510(k) SUMMARY

JUN 17 2013

This summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The Assigned 510(k) number is: K122809

Submitter:

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Product Names:

Advin Multi-Drug Screen Test Cassette
Advin Multi-Drug Screen Test Dipcard
Advin Multi-Drug Screen Test Cup

Common Name:

Immunochromatographic test for the qualitative detection of multi-drugs and/or their metabolites in human urine.

Device Classification:

The Advin Multi–Drug Screen Test Cassette, Dipcard and Cup are similar to other FDA-cleared devices for the qualitative detection of following drugs in urine specimens:

Drug Test	Calibrator	Cutoff
Amphetamine (AMP)	d-Amphetamine	500 ng/mL
Barbiturates (BAR)	Secobarbital	300 ng/mL
Benzodiazepines (BZO)	Oxazepam	300 ng/mL
Buprenorphine (BUP)	Buprenorphine	10 ng/mL
Cocaine (COC)	Benzoylecgonine	150 ng/mL
EDDP	2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine	300 ng/mL

Drug Test	Calibrator	Cutoff
Ecstasy (MDMA)	Methylenedioxymethamphetamine	500 ng/mL
Methamphetamine (MET)	d-Methamphetamine	500 ng/mL
Methadone (MTD)	Methadone	300 ng/mL
Morphine (MOR300)	Morphine	300 ng/mL
Opiates (OPI)	Morphine	2,000 ng/mL
Oxycodone (OXY)	Oxycodone	100 ng/mL
Phencyclidine (PCP)	Phencyclidine	25 ng/mL
Propoxyphene (PPX)	Propoxyphene	300 ng/mL
Tricyclic-antidepressant (TCA)	Nortriptyline	1,000 ng/mL
Marijuana (THC)	11-nor-Δ9-THC-9-COOH	50 ng/mL

These tests are used to provide only preliminary test results. The test systems have been classified as Class II devices with moderate complexity.

Classification Name:

Amphetamine Test System
Methamphetamine Test System
Barbiturates Test System
Benzodiazepine Test system
Antidepressant test system
Opiate Test System
Cannabinoids Test System
Cocaine and cocaine metabolite Test System
Methadone Test System
Tricyclic Antidepressants Test System
Methadone Test System
Propoxyphene test system

Intended Use:

The Advin Multi-Drug Screen Test is a one-step immunoassay for the qualitative detection
of multiple drugs of abuse and/or their metabolites in human urine at the following cutoff levels:

Drug Test	Calibrator	Cutoff
Amphetamine (AMP)	d-Amphetamine	500
Barbiturates (BAR)	Secobarbital	300
Benzodiazepines	Oxazepam	300
Buprenorphine (BUP)	Buprenorphine	10 ng/mL
Cocaine (COC)	Benzoylecgnine	150
EDDP	2-ethylidene-1,5-dimethyl-3,3-	300
Ecstasy (MDMA)	Methylenedioxymethamphetamine	500

Methamphetamine	d-Methamphetamine	500
Methadone (MTD)	Methadone	300
Morphine (MOR300)	Morphine	300
Opiates (OPI)	Morphine	2,000
Oxycodone (OXY)	Oxycodone	100
Phencyclidine (PCP)	Phencyclidine	25 ng/mL
Propoxyphene (PPX)	Propoxyphene	300
Tricyclic-antidepressant	Nortriptynine	1,000 ng/mL
Marijuana (THC)	11-nor-Δ9-THC-9-COOH	50 ng/mL

The Advin Multi-Drug Screen Test consists of three formats: a Cassette, a Dipcard and a Cup format, which may be configured in any combination of the drugs analytes listed in the above table.

Advin Multi-Drug Screen Test is used to obtain a visual, qualitative, preliminary test result for prescription use in point of care sites, laboratory settings and is also intended for workplace and over-the-counter use. The Propoxyphene test strip is not intended for over-the-counter use.

This test does not distinguish between drugs of abuse and certain medications. It will yield preliminary positive results when prescription drugs TCA, Barbiturates, Benzodiazepine, Methadone, Buprenorphine and Opiates drugs are ingested, even at or above therapeutic doses. There are no uniformly recognized drug levels for these prescription drugs in urine.

This assay provides only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical test result. Gas chromatography/mass spectrometry (GC/MS), Liquid Chromatography / Mass Spectrometry/Mass (LC/MS/MS) and High Performance Liquid Chromatography (HPLC) are the preferred confirmatory methods.

Clinical considerations and professional judgment should always be applied to interpret any drug of abuse test result, particularly in evaluating a preliminary positive test result.

