K100227

FEB 23 2010

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
SAS™ *FluAlert* A Test

This 510(k) summary of safety and effectiveness submission is in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Submitted by:	SA Scientific, Ltd. 4919 Golden Quail San Antonio, TX 78240 210-699-8800
Establishment Reg. No:	1645225
Contact Person:	Robbi Perry
Date Prepared:	January 22, 2010
Proprietary Name:	SAS™ *FluAlert* A Test
Classification Name:	Antigens, CF (including CF control), Influenza virus A, B, C
Device Classification:	21 CFR Part 866.3330
Regulatory Class:	Class I
Classification Advisory Committee:	Microbiology
Product Code:	GNX
Substantial Equivalence:	SAS™ *FluAlert* A Test, manufactured by SA Scientific, Ltd., San Antonio, TX.
Device Description:	The SAS™ *FluAlert* A Test utilizes antibodies against influenza type A viral nucleoproteins. The SAS™ *FluAlert* A test begins with an extraction of Type A nucleoproteins. After the extraction has been completed, the sample is placed into the sample well of the test. The specimen is absorbed and migrates via capillary action through membranes that contain dried gold conjugated antibody, which is specific for influenza A viral nucleoproteins. If these nucleoproteins are present, a "half-sandwich" immunocomplex is formed. The membrane contains immobilized antibody to influenza A nucleoproteins, which binds the "half sandwich" complex. Thus, in the presence of influenza A nucleoproteins, a "whole sandwich" immunocomplex is formed and a visible, pink-colored line develops in the specimen zone of the test device. In the absence of an influenza A antigen, a "sandwich" immunocomplex is not formed and a negative result is indicated. To serve as a procedural control, a pink-colored control line will always appear in the control zone of each strip regardless of the presence or absence of influenza A nucleoproteins.
Intended Use:	SAS™ *FluAlert* A Test is a visual and rapid assay for the presumptive *in-vitro* qualitative detection of influenza A viral nucleoprotein antigens from nasal washes and nasal aspirates of symptomatic patients. Negative results should be confirmed via culture. This test is not intended for the detection of Influenza Type B or Influenza Type C viral antigen. This test is for professional use only.

Negative results do not preclude infection with influenza A and should not be used as the sole basis for treatment or other patient management decisions. It is recommended that negative results be confirmed by cell culture.

Conditions for Use: For prescription use only.

Quality Controls: The SAS™ *FluAlert* A Test provides an internal procedural quality control. It is recommended that external quality controls be assayed following the user's laboratory's standard quality control procedures and in conformance with local, state and federal regulations or accreditation organizations as applicable

Device comparison: The SAS™ *FluAlert* A is a rapid immunoassays utilizing immunochromatographic technology for the visualization of influenza A antigen. Each utilizes an antibody conjugated to colored particles and an antibody printed onto a membrane.

Performance Summary: This test has been shown to detect the FluA/California/04/2009 (H1N1) virus cultured from a positive human specimen however, the performance characteristics of this test with clinical specimens that are positive for the 2009 H1N1 influenza virus have not been established. The SAS FluAlert A Test can detect influenza A virus, but cannot differentiate influenza subtypes.

Clinical Summary: Please see K041441 for Clinical Summary

Note: Performance characteristics for detecting the 2009 H1N1 influenza virus from human specimens have not been established

Analytical Sensitivity (Limit of Detection): The analytical sensitivity of the SAS™ *FluAlert* A Test was determined for 2009 H1N1 using strain A/California/04/09. 2009 H1N1 using strain A/California/04/09. Each strain was serially diluted in SAS™ *FluAlert* A extraction buffer. Results for A/California/04/09 are included in the summary table below.

Influenza Viral Strain	ATCC	LoD $TCID_{50}$/0.2 ml
H1N1 A/PR/3/34	VR-95	1.2×10^5
H3N2 A/Aichi/2/68	VR-547	5.6×10^2
H3N2 A/Hong Kong/8/6/8	VR-544	3.5×10^3
H1N1 A/FM/147	VR-97	7.9×10^3
H3N2 A/Victoria/3/75	VR-822	4.5×10^5
H1N1 A/California/04/09	NR-13658	1.4×10^3

*This test has been shown to detect the FluA/California/04/2009 (H1N1) virus cultured from a positive human specimen however, the performance characteristics of this test with clinical specimens that are positive for the 2009 H1N1 influenza virus have not been established. The SAS *FluAlert* A Test can detect influenza A viruses, but cannot differentiate influenza subtypes.
**This viral strain was obtained from ATCC with a known titer. SA Scientific, Ltd did not verify this titer.

Conclusion: The information presented in the premarket notification demonstrates that the SAS™ *FluAlert* A Test reacts with a cultured strain of 2009 H1N1

(FluA/California/04/2009). Although this test has been shown to detect the 2009 H1N1 from a cultured isolate, the performance characteristics of this test with clinical specimens that are positive for the 2009 H1N1 influenza virus have not been established. The SAS *FluAlert* A Test can detect influenza A viruses, but cannot differentiate influenza subtypes. This viral strain used in this study was obtained from ATCC with a known titer. SA Scientific, Ltd did not verify this titer.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

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Silver Spring, MD 20993-0002

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SA Scientific, Inc.
c/o Ms. Robbi Perry MT (ASCP)
Regulatory Affairs Specialist
4919 Golden Quail
San Antonio, Texas 78240

Re: k100227
Trade/Device Name: SAS FluAlert A Test
Regulation Number: 21 CFR 866.3330
Regulation Name: Influenza Virus Serological Reagents
Regulatory Class: Class I
Product Code: GNX
Dated: February 23, 2010
Received: January 26, 2010

Dear Ms. Perry:

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.

If your device is classified (see above) into class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket

notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. 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 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/cdrh/industry/support/index.html

Sincerely yours,

Sally A. Hojvat, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): k100227

Device Name: SAS™ FluAlert A Test

Indication For Use:

SAS™ FluAlert A Test is a visual and rapid assay for the presumptive *in-vitro* qualitative detection of Influenza A viral nucleoprotein antigens from nasal washes and nasal aspirates of symptomatic patients. The test is not intended for the detection of Influenza Type B viral antigen or Influenza Type C viral antigen. This test is for professional use only.

Negative results do not preclude infection with influenza A and should not be used as the sole basis for treatment or other patient management decisions. It is recommended that negative results be confirmed by cell culture.

Prescription Use __X__ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____. (21 CFR Part 801 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

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

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k)_____