DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

June 24, 2016

ALFA SCIENTIFIC DESIGNS, INC.
JIMMY JING
DIRECTOR OF REGULATORY AFFAIRS
13200 GREGG ST.
POWAY CA 92064

Re: k152122
Trade/Device Name: Instant-View Multi-Drug Urine Test Cup (Home Use),
Instant-View Multi-Drug Urine Test Panel (Home Use)
Regulation Number: 21 CFR 862.3100
Regulation Name: Amphetamine Test System
Regulatory Class: II
Product Code: DKZ, JXM, DIO, LDJ, DJC, LCM, DIS, DJG, DJR, LFG
Dated: May 20, 2016
Received: May 24, 2016

Dear Dr. Jing:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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 Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney H. Lias -S

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
k152122

Device Name
Instant-View® Multi-Drug Urine Test Cup (Home Use)
Instant-View® Multi-Drug Urine Test Panel (Home Use)

Indications for Use *(Describe)*
The Instant-View® Multi-Drug Urine Test Cup (Home Use) and Instant-View® Multi-Drug Urine Test Panel (Home Use) are rapid, qualitative immunoassays for the detection in human urine of one or more of the drugs at the cutoff concentrations listed below. These devices will detect up to 13 of the drugs below in any combination. The tests are not intended to distinguish prescription use or abuse of any drugs.

Abbreviation	Test	Calibrator	Cut-off (ng/ml)
AMP	Amphetamine	d-Amphetamine	1000
BAR	Barbiturates	Secobarbital	200
BUP	Buprenorphine	Buprenorphine	10
BZD	Benzodiazepine	Oxazepam	300
COC	Cocaine	Benzoylecgonine	300
MDMA	MDMA or Ecstasy	Methylenedioxy-methamphetamine	500
MET	Methamphetamine	d-Methamphetamine	1000
MTD	Methadone	Methadone	300
MOR	Morphine/Opiate	Morphine	2000
OXY	Oxycodone	Oxycodone	300
PCP	Phencyclidine	Phencyclidine	25
TCA	Tricyclic Antidepressants	Nortriptyline	1000
THC	Marijuana	11-nor-Δ9-THC-9-COOH	50

These devices provide only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Chromatography/mass spectrometry 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 obtained.

This test is intended for over-the-counter (OTC) consumer use as the first step in a two step process to provide consumers, including but not limited to concerned parents, with information concerning the presence or absence of the above stated drugs or their metabolites in a urine sample. Information regarding confirmatory testing- the second step in the process, is provided in the package labeling.

Tests for prescription drugs will yield preliminary positive results when these drugs are ingested at or above therapeutic doses. There are no uniformly recognized drug levels for prescription drugs in urine. This multi-drug of abuse urine test device shows the drug was or was not present at the cutoff level.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

Safety and effectiveness as required by 21 CFR 807.92

Manufacturer and Submitter	**Name:**	Alfa Scientific Designs, Inc.
	Address:	13200 Gregg Street Poway, CA 92064 Telephone: 858-513-3888 Fax: 858-513-8388
	Contact Person:	Jimmy Jing, Ph.D. Email: jjing@alfascientific.com 858-413-1279 (direct)
Device Name	**Trade Name:** Instant View® Multi-Drug Urine Test Cup (Home Use) Instant View® Multi-Drug Urine Test Panel (Home Use) **Common Name:** Immunoassay, Drug of Abuse Screening Urine Test **Classification Name:** Amphetamine Test System, Barbiturate Test System, Buprenorphine Test System, Benzodiazepine Test System, Cocaine and Cocaine Metabolite Test System, Methamphetamine Test System, Opiate/ Morphine Test System, Cannabinoid Test System, Methadone Test System, Tricyclic Antidepressant Drugs Test System, Phencyclidine Test System **Product Code:** DKZ (21 CFR 862.3100), DIS (21 CFR 862.3150), JXM (21 CFR 862.3170), DIO (21 CFR 862.3250), DJC (21 CFR 862.3610), DJG (21 CFR 862.3650), DJR (21 CFR 862.3620), LCM (21 CFR 862.3100), LFG (21 CFR 862.3910), LDJ (21 CFR 862.3870)	
Date of Summary Preparation	6/23/2016	
Predicate Devices	Instant View® Multi-Drug Urine Test (510(k) Number: k063545) Made by Alfa Scientific Designs, Inc	

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Device Description

The Instant View® Multi-Drug Urine Test Cup (Home Use) and the Instant View® Multi-Drug Urine Test Panel (Home Use) are one-step lateral flow chromatographic immunoassays. Each device consists of any combination of one to thirteen individual test strip(s) for the analyte(s) being tested. Each test strip in the device consists of 1) a conjugate pad containing colloidal gold coupled with the anti-drug antibodies and 2) nitrocellulose membrane containing a test line (T line) coated with the conjugated drug antigen and a control line (C line). The C line serves as an internal quality control of the system and appears as a burgundy-colored band during the test regardless of the presence of the drug.