Description:

The Advin Multi-Drug Screen Test is a lateral flow immunochromatographic competitive binding assay and is intended for prescription use, CLIA Waived use and OTC use. It is used as *in vitro* diagnostics to visually and qualitatively detect some of the most common drugs of abuse and/or their metabolites in human urine specimens. The test is based on the principle of competitive binding antigen-antibody immunochemistry. It utilizes anti-drug antibody to selectively detect elevated levels of multi-drugs and/or their metabolites in urine at a specified cutoff for each drug. These visual read tests are performed without the use of an instrument.

A drug-Positive urine specimen **will not** generate a colored-line in the designated test region, while a drug-Negative urine specimen or a urine specimen containing drug(s) at the concentration below the cut-off level **will** generate a colored-line in the test region. To serve as a procedural control, a

colored-line will always appear at the control region, indicating that proper volume of urine specimen has been added and membrane wicking has occurred.

Some of the Advin Multi-Drug Screen Test will be sold with either one or two adulteration test strips for the detection of adulterants added to the urine specimen. Each Adulteration strip consists of one to three reagent pads which consist of tests for oxidant, specific gravity, pH, glutaraldehyde, creatinine and nitrite.

Predicate Devices and 510(k) Numbers:

Innovacon Spectrum II Test Card and Test Card with Integrated Test Cup (K061718)

Comparison to a Predicate Device:

The ADVIN Multi–Drug Screen Test (Cassette, Dipcard and Cup) have following similarities compared to the above predicate devices:

- All tests are assays intended for the qualitative detection of drugs in urine samples.
- All tests are intended as a screening method that provides a preliminary qualitative analytical test result.
- All tests are immunochromatographic, lateral flow, competitive binding assays for the rapid detection of drug and drug metabolites with a visual, qualitative end result.
- All tests utilize the same basic immunoassay principles that rely on antigen/ antibody interaction to indicate a positive or a negative result.
- All tests have the same cutoff for each of drugs with the exception of Amphetamine test.

Feature	Advin Multi-Drug Screen Test	Predicate devices
Indication of use	A rapid chromatographic immunoassay for the qualitative detection of multiple drugs/metabolites in human urine.	A rapid chromatographic immunoassay for the qualitative and simultaneous detection of multiple drugs and metabolites in human urine.
Cutoff Concntrations (ng/mL)	Amphetamine 500 Barbiturates 300 Benzodiazepines 300 Buprenorphine 10 Cocaine 150 Methadone 300 MDMA 500 THC 50 Methamphetamine 500 morphine 300, or opiates 2,000 Oxycodone 100 Phencyclidine 25 Propoxyphene 300 Tricyclic antidepressants 1;000, EDDP 300	Amphetamine 1000 or 300 Barbiturates 300 Benzodiazepines 300 Buprenorphine 10 Cocaine 150 or 300 Methadone 300 MDMA 500 THC 50 Methamphetamine 500 or 1,000 morphine 300, or opiates 2,000 Oxycodone 100 Phencyclidine 25 Propoxyphene 300 Tricyclic antidepressants 1,000 EDDP 300

Intended use	Prescription use, CLIA-waived laboratory and Over-the –Counter use	Professionals and point of care sites
Intended specimen	Urine	Urine
Endpoint	Colored Lines	Same
Materials provided	Test Devices (Cassette, Dipcard, Cup) Package Insert	Test Devices (Test Card, Cup) Package Insert
Methodology	Membrane Particle Assay	Same
Test Time	5 minutes	Same
Format	Immunochemical Antigen/Antibody Immunoassay	Same

Safety and Effectiveness Data:

Accuracy

The accuracy of Advin Multi-Drug Screen Test was evaluated in comparison to GC/MS analysis data. Forty drug-free urine specimens collected from presumed non-user volunteers were tested with Advin Multi-Drug Screen Test. Of these 40 negative specimens tested, all were correctly identified as negative. 10% of these negative specimens were confirmed with GC/MS as drug negative urine specimens. At least 40 drug positive urine specimens for each drug test were obtained from reference labs throughout the United States. The drug concentration in each of the positive specimen was confirmed with GC/MS and LC/MS (for TCA analysis). Summary of accuracy results on Advin Multi-Drug Screen Test Cassette, Dipcard and Cup are shown in tables below:

