K022693

510(k) Summary of

DEC 0 9 2002

Safety and Effectiveness as Required by 21 CFR 807.92

Submitter	**Name:**	Alfa Scientific Designs, Inc.
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	Contact Person:	Naishu Wang, MD, Ph.D.
	E-mail:	wnss@alfascientific.com
Device Name	**Trade Name:** *Instant-View ™ TCA Urine Test* **Common Name:** Immunoassay, TCA Urine Test **Classification:** Tricyclic antidepressant drugs test system (21 CFR 862.3910) Class II	
Date of Summary Preparation	November, 5, 2002	
Predicate Device	SureStep™ Drug Screen TCA Test, Applied Biotech, Inc., **K981605**	
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-TCA antibodies; 2) nitrocellulose membrane containing a test line (T line) and a control line (C line). The Test line is coated with TCA- BSA, and the Control line is coated with goat anti-mouse IgG antibody.	
Summary of the Similarity to the Predicate Device	• Both are one-step lateral-flow chromatographic immunoassay. • Both are intended to provide qualitative detection of Tricyclic Antidepressants at 1000 ng/ml, the cutoff level. • Both are based on the similar mechanism of competitive binding immunoassay. • Both use a C line as built-in control to indicate that an appropriate volume of sample is applied and whether the device functions properly • Both provide a preliminary result and need to be confirmed with a more solid reference method, e.g. GC/MS or HPLC.	

Intended Use	This device is a one-step immunoassay intended to provide qualitative rapid detection of tricyclic antidepressants (TCA) at a cutoff level of 1000 ng/ml in human urine. It is for health care professional use only.
Accuracy studies	The accuracy of the device was evaluated with 80 clinical urine samples calibrated with GC/MS. The negative results agreed 96.7% (58/60). The positive results agreed 100% (20/20). The overall accuracy was 97.5%.
Reproducibility studies	The reproducibility of this device was studied 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 99%, indicating a high reproducibility of the device.
Specificity studies	*Instant-View ™ TCA Urine Test* has positive responses to structurally related compounds, Amitriptyline, Desipramine, Imipramine, Nortriptyline, and Nordoxepine, at a concentration of 1000 ng/ml; to Cyclobenzaprine, Protriptyline, and Trimipramine at a concentration higher than 1500 ng/ml; to Doxepine and Clomipramine at a concentration higher than 3000 ng/ml. No significant interference observed with this device by the structurally unrelated compounds tested at a concentration of 1 mg/ml.
Conclusion	The results of accuracy, reproducibility, and specificity studies demonstrate that the *Instant-View ™TCA 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

DEC 0 9 2002

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

Re: k022693
Trade/Device Name: Instant-View™ TCA Urine Test
Regulation Number: 21 CFR § 862.3910
Regulation Name: Tricyclic antidepressant drugs test system
Regulatory Class: II
Product Code: MLK
Dated: November 6, 2002
Received: November 12, 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 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). 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
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

510(K) NUMBER (IF KNOWN): K022693

DEVICE NAME: *Instant-View™ TCA Urine Test*

INDICATIONS FOR USE:

It is for health care professional, in-vitro diagnostic use only.

This device is a one-step immunoassay intended to provide qualitative rapid detection of tricyclic antidepressants (TCA) at a cutoff concentration of 1,000 ng/ml in human urine. It is for health care professional use only.

Instant-View™ TCA Urine 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 ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K022693