Intended Use

Instant View® Multi-Drug Urine Test Cup (Home Use)
Instant View® Multi-Drug Urine Test Panel (Home Use)

The Instant-View Multi-Drug Urine Test Cup (Home Use) and Instant-View Multi-Drug Urine Test Panel (Home Use) are rapid, qualitative immunoassays for the detection in human urine of one or more of the drugs at the cutoff concentrations listed below. These devices will detect up to 13 of the drugs below in any combination. The tests are not intended to distinguish prescription use or abuse of any drugs.

Abbreviation	Test	Cutoff
AMP	Amphetamine	1000 ng/mL
BAR	Barbiturates	200 ng/mL
BUP	Buprenorphine	10 ng/ml
BZD	Benzodiazepine	300 ng/mL
COC	Cocaine	300 ng/mL
MDMA	MDMA or Ecstasy	500 ng/mL
MET	Methamphetamine	1000 ng/mL
MTD	Methadone	300 ng/mL
MOR	Morphine/Opiate	2000 ng/mL
OXY	Oxycodone	300 ng/mL
PCP	Phencyclidine	25 ng/mL
TCA	Tricyclic antidepressants	1000 ng/mL
THC	Marijuana	50 ng/mL

These devices provide only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Chromatography/mass spectrometry 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 obtained.

This test is intended for over-the-counter (OTC) consumer use as the first step in a two step process to provide consumers, including but not limited to concerned parents, with information concerning the presence or absence of the above stated drugs or their metabolites in a urine sample. Information regarding confirmatory testing- the second step in the process, is provided in the package labeling.

Tests for prescription drugs will yield preliminary positive results when these drugs are ingested at or above therapeutic doses. There are no uniformly recognized drug levels for prescription drugs in urine. This multi-drug of abuse urine test device shows the drug was or was not present at the cutoff level.

Similarity to Predicate Devices

- Devices are one-step lateral-flow chromatographic immunoassays.
- Devices are intended to provide qualitative detection of drug abuse.
- Devices have built-in quality control feature, C line, to indicate that an adequate volume of specimen is applied and the liquid flow occurred properly.
- Devices consist test strips, each for one analyte.

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Performance Characteristics

The proposed multi-drug urine test devices use the same technology and formulations for the detection of the drugs as individual test devices.

The performance characteristics, such as accuracy, reproducibility, sensitivity and specificity of this drug of abuse test are the same as the predicate device.

Lay-user study:

A lay user study was performed at three intended user sites with 400 lay persons testing cup and panel devices. A total of 210 females and 190 males tested the devices. They had diverse educational and professional backgrounds and ranged in age from 18 to >60 years. The participants had no previous experience with an over the counter (OTC) drug test. Urine samples were prepared at the following concentrations: negative, ± 50%, ± 25% of the cutoff by spiking drugs into drug free-pooled urine specimens. The concentrations of the samples were confirmed by GC/MS. Each sample was aliquoted into individual containers and blind-labeled. Each participant was provided with the package inserts for the test cup and the test panel, 2 different blinded samples, 1 test cup, and 1 test panel. Each participant tested 1 test cup device and 1 test panel device using 2 different blinded samples.

The lay user study results are summarized in the tables below:

Summary of the Results - Cup

Drug	Cutoff Concentration% (ng/ml)	Number of studies	Correctly interpreted	Incorrectly interpreted	% of agreement
AMP	0% (0)	350	350	0	100%
	75% (750)	10	8	2	80%
	125% (1250)	10	9	1	90%
	150% (1500)	30	30	0	100%
					average = 99.25%
BAR	0% (0)	350	350	0	100%
	75% (150)	10	9	1	90%
	125% (250)	10	9	1	90%
	150% (300)	30	30	0	100%
					average = 99.5%
BUP	0% (0)	20	20	0	100%
	50% (5)	60	60	0	100%
	75% (7.5)	60	56	4	93.3%
	125% (12.5)	120	109	11	90.8%
	150% (15)	140	140	0	100%
					average = 96.25%
BZD	0% (0)	350	350	0	100%
	75% (225)	10	9	1	90%
	125% (375)	10	9	1	90%

