February 23, 2018

Alfa Scientific Designs, Inc
Naishu Wang
CTO
13200 Gregg Street
Poway, CA 92064

Re: k173303
Trade/Device Name: INSTANT-VIEW plus Multi-Drug of Abuse Urine Test - Simple Cup (OTC Use)
INSTANT-VIEW plus Multi-Drug Urine Test - Simple Cup (Prescription Use)
Regulation Number: 21 CFR 862.3100
Regulation Name: Amphetamine test system
Regulatory Class: Class II
Product Code: DKZ, DIS, DJG, JXM, DIO, DJC, DJR, LCM, LFG, LDJ, DNK, NFT, PTH, NFV, NFY, NGG, PTG, NGM, NFW, NGI, NGL, QAW
Dated: January 16, 2018
Received: January 22, 2018

Dear Naishu 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. 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 Part 801 and Part 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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Kellie B. Kelm -S

for 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
k173303

Device Name
INSTANT-VIEW plus Multi-Drug of Abuse Urine Test - Simple Cup (OTC Use)

Indications for Use *(Describe)*
The INSTANT-VIEW plus Multi-Drug of Abuse Urine Test - Simple Cup (OTC Use) device is a rapid, qualitative immunoassay device for the detection of one or more drugs or metabolites at the designated cutoff concentrations in human urine. The device can detect up to 13 drugs or their metabolites:

Analyte	Calibrator	Cutoff (ng/mL)
Amphetamines	d-Amphetamine	1000
Barbiturates	Secobarbital	200
Buprenorphine	Buprenorphine	10
Benzodiazepines	Oxazepam	300
Cocaine	Benzoylecgonine	300
Methamphetamine	d-Methamphetamine	1000
Methadone	Methadone	300
Phencyclidine	Phencyclidine	25
Tricyclic Antidepressants	Nortriptyline	1000
Cannabinoids	11-nor-Δ9-THC-9-COOH	50
MDMA	Methylenedioxymethamphetamine	500
Morphine	Morphine	2000
Oxycodone	Oxycodone	300

These assays may yield positive results when barbiturates, benzodiazepines, or tricyclic antidepressants are ingested at or above therapeutic doses. There are no uniformly recognized cutoff levels for barbiturates, benzodiazepines, or tricyclic antidepressants in urine. The assays are not intended to distinguish between prescription use or abuse of these drugs.

This device provides 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.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
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Amphetamines	d-Amphetamine	1000
Barbiturates	Secobarbital	200
Buprenorphine	Buprenorphine	10
Benzodiazepines	Oxazepam	300
Cocaine	Benzoylecgonine	300
Methamphetamine	d-Methamphetamine	1000
Methadone	Methadone	300
Phencyclidine	Phencyclidine	25
Tricyclic Antidepressants	Nortriptyline	1000
Cannabinoids	11-nor-Δ9-THC-9-COOH	50
MDMA	Methylenedioxymethamphetamine	500
Morphine	Morphine	2000
Oxycodone	Oxycodone	300

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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: Naishu Wang, MD, PhD
Email: wnss@alfascientific.com

Device Name

Trade Name:

INSTANT-VIEW plus Multi-Drug of Abuse Urine Test - Simple Cup (OTC Use)
INSTANT-VIEW plus Multi-Drug Urine Test - Simple Cup (Prescription Use)

Common Name:

Immunoassay, Drug of Abuse Screening Urine Test

Classification Name:

Amphetamine Test System, Barbiturate Test System, Benzodiazepine Test System, Cocaine and Cocaine Metabolite Test System, Methamphetamine Test System, Morphine Test System, Cannabinoid Test System, Methadone Test System, Tricyclic Antidepressant Drugs Test System, Phencyclidine Test System, Opiate Test System

Analyte	Regulation Number	Product code (OTC use)	Product code (prescription use)
Amphetamines	862.3100	NFT	DKZ
Barbiturates	862.3150	PTH	DIS
Buprenorphine	862.3650	NGL	DJG
Benzodiazepines	862.3170	NFV	JXM
Cocaine	862.3250	NFY	DIO
Methamphetamine	862.3610	NGG	DJC
Methadone	862.3620	PTG	DJR
Phencyclidine	unclassified	NGM	LCM
Tricyclic Antidepressants	862.3910	QAW	LFG
Cannabinoids	862.3870	NFW	LDJ
MDMA	862.3610	NGG	DJC
Morphine	862.3640	NGI	DNK
Oxycodone	862.3650	NGL	DJG