A. Summary of Accuracy Results on Advin Multi-Drug Screen Test Cassette:

Drug Test	Test Result	Compared to GC/MS Analysis Data						
		Drug-free	-50% C/O to < -25% C/O	-25 C/O % to C/O	C/O to +25% C/O	>+25% C/O to +50% C/O	>+50% C/O	% agreement
AMP 500	Neg	40	3	0	0	0	0	97.7%
	Pos	0	0	1	2	2	45	100%
BAR 300	Neg	40	1	1	0	0	0	95.2%
	Pos	0	0	2	5	2	36	100%
BUP 10	Neg	40	1	1	0	0	0	95.5%
	Pos	0	0	2	8	0	32	100%
BZO 300	Neg	40	0	1	0	0	0	93.2%
	Pos	0	0	3	1	6	34	100%
COC 150	Neg	40	0	3	0	0	0	97.7%
	Pos	0	0	1	4	1	53	100%
EDDP 300	Neg	40	0	1	0	0	0	93.2%
	Pos	0	0	3	5	2	33	100%
MDMA 500	Neg	40	1	1	0	0	0	95.5%
	Pos	0	0	2	5	1	34	100%
MET 500	Neg	40	1	0	0	0	0	93.2%
	Pos	0	0	3	1	3	51	100%
MOR 300	Neg	40	0	1	0	0	0	93.2%
	Pos	0	0	3	4	0	53	100%
MTD 300	Neg	40	0	2	0	0	0	95.5%
	Pos	0	0	2	4	0	37	100%
OPI	Neg	40	1	0	0	0	0	93.2%

2,000	Pos	0	0	2	4	3	40	100%
OXY	Neg	40	1	0	0	0	0	93.2%
100	Pos	0	0	3	7	1	33	100%
PCP	Neg	40	0	3	0	0	0	97.7
25	Pos	0	0	1	3	8	33	100%
PPX	Neg	40	0	1	0	0	0	95.3%
300	Pos	0	0	2	5	2	33	100%
TCA	Neg	40	0	2	0	0	0	95.5%
1,000	Pos	0	0	2	5	7	28	100%
THC	Neg	40	1	2	0	0	0	97.7%
50	Pos	0	0	1	4	7	44	100%

B. Summary of Accuracy Results on Advin Multi-Drug Screen Test Dipcard:

Drug Test with Cutoff (ng/mL)	Test Result	Compared to GC/MS Analysis Data						
		Drug-free	-50% C/O to < -25% C/O	-25 C/O % to C/O	Drug-free	>+25% C/O to +50% C/O	>+50% C/O	Drug-free
AMP	Neg	40	3	0	0	0	0	97.7%
500	Pos	0	0	1	2	2	45	100%
BAR	Neg	40	1	1	0	0	0	95.2%
300	Pos	0	0	2	5	2	36	100%
BUP	Neg	40	1	1	0	0	0	95.5%
10	Pos	0	0	2	8	0	32	100%
BZO	Neg	40	0	1	0	0	0	93.2%
300	Pos	0	0	3	1	6	34	100%
COC	Neg	40	0	3	0	0	0	97.7%
150	Pos	0	0	1	4	1	53	100%
EDDP	Neg	40	0	1	0	0	0	93.2%
300	Pos	0	0	3	5	2	33	100%
MDMA	Neg	40	1	1	0	0	0	95.5%
500	Pos	0	0	2	5	1	34	100%
MET	Neg	40	1	0	0	0	0	93.2%
500	Pos	0	0	3	1	3	51	100%
MOR	Neg	40	0	1	0	0	0	93.2%
300	Pos	0	0	3	4	0	53	100%
MTD	Neg	40	0	2	0	0	0	95.5%
300	Pos	0	0	2	4	0	37	100%
OPI	Neg	40	1	0	0	0	0	93.2%
2,000	Pos	0	0	2	4	3	40	100%
OXY	Neg	40	1	0	0	0	0	93.2%
100	Pos	0	0	3	7	1	33	100%
PCP	Neg	40	0	3	0	0	0	97.7
25	Pos	0	0	1	3	8	33	100%
PPX	Neg	40	0	1	0	0	0	95.3%
300	Pos	0	0	2	5	2	33	100%
TCA	Neg	40	0	2	0	0	0	95.5%
1,000	Pos	0	0	2	5	7	28	100%
THC	Neg	40	1	2	0	0	0	97.7%
50	Pos	0	0	1	4	7	44	100%