	150% (450)	30	30	0	100%
					average = 99.5%
COC	0% (0)	350	350	0	100%
	75% (225)	10	9	1	90%
	125% (375)	10	8	2	80%
	150% (450)	30	30	0	100%
					average = 99.25%
MET	0% (0)	350	350	0	100%
	75% (750)	10	9	1	90%
	125% (1250)	10	9	1	90%
	150% (1500)	30	30	0	100%
					average = 99.5%
MTD	0% (0)	350	350	0	100%
	75% (225)	10	8	2	80%
	125% (375)	10	10	0	100%
	150% (450)	30	30	0	100%
					average = 99.5%
PCP	0% (0)	350	350	0	100%
	50% (12.5)	10	10	0	100%
	125% (31.25)	10	9	1	90%
	150% (37.5)	30	30	0	100%
					average = 99.75%
TCA	0% (0)	350	350	0	100%
	50% (500)	10	10	0	100%
	125% (1250)	10	9	1	90%
	150% (1500)	30	30	0	100%
					average = 99.75%
THC	0% (0)	350	350	0	100%
	50% (25)	10	10	0	100%
	125% (62.5)	10	8	2	80%
	150% (75)	30	30	0	100%
					average = 99.5%
MDMA	0% (0)	350	350	0	100%
	50% (250)	10	10	0	100%
	125% (625)	10	9	1	90%
	150% (750)	30	30	0	100%
					average = 99.75%
MOR	0% (0)	350	350	0	100%
	50% (100)	10	10	0	100%
	125% (2500)	10	8	2	80%
	150% (3000)	30	30	0	100%
					average = 99.5%
OXY	0% (0)	350	350	0	100%
	50% (150)	10	10	0	100%
	125% (375)	10	8	2	80%
	150% (450)	30	30	0	100%
					average = 99.5%

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Summary of the Results - Panel

Drug	Cutoff Concentration% (ng/ml)	Number of studies	Correctly interpreted	Incorrectly interpreted	% of agreement
AMP	0% (0)	350	350	0	100%
	75% (750)	10	9	1	90%
	125% (1250)	10	9	1	90%
	150% (1500)	30	30	0	100%
					average = 99.5%
BAR	0% (0)	350	350	0	100%
	75% (150)	10	9	1	90%
	125% (250)	10	8	2	80%
	150% (300)	30	30	0	100%
					average = 99.25%
BUP	0% (0)	20	20	0	100%
	50% (5)	60	60	0	100%
	75% (7.5)	60	55	5	91.7%
	125% (12.5)	120	112	8	93.3%
	150% (15)	140	140	0	100%
					average = 96.75%
BZD	0% (0)	350	350	0	100%
	75% (225)	10	9	1	90%
	125% (375)	10	9	1	90%
	150% (450)	30	30	0	100%
					average = 99.5%
COC	0% (0)	350	350	0	100%
	75% (225)	10	9	1	90%
	125% (375)	10	9	1	90%
	150% (450)	30	30	0	100%
					average = 99.5%
MET	0% (0)	350	350	0	100%
	75% (750)	10	8	2	80%
	125% (1250)	10	10	0	100%
	150% (1500)	30	30	0	100%
					average = 99.5%
MTD	0% (0)	350	350	0	100%
	75% (225)	10	9	1	90%
	125% (375)	10	9	1	90%
	150% (450)	30	30	0	100%
					average = 99.5%
PCP	0% (0)	350	350	0	100%
	50% (12.5)	10	10	0	100%
	125% (31.25)	10	9	1	90%
	150% (37.5)	30	30	0	100%
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TCA	0% (0)	350	350	0	100%
	50% (500)	10	10	0	100%
	125% (1250)	10	9	1	90%
	150% (1500)	30	30	0	100%
					average = 99.75%
	0% (0)	350	350	0	100%

THC	50% (25)	10	10	0	100%
	125% (62.5)	10	8	2	80%
	150% (75)	30	30	0	100%
					average = 99.5%
MDMA	0% (0)	350	350	0	100%
	50% (250)	10	10	0	100%
	125% (625)	10	9	1	90%
	150% (750)	30	30	0	100%
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MOR	0% (0)	350	350	0	100%
	50% (100)	10	10	0	100%
	125% (2500)	10	9	1	90%
	150% (3000)	30	30	0	100%
					average = 99.75%
OXY	0% (0)	350	350	0	100%
	50% (150)	10	10	0	100%
	125% (375)	10	8	2	80%
	150% (450)	30	30	0	100%
					average = 99.5%

In both formats, the participants were able to read the results correctly at an average of higher than 96%, and 100% at 150% and above, as well as at 50% and below in this study.

Compared with GC/MS results, the lay users are able to obtain similar results with Instant-View® Multi-Drug urine test panel (Home Use) and Instant-View® Multi-Drug urine test cup (Home Use) devices.

All participants completed questionnaires after they completed the testing. The majority of the participants commented that the devices are very easy to operate and they have no difficulties in interpreting the results.

Summary of Survey and Labeling Assessments

	Very easy to understand	Easy to understand	Understandable w/ some difficulty	Difficult to understand	Impossible to understand	Total
Explanation of intended use of the test	166 (41.5%)	217 (54.25%)	17 (4.25%)	0	0	400
Directions to do the test	154 (38.5%)	231 (57.75%)	15 (3.75%)	0	0	400
Performing the test	178 (44.5%)	202 (50.5%)	20 (5%)	0	0	400
Direction to interpret the results	164 (41%)	223 (55.75%)	13 (3.25%)	0	0	400
Actual interpretation of the test results	164 (41%)	220 (55%)	16 (4%)	0	0	400

Additionally, a Flesh-Kincaid reading analysis revealed that package inserts (cup and panel) had a reading grade level of 7.

Conclusion The proposed test is substantially equivalent to the predicate device.