Date of Preparation	02/22/2018
Predicate Devices	k152122 Instant-View Multi-Drug Urine Test Cup (Home Use), Instant-View Multi-Drug Urine Test Panel (Home Use)
Device Description	These devices are one-step lateral flow chromatographic immunoassays consisting of any combination of one (1) to thirteen (13) individual test strip(s). 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

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Benzodiazepines	Oxazepam	300
Cocaine	Benzoylecgonine	300
Methamphetamine	d-Methamphetamine	1000
Methadone	Methadone	300
Phencyclidine	Phencyclidine	25
Tricyclic Antidepressants	Nortriptyline	1000
Cannabinoids	11-nor-Δ9-THC-9-COOH	50
MDMA	Methylenedioxy-methamphetamine	500
Morphine	Morphine	2000
Oxycodone	Oxycodone	300

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Methamphetamine	d-Methamphetamine	1000
Methadone	Methadone	300
Phencyclidine	Phencyclidine	25
Tricyclic Antidepressants	Nortriptyline	1000
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_____

Comparison to
Predicate Devices

Similarities		
Item	Device	Predicate
Intended Use	Same	Qualitative detection of drugs of abuse in urine
Test Principle	Same	Lateral flow immunochromatographic
Matrix	Same	Urine
Number of strips per device	Same	1 – 13 depending upon configuration
Analyte cutoffs (ng/mL)	Same	AMP – 1000 BAR – 200 BUP – 10 BZD – 300 COC – 300 MDMA – 500 MET – 1000 MTD – 300 MOR – 2000 OXY – 300 PCP – 25 TCA – 1000 THC – 50
Shelf life	Same	24 months

Differences		
Item	Device	Predicate
Sample application procedure	User urinates into cup and urine contacts the test strips immediately.	User urinates into cup, but the urine sample does not contact test strips until a knob is pushed, allowing the sample to flow to the bottom of the cup.
Storage conditions	Same	15^{o} – 30^{o} C

Performance Characteristics

To assess precision, each analyte was tested at the following concentrations: Negative, -75%, -50%, -25%, cutoff, +25%, +50%, +75%, and +100% of the cutoff for each analyte. The panels were blinded and randomized prior to testing. Testing was performed using three lots of test strips and was performed by 10 operators over ten non- consecutive days, and the results of this testing are summarized as follows for each analyte.

Amphetamines

Conc (ng/mL)	% of cutoff	Results (Neg/Pos) Lot 1	Results (Neg/Pos) Lot 2	Results (Neg/Pos) Lot 3
0	0	50/0	50/0	50/0
250	-75%	50/0	50/0	50/0
500	-50%	50/0	50/0	50/0
750	-25%	50/0	50/0	50/0
1000	cutoff	2/48	1/49	1/49
1250	+25%	0/50	0/50	0/50
1500	+50%	0/50	0/50	0/50
1750	+75%	0/50	0/50	0/50
2000	+100%	0/50	0/50	0/50

Barbiturates

Conc (ng/mL)	% of cutoff	Results (Neg/Pos) Lot 1	Results (Neg/Pos) Lot 2	Results (Neg/Pos) Lot 3
0	0	50/0	50/0	50/0
50	-75%	50/0	50/0	50/0
100	-50%	50/0	50/0	50/0
150	-25%	50/0	50/0	50/0
200	cutoff	1/49	3/47	2/48
250	+25%	0/50	0/50	0/50
300	+50%	0/50	0/50	0/50
350	+75%	0/50	0/50	0/50
400	+100%	0/50	0/50	0/50

Buprenorphine

Conc (ng/mL)	% of cutoff	Results (Neg/Pos) Lot 1	Results (Neg/Pos) Lot 2	Results (Neg/Pos) Lot 3
0	0	50/0	50/0	50/0
2.5	-75%	50/0	50/0	50/0
5	-50%	50/0	50/0	50/0
7.5	-25%	50/0	50/0	50/0
10	cutoff	1/49	2/48	2/48
12.5	+25%	0/50	0/50	0/50
15	+50%	0/50	0/50	0/50
17.5	+75%	0/50	0/50	0/50
20	+100%	0/50	0/50	0/50

Benzodiazepines

Conc (ng/mL)	% of cutoff	Results (Neg/Pos) Lot 1	Results (Neg/Pos) Lot 2	Results (Neg/Pos) Lot 3
0	0	50/0	50/0	50/0
75	-75%	50/0	50/0	50/0
150	-50%	50/0	50/0	50/0
225	-25%	50/0	50/0	50/0
300	cutoff	2/48	2/48	2/48
375	+25%	0/50	0/50	0/50
450	+50%	0/50	0/50	0/50
525	+75%	0/50	0/50	0/50
600	+100%	0/50	0/50	0/50

