal aspirate/wash
Read Result Time	15 Minutes	15 Minutes
External Controls	Test kit contains Positive and Negative Control swabs	Test kit contains Positive and Negative Control swabs

Summary of Performance Data:

An analytical study was performed to assess the ability of the Sofia Influenza A+B FIA to detect the Influenza A virus H7N9 (A/Anhui/1/2013) and establish the Limit of Detection.

Conclusion:

The results of this study show that Sofia Influenza A+B FIA detects H7N9 with a minimum detectable level of 3.95×10^6 Egg Infective Dose $(EID)_{50}$/mL. The Sofia Influenza A+B FIA is substantially equivalent with the current Sofia Influenza A+B FIA.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

JOHN D TAMERIUS
SENIOR VICE PRESIDENT OF CLINICAL AND REGULATORY AFFAIRS
QUIDEL CORPORATION
10165 MCKELLAR COURT
SAN DIEGO CA 92121

July 5,2013

Re: K131606
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: May 30, 2013
Received: June 05, 2013

Dear Dr. Tamerius:

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 Small Manufacturers, International and Consumer Assistance 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" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

Sally A. Hojvat -S

Sally A. Hojvat Ph.D. M.Sc
Director, Division of Microbiology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Intended Use

510(k) Number (if known): k131606

Device Name: 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 specimens taken directly 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.

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Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH; Office of In Vitro Diagnostics and Radiological Health (OIR)

Tamara V. Feldblyum -S

Division Sign-Off
Office of In Vitro Diagnostics and Radiological Health

510(k) k131606