510 (k) SUMMARY AS REQUIRED BY SECTION 807.92(c)

I. Product Name: *Instant-View™* Multi-Drug Screen Urine Test

II. Manufacturer:

Alfa Scientific Designs, Inc.
12330 Stowe Drive
Poway, CA 92064
Telephone: (858) 513-3888
Fax: (858) 513-8388
Email: info@alfascientific.com

III. Common Name of the Device: Multiple Drugs of Abuse Urine Test

IV. Trade Name of the Device: *Instant-View ™*Multi-Drug Screen Urine Test

V. Establishment Registration Number: 2060833

VI. Classification of the Device:

The Test Device is classified as Class II

VII. Intended Use:

The intended use of the modified device, *Instant-View™* Multi-Drug Screen Urine Test, has not changed as a result of the modification(s).

The Instant-View™ Multi-Drug Screen Urine Test is a qualitative immunoassay intended to be used to detect any combination (variants from 2 to 12) of the following drugs and/or drug metabolites in human urine at the specified cutoff levels. It is intended for professional use only.

Drug	Cutoff Level (ng/ml)
Amphetamine (AMP)	1000
Barbiturate (BAR)	200
Benzodiazepine (BZD)	300
Cocaine (COC)	300
Marijuana (THC)	50
Methadone (MTD)	300
Methamphetamine (METH)	1000
Methamphetamine (METH)	500
Morphine (MOR)	300
Morphine (MOR)	2000
Phencyclidine (PCP)	25

Instant-View ™ Multi-Drug Screen Urine Test provides only a preliminary analytical test result. A more specific alternate chemical method must be used 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.

VIII. Fundamental Scientific Technology:

The *Instant-View™* Multi-Drug Screen Urine Test device is an assemblage of single test devices. It works similarly as the single devices because each device functions independently, but conveniently provides the detection of multiple drugs instead of only one in the same time frame. The 510(k)-approved *Instant View™* single test devices are used for substantial equivalence predicate kit, for there is no change for each device in the intended use, in the way the test actually runs, and in the expected result. All the devices are based on the same immunochemical principle of recognition and formation.

IX. Performance Summary:

The performance characteristics of *Instant-View*™ Multi-Drug Screen Urine Test are significantly based on the single test devices, which are independently 510(k) cleared. During the in-house evaluation, no interference was observed between different single test devices while each test device performed normally. Moreover, the study on accelerated degradation of the device demonstrates that the device have a lifetime of at least two years, further indicating that the assembled devices perform independently as single devices and do not affect each other.

X. Conclusion:

For the reasons mentioned above, it is possible to conclude that the *Instant-View™* Multi-Drug Screen Urine Test is substantially equivalent to the *Instant-View™* single drug of abuse urine tests presently distributed commercially.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

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

AUG 3 0 2002

Re: k022564
Trade/Device Name: *Instant-View*™ Multi-Drug Screen Urine Test
Regulation Number: 21 CFR § 862.3100
Regulation Name: Amphetamine Test System
Regulatory Class: II
Product Code: DKZ, DIO, DIS, DJC, DJR, DOE, DPK, JXM, LAF, LCM, LDJ
Dated: August 15, 2002
Received: August 19, 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): K022564

DEVICE NAME: *Instant-View™* Multi-Drug Screen Urine Test

INDICATIONS FOR USE:

The Instant-View™ Multi-Drug Screen Urine Test is a qualitative immunoassay intended to be used to detect any combination (variants from 2 to 12) of the following drugs and/or drug metabolites in human urine at the specified cutoff levels. It is intended for professional use only.

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Joan Cooper

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K022564

(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)