Cocaine

Conc (ng/mL)	% of cutoff	Results (Neg/Pos) Lot 1	Results (Neg/Pos) Lot 2	Results (Neg/Pos) Lot 3
0	0	50/0	50/0	50/0
75	-75%	50/0	50/0	50/0
150	-50%	50/0	50/0	50/0
225	-25%	50/0	50/0	50/0
300	cutoff	1/49	2/48	1/49
375	+25%	0/50	0/50	0/50
450	+50%	0/50	0/50	0/50
525	+75%	0/50	0/50	0/50
600	+100%	0/50	0/50	0/50

Methamphetamine

Conc (ng/mL)	% of cutoff	Results (Neg/Pos) Lot 1	Results (Neg/Pos) Lot 2	Results (Neg/Pos) Lot 3
0	0	50/0	50/0	50/0
250	-75%	50/0	50/0	50/0
500	-50%	50/0	50/0	50/0
750	-25%	50/0	50/0	50/0
1000	cutoff	1/49	2/48	1/49
1250	+25%	0/50	0/50	0/50
1500	+50%	0/50	0/50	0/50
1750	+75%	0/50	0/50	0/50
2000	+100%	0/50	0/50	0/50

Methadone

Conc (ng/mL)	% of cutoff	Results (Neg/Pos) Lot 1	Results (Neg/Pos) Lot 2	Results (Neg/Pos) Lot 3
0	0	50/0	50/0	50/0
75	-75%	50/0	50/0	50/0
150	-50%	50/0	50/0	50/0
225	-25%	50/0	50/0	50/0
300	cutoff	2/48	2/48	2/48
375	+25%	0/50	0/50	0/50
450	+50%	0/50	0/50	0/50
525	+75%	0/50	0/50	0/50
600	+100%	0/50	0/50	0/50

Phencyclidine

Conc (ng/mL)	% of cutoff	Results (Neg/Pos) Lot 1	Results (Neg/Pos) Lot 2	Results (Neg/Pos) Lot 3
0	0	50/0	50/0	50/0
6.25	-75%	50/0	50/0	50/0
12.5	-50%	50/0	50/0	50/0
18.75	-25%	50/0	50/0	50/0
25	cutoff	1/49	2/48	2/48
31.25	+25%	0/50	0/50	0/50
37.5	+50%	0/50	0/50	0/50
43.75	+75%	0/50	0/50	0/50
50	+100%	0/50	0/50	0/50

Tricyclic Antidepressants

Conc (ng/mL)	% of cutoff	Results (Neg/Pos) Lot 1	Results (Neg/Pos) Lot 2	Results (Neg/Pos) Lot 3
0	0	50/0	50/0	50/0
250	-75%	50/0	50/0	50/0
500	-50%	50/0	50/0	50/0
750	-25%	50/0	50/0	50/0
1000	cutoff	3/47	2/48	1/49
1250	+25%	0/50	0/50	0/50
1500	+50%	0/50	0/50	0/50
1750	+75%	0/50	0/50	0/50
2000	+100%	0/50	0/50	0/50

Cannabinoids

Conc (ng/mL)	% of cutoff	Results (Neg/Pos) Lot 1	Results (Neg/Pos) Lot 2	Results (Neg/Pos) Lot 3
0	0	50/0	50/0	50/0
12.5	-75%	50/0	50/0	50/0
25	-50%	50/0	50/0	50/0
37.5	-25%	50/0	50/0	50/0
50	cutoff	1/49	1/49	1/49
62.5	+25%	0/50	0/50	0/50
75	+50%	0/50	0/50	0/50
87.5	+75%	0/50	0/50	0/50
100	+100%	0/50	0/50	0/50

MDMA

Conc (ng/mL)	% of cutoff	Results (Neg/Pos) Lot 1	Results (Neg/Pos) Lot 2	Results (Neg/Pos) Lot 3
0	0	50/0	50/0	50/0
125	-75%	50/0	50/0	50/0
250	-50%	50/0	50/0	50/0
375	-25%	50/0	50/0	50/0
500	cutoff	3/47	2/48	2/48
625	+25%	0/50	0/50	0/50
750	+50%	0/50	0/50	0/50
875	+75%	0/50	0/50	0/50
1000	+100%	0/50	0/50	0/50

