K123793

510(k) SUMMARY

JUN 17 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:	June 11, 2013
Device Trade Name:	Sofia® Strep A FIA and Sofia Analyzer
Common Name:	Strep A immunological test system and Fluorometer
Predicate Devices:	QuickVue® Dipstick Strep A Test, K011097 Sofia Analyzer, K112177
Device Classification/Name:	21 CFR 866.3740 / Streptococcus Group A serological reagents
Intended Use:	The Sofia Strep A FIA employs immunofluorescence technology to detect Group A Streptococcal antigens from throat swabs of symptomatic patients. All negative test results should be confirmed by bacterial culture because negative results do not preclude Group A Strep infection and should not be used as the sole basis for treatment. The test is intended for professional and laboratory use as an aid in the diagnosis of Group A Streptococcal infection.
Physiologic Basis of the Test:	Group A Streptococcus is one of the most important causes of acute upper respiratory tract infection. Early diagnosis and treatment of Group A Streptococcal pharyngitis has been shown to reduce the severity of symptoms and serious complications such as rheumatic fever and glomerulonephritis. Conventional procedures for identification of Group A Streptococcus from throat swabs involve the culture, isolation, and subsequent identification of viable pathogen and 24 to 48 hours or longer for results.

Device Description:

The Sofia Strep A FIA employs immunofluorescence technology that is used with the Sofia Analyzer to detect Group A Streptococcal antigens.

The Sofia Strep A FIA is a lateral-flow immunoassay that uses polyclonal antibodies that are specific for Group A Streptococcal antigens.

Throat swab specimens are used for this test. The patient specimen is placed in the Reagent Tube, during which time the bacteria in the specimen are disrupted, exposing Group A Streptococcal antigens. 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 the Group A Streptococcal 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:

Note: The **shaded cells** in the table below identify where there are differences between the proposed and predicate devices.

Item	Proposed Device	Predicate Device for Assay	Predicate Device for Analyzer
Features	Sofia Analyzer and Strep A FIA	QuickVue Dipstick Strep A Test	Sofia Analyzer and Influenza A+B FIA
Intended Use	The Sofia Strep A FIA employs immunofluorescence technology to detect Group A Streptococcal antigens from throat swabs of symptomatic patients. All negative test results should be confirmed by bacterial culture because negative results do not preclude Group A Strep infection and should not be used as the sole basis for treatment. The test is intended for professional and laboratory use as an aid in the diagnosis of Group A Streptococcal infection.	The QuickVue Dipstick Strep A is a sensitive immunoassay for the qualitative detection of Group A Streptococcal antigen from throat swab specimens or confirmation of presumptive Group A Streptococcal colonies from culture. This test is to be used to aid in the diagnosis of disease caused by Group A Streptococcus.	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. 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	Predicate Device for Assay	Predicate Device for Analyzer
Features	Sofia Analyzer and Strep A FIA	QuickVue Dipstick Strep A Test	Sofia Analyzer and Influenza A+B FIA
FDA File Number	TBD	K011097	K112177
Manufacturer	Quidel Corporation and LRE	Quidel Corporation	Quidel Corporation and LRE
Regulation Number	21 CFR 866.3740 and 21 CFR 866.2560	21 CFR 866.3740	21 CFR 866.3330 and 21 CFR 866.2560
Classification Product Code	GTY and KHO	GTY	GNX and KHO
Instrument	Sofia Analyzer	None	Sofia Analyzer
Analyte	Group A Streptococcal	Group A Streptococcal	Influenza A and Influenza B
Automated Analysis	Yes	No	Yes
Read Results	Read results on instrument screen or print with optional printer	Visual read for presence or absence of control and test lines	Read results on instrument screen or print with optional printer
Calibrator	Yes – Calibration Cassette and QC Card provided	Not Applicable	Yes – Calibration Cassette and QC Card provided
Read Result Time	5 Minutes	5 Minutes	15 Minutes
Specimen Types	Throat swab	Throat swab or culture colonies	Nasal swab, nasopharyngeal swab, and nasopharyngeal aspirate/wash
Qualitative	Yes	Yes	Yes
Test Principle	Immunofluorescence Device	Immunoassay	Immunofluorescence Device
Format	Lateral-flow Test Cassette	Lateral-flow dipstick	Lateral-flow Test Cassette
Antibodies Used	Polyclonal rabbit antibodies that are specific to Group A Streptococcus	Polyclonal rabbit antibodies that are specific to Group A Streptococcus	Monoclonal antibodies to influenza A nucleoprotein and monoclonal antibodies to influenza B nucleoprotein
Detection Particle	Polystyrene microparticles dyed with Europium chelate	Polystyrene microparticles dyed with red colorant	Polystyrene microparticles dyed with Europium chelate
Storage	Room Temperature	Room Temperature	Room Temperature
Reagent	One reagent bottle containing sodium nitrite and acetic acid in glass ampoule	Two reagent bottles: one containing sodium nitrite and one containing acetic acid	Lyophilized buffer containing detergents
Transfer Device	Fixed volume pipette used to transfer patient sample mixed with reagent into Test Cassette	Directly add dipstick to test tube containing patient sample mixed with reagent	Fixed volume pipette used to transfer patient sample mixed with reagent into Test Cassette
External Controls	Test kit contains Positive and Negative Control Swabs	Test kit contains Positive and Negative Liquid Controls	Test kit contains Positive and Negative Control Swabs

