NOV 13 2002

510(k) Summary of

Safety and Effectiveness as Required by 21 CFR 807.92

Submitter and manufacture	**Name:**	Alfa Scientific Designs, Inc.
	Address:	12330 Stowe Drive Poway, CA 92064
	Contact Person:	Naishu Wang, MD, Ph.D. Telephone: (858) 513-3888 x 308 Fax: (858) 513-8388
	E-mail:	wnss@alfascientific.com
Device Name	**Trade Name:** *Instant-View™MDMA (Ecstasy, XTC) Urine Test* **Common Name:** Immunoassay, MDMA Urine Test **Classification:** Amphetamine Test System (21 CFR 862.3100) Class II	
Date of Summary Preparation	October 28, 2002	
Predicate Device	Microgenics A-Sure™ Ecstasy Drug Screen Test made by Applied Biotech, Inc. **K011133**	
Device Description	A one-step lateral flow chromatographic immunoassay. The test strip in the device includes 1) a conjugate pad containing colloidal gold coupled with mouse anti-MDMA antibody; 2) nitrocellulose membrane containing a test line (T line) coated with MEMA-BSA and a control line (C line) coated with Goat anti mouse antibody.	
Similarity to the Predicate Device	• Both are one-step later-flow chromatographic immunoassay. • Both are used for qualitative detection of MDMA (Ecstasy, XTC) at a cutoff of 500 ng/ml. • Both are based on the similar mechanism • Both use a C line as built-in control to indicate that an appropriate volume of sample is applied and the device performs properly. • Both provide a preliminary result and a positive result needs to be confirmed with a more solid reference method.	

Intended Use	This device is a one-step immunoassay intended to provide rapid qualitative detection of methylenedioxymeth-amphetamine (MDMA, also Ecstasy, or XTC) in human urine at a cutoff concentration of 500ng/ml. It is for health care professional use only.
Accuracy studies	Eighty clinical urine specimens with MDMA GC/MS data was evaluated with the Instant-*View™ MDMA (Ecstasy, XTC) Urine Test*. The results from the Instant-*View™ MDMA (Ecstasy, XTC) Urine Test* agreed 100% with the MDMA GC/MS data of the clinical specimens at the level below 75% of the cutoff and above the cutoff. Two (2) discrepancies were observed on the specimens with the MDMA GC/MS data between the cutoff level and the level of 75% cutoff. The overall agreement is 97.5%.
Reproducibility studies	The reproducibility of this device was studied outside of Alfa at three Physician's Office Laboratories (POL) and one reference laboratory. Evaluations were performed by personnel with diverse educational backgrounds and working experiences. The results from the four evaluation sites agreed 97.5%, indicating a high reproducibility of this device.
Specificity studies	Two of the structurally related compounds showed cross reactivity with this device: methylenedioxyampphetamine (MDA) at 2000 ng/ml and methylenedioxyethylamphetamine (MDEA) at 1000 ng/ml. Other structurally related compounds tested did not show cross reactivity or interference with this device at the concentration of 100 μg/ml.
Conclusion	The results of accuracy, reproducibility, and specificity studies demonstrate that the *Instant-View™ MDMA (Ecstasy, XTC) Urine Test* is substantially equivalent to the legally marketed test.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

NOV 13 2002

Naishu Wang, M.D., Ph.D.
President
Alfa Scientific Designs, Inc.
12330 Stowe Drive
Poway, CA 92064

Re: k022501
Trade/Device Name: Instant-View™ MDMA (Ecstasy, XTC) Urine Test
Regulation Number: 21 CFR 862.3610
Regulation Name: Methanphetamine test system
Regulatory Class: Class II
Product Code: DJC
Dated: October 28, 2002
Received: October 31, 2002

Dear Dr. Wang:

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 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 Part 801); 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.

This letter will allow you to begin marketing your device as described in your 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 Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained 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,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory-Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(K) NUMBER (IF KNOWN): K022501

DEVICE NAME: *Instant-View*^{TM} MDMA (Ecstasy, XTC) Urine Test

INDICATIONS FOR USE:

This device is a one-step immunoassay intended to provide qualitative rapid detection of methylenedioxymethamphetamine (MDMA, or Ecstasy, XTC) in human urine at a cut-off concentration of 500ng/ml. It is for health care professional use only.

This test provides only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas Chromatography/Mass Spectrometry (GC/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are used.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ (Per 21 CFR 801.109) OR Over-The-Counter Use _____ (Optional Format 1-2-96)

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K022501