Morphine

Conc (ng/mL)	% of cutoff	Results (Neg/Pos) Lot 1	Results (Neg/Pos) Lot 2	Results (Neg/Pos) Lot 3
0	0	50/0	50/0	50/0
500	-75%	50/0	50/0	50/0
1000	-50%	50/0	50/0	50/0
1500	-25%	50/0	50/0	50/0
2000	cutoff	2/48	1/49	2/48
2500	+25%	0/50	0/50	0/50
3000	+50%	0/50	0/50	0/50
3500	+75%	0/50	0/50	0/50
4000	+100%	0/50	0/50	0/50

Oxycodone

Conc (ng/mL)	% of cutoff	Results (Neg/Pos) Lot 1	Results (Neg/Pos) Lot 2	Results (Neg/Pos) Lot 3
0	0	50/0	50/0	50/0
75	-75%	50/0	50/0	50/0
150	-50%	50/0	50/0	50/0
225	-25%	50/0	50/0	50/0
300	cutoff	2/48	2/48	2/48
375	+25%	0/50	0/50	0/50
450	+50%	0/50	0/50	0/50
525	+75%	0/50	0/50	0/50
600	+100%	0/50	0/50	0/50

A lay user study was also performed. A total of four-hundred (400) participants were recruited, and each participant was provided one (1) package insert, one (1) blind labeled test solution, and one (1) test device. Test solutions were randomly picked for participants, one for each. Every participant was requested to read the provided materials, perform the testing, and then filled out the forms. Participants recruited were with diverse educational backgrounds and ranged in age from 18 to >60. Results were as follows:

Drug (cutoff ng/ml)	Cutoff Concentration% (ng/ml)	Number of samples	Negative	Positive
AMP (1000)	0% (0)	350	350	0
	75% (750)	10	9	1
	125% (1250)	10	1	9
	150% (1500)	30	0	30
BAR (200)	0% (0)	350	350	0
	75% (150)	10	9	1
	125% (250)	10	1	9
	150% (300)	30	0	30
BUP (10)	0% (0)	20	20	0
	50% (5)	60	60	0
	75% (7.5)	60	57	3
	125% (12.5)	120	9	111
	150% (15)	140	0	140
BZD (300)	0% (0)	350	350	0
	75% (225)	10	9	1
	125% (375)	10	1	9
	150% (450)	30	0	30
COC (300)	0% (0)	350	350	0
	75% (225)	10	9	1
	125% (375)	10	0	10
	150% (450)	30	0	30
MET (1000)	0% (0)	350	350	0
	75% (750)	10	9	1
	125% (1250)	10	1	9
	150% (1500)	30	0	30
MTD (300)	0% (0)	350	350	0
	75% (225)	10	8	2
	125% (375)	10	0	10
	150% (450)	30	0	30
PCP (25)	0% (0)	350	350	0
	75% (18.75)	10	10	0
	125% (31.25)	10	1	9
	150% (37.5)	30	0	30
TCA (1000)	0% (0)	350	350	0
	75% (750)	10	9	1
	125% (1250)	10	1	9
	150% (1500)	30	0	30

THC (50)	0% (0)	350	350	0
	75% (37.5)	10	10	0
	125% (62.5)	10	2	8
	150% (75)	30	0	30
XTC (MDMA) (500)	0% (0)	350	350	0
	75% (37.5)	10	10	0
	125% (625)	10	1	9
	150% (750)	30	0	30
MOR (2000)	0% (0)	350	350	0
	75% (1500)	10	10	0
	125% (2500)	10	2	8
	150% (3000)	30	0	30
OXY (300)	0% (0)	350	350	0
	75% (225)	10	10	0
	125% (375)	10	2	8
	150% (450)	30	0	30

Surveys and labeling assessments

	Very easy to understand	Easy to understand	Understand w/ some difficulty	Difficult or impossible to understand
Explanation of intended use of the test	171 (42.75%)	215 (53.75%)	14 (3.5%)	0
Directions to do the test	226 (59%)	163 (40.75%)	11 (2.75%)	0
Performing the test	186 (46.5%)	202 (50.5%)	12 (3%)	0
Direction to interpret the results	246 (61.5%)	151 (37.75%)	13 (32.5%)	0
Actual interpretation of the test results	182 (45.5%)	212 (53%)	16 (4%)	0

Conclusion The INSTANT-VIEW plus Multi-Drug of Abuse Urine Test - Simple Cup (OTC Use) and INSTANT-VIEW plus Multi-Drug Urine Test - Simple Cup (Prescription Use) are substantially equivalent to the predicate device.