K041441

JUL 22 2004

510 (k) SUMMARY OF SAFETY AND EFFECTIVENESS

SAS™ Influenza 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, Inc. 4919 Golden Quail San Antonio, TX 78240
Establishment Reg. No.:	1645225
Contact Person:	Ricardo R. Martinez
Date Prepared:	August 14, 2003
Proprietary Name:	SAS™ Influenza A Test
Common Name:	SAS™ Influenza A Test, SAS™ Flu 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
Product Code:	GNX
Substantial Equivalence:	Binax™ NOW® Flu A Test (K021649) manufactured by Binax™ Inc., Portland, Maine.
Device Description:	The SAS™ Influenza A test utilizes a set monoclonal antibodies against Influenza Type A viral nucleoproteins. The SAS™ Influenza test begins with an extraction of Type A nucleoproteins. After the extraction has been completed, the sample is placed into the test and observed for the formation of colored lines. The specimen is absorbed and migrates via capillary action through a membrane that contains dried gold conjugated antibody, which is specific for Influenza Type A nucleoproteins. If Type A nucleoproteins are present, a "half-sandwich" immuno-complex is formed. The membrane contains immobilized antibody to Influenza Type A nucleoproteins, which binds the "half sandwich" complex. Thus, in the presence of Influenza nucleoproteins, a "whole sandwich" immuno-complex is formed and a visible, pink colored line develops in the specimen zone of the test device. In the absence of an Influenza antigen, a "sandwich" immuno-complex 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 regardless of the presence or absence of Influenza nucleoproteins.
Intended Use:	SAS™ Influenza A Test is a visual and rapid assay for the presumptive qualitative detection of Influenza Type A antigens from nasal washes and aspirates. Negative results should be

confirmed via culture. This test is not intended for the detection of Influenza Type B or C viral antigen.

Quality Controls: The SAS™ Influenza A test provides two (2) internal procedural quality controls. It is recommended that external quality controls should be assayed at least once per lot.

Device comparison: The SAS™ Influenza A and Binax™ NOW® Flu A tests are rapid immunoassays tests 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: The SAS™ Influenza A test performed substantially equivalent to the predicate device, Binax™ NOW® Flu A test. This was verified by comparison to freshly collected nasal wash specimens.

Cross reactivity and interference studies were performed on viral and bacterial strains commonly found in the human respiratory tract. None of the organisms interfered or cross-reacted with the performance of the SAS™ Influenza A test.

Prepared by: _____ Date: 05-19-2004
Ricardo R. Martinez, Director Regulatory Affairs

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUL 22 2004

Mr. Ricardo R. Martinez
Director, Regulatory Affairs
SA Scientific, Inc.
4919 Golden Quail
San Antonio, TX 78240

Re: k041441
Trade/Device Name: SAS™ Influenza A Test
Regulation Number: 21 CFR 866.3330
Regulation Name: Influenza virus serological reagents
Regulatory Class: Class I
Product Code: GNX
Dated: July 7, 2004
Received: July 16, 2004

Dear Mr. Martinez:

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.

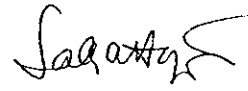
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish 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); 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 information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.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): K041441

Device Name: SAS™ Influenza A Test

Indications For Use:

SAS™ Influenza A Test is a visual and rapid assay for the presumptive qualitative detection of Influenza Type A antigens from nasal washes and aspirates. Negative results should be confirmed via culture. This test is not intended for the detection of Influenza Type B or C viral antigen. The test is for professional use.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (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 Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K041441