Item	Proposed Device	Predicate Device for Assay	Predicate Device for Analyzer
Features	Sofia Analyzer and Strep A FIA	QuickVue Dipstick Strep A Test	Sofia Analyzer and Influenza A+B FIA
Quality Control Features	Built-in features include: • Built-in procedural control zone scanned by the analyzer to determine whether adequate flow occurred • Analyzer prevents used or expired cartridge from being read by the reader • Cassette properly inserted	Built-in procedural control line interpreted by the operator to determine whether adequate flow occurred and clearing of background	Built-in features include: • Built-in procedural control zone scanned by the analyzer to determine whether adequate flow occurred • Analyzer prevents used or expired cartridge from being read by the reader • Cassette properly inserted • Built-in negative control line scanned by the analyzer to measure degree of non-specific binding

Summary of Performance Data:

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

1. A multi-center field clinical study was undertaken to document the performance characteristics of the test. Sensitivity and specificity were calculated using throat swab specimens.
2. A reproducibility study was performed to demonstrate intra- and inter-operator reproducibility and intra- and inter-laboratory reproducibility with a panel of test samples at various Strep A concentrations.
3. Analytical studies included Limit of Detection, analytical inclusivity, cross-reactivity, interfering substances, operating temperature, transport stability, inter-analyzer precision, calibration cycle, and various flex studies.

Conclusion:

These studies demonstrated the substantial equivalence of the Sofia Strep A FIA with the Sofia Analyzer to the existing products already marketed, QuickVue Dipstick Strep A Test (K011097) and Sofia Analyzer/Sofia Influenza A+B FIA (K112177).

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 TAMERIUS
SR. VICE PRES., CLINICAL AND REGULATORY AFFAIRS
QUIDEL CORPORATION
10165 MCKELLAR COURT
SAN DIEGO CA 92121

June 17 2013

Re: K123793
Trade/Device Name: Sofia® Strep A FIA and Sofia™ Analyzer
Regulation Number: 21 CFR 866.3740
Regulation Name: Streptococcusspp. serological reagents
Regulatory Class: I
Product Code: GTY, KHO
Dated: May 24, 2013
Received: May 28, 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 Hojvat, M.Sc., Ph.D.
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): K123793

Device Name: Sofia Strep A FIA

Indications for Use:

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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 In Vitro Diagnostic Devices (OIVD)

John Hobson -S
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Division Sign-Off
Office of In Vitro Diagnostic Device Evaluation and Safety

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Division Sign-Off

Office of In Vitro Diagnostics and Radiological Health

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