C. Summary of Accuracy Results on Advin Multi-Drug Screen Test Cup:

Drug Test with Cutoff (ng/mL)	Test Result	Compared to GC/MS Analysis Data						
		Drug-free	-50% C/O to < -25%C/O	-25% C/O to C/O	C/O to +25% C/O	>+25% C/O to +50% C/O	>+50% C/O	% agreement
AMP	Neg	40	3	0	0	0	0	97.7%
500	Pos	0	0	1	2	2	45	100%
BAR	Neg	40	1	1	0	0	0	95.2%
300	Pos	0	0	2	5	2	36	100%
BUP	Neg	40	1	1	0	0	0	95.5%
10	Pos	0	0	2	8	0	32	100%
BZO	Neg	40	0	1	0	0	0	93.2%
300	Pos	0	0	3	1	6	34	100%
COC	Neg	40	0	3	0	0	0	97.7%
150	Pos	0	0	1	4	1	53	100%
EDDP	Neg	40	0	1	0	0	0	93.2%
300	Pos	0	0	3	5	2	33	100%
MDMA	Neg	40	1	1	0	0	0	95.5%
500	Pos	0	0	2	5	1	34	100%
MET	Neg	40	1	0	0	0	0	93.2%
500	Pos	0	0	3	1	3	51	100%
MOR	Neg	40	0	1	0	0	0	93.2%
300	Pos	0	0	3	4	0	53	100%
MTD	Neg	40	0	2	0	0	0	95.5%
300	Pos	0	0	2	4	0	37	100%
OPI	Neg	40	1	0	0	0	0	93.2%
2,000	Pos	0	0	2	4	3	40	100%
OXY	Neg	40	1	0	0	0	0	93.2%
100	Pos	0	0	3	7	1	33	100%
PCP	Neg	40	0	3	0	0	0	97.7
25	Pos	0	0	1	3	8	33	100%
PPX	Neg	40	0	1	0	0	0	95.3%
300	Pos	0	0	2	5	2	33	100%
TCA	Neg	40	0	2	0	0	0	95.5%
1,000	Pos	0	0	2	5	7	28	100%
THC	Neg	40	1	2	0	0	0	97.7%
50	Pos	0	0	1	4	7	44	100%

Analytical Specificity

The following compounds are detected positive in urine by the Advin Multi- Drug Screen Test Cassette, Dip card, and Cup; the concentration of each cross-reactive compound which produced a positive result is in ng/mL and the percentage of the cross-reactivity relative to the calibrator is in parenthesis:

Compounds	Concentration (%)	Compounds	Concentration (%)
AMP			
D-Amphetamine	500 (100%)	L-amphetamine	50,000 (1%)
MDA	8,000 (6.5%)	Phentermine	45,000 (1.1%)
BAR			
Secobarbital	300 (100%)	Amobarbital	2,500 (12%)
Aprobarbital	500 (60%)	Butabarbital	100 (300%)

Butalbital	300 (100%)	Cyclopentobarbital	500 (60%)
Phenobarbital	300 (100%)	Phentobarbital	250 (120%)
BUP			
Buprenorphine	10 (100%)		
BZO			
Oxazepam	300 (100%)	Alpha-hydroxyalprazolam	1,900 (15.8%)
Alprazolam	200 (150%)	Bromazepam	1,000 (30%)
Clobazam	200 (150%	Clorazepam	750 (40%)
Desalkyflurazepam	1,200 (25%)	Diazepam	1,000 (30%)
Flunitrazepam	250 (120%)	Lorazepam	3,900 (7.7%)
Nitrazepam	250 (120%)	Lorazepam-glucuronide	5,000 (6%)
Nordiazepam	390 (76.9%)	Nordiazepoxide	400(75%)
Temazepam	150 (200%)	Norchlordiazepapoxide	500 (60%)
Triazolam	2,500 (12%)		
COC			
Benzoylecgonine	150 (100%)	Cocaine	5,000 (3%)
Cocaethylene	50,000 (0.3%)	Ecgonine	50,000 (0.3%)
EDDP			
EDDP	300 (100%)		
MET			
d-Methamphetamine	500 (100%)	1R,2S(-) -Ephedrine	100,000 (0.5%)
d-Amphetamine	50,000 (1%)	L-Amphetamine	50,000 (1%)
MDEA	30,000 (1.7%)	Mephentermine	75,000 (0.7%)
MDMA	3,500 (14.3%)		
MDMA			
(+/-) – MDMA	500 (100%)	(+/-)-MDA	3,900 (12.8%)
(+/-)- MDEA	500 (100%)		
MTD			
Methadone	300 (100%)		
MOR			
Morphine	300 (100%)	Codeine	100 (300%)
Ethylmorphine	100 (300%)	Heroine	8,000 (37.5%)
Hydrocodone	1,250 (24%)	Hydromorphone	2,500 (12%)
Levophenol	50,000 (0.6%)	Morphine 3-glucuronide	400 (75%)
Norcodeine	6,000 (1.9%)	Oxycodone	75,000 (0.4%)
Thebaine	90,000 (0.3%)		
PCP			
Phencyclidine	25 (100%)	4-hydroxy-PCP	1,500 (1.7%)
OPI			
Morphine	2,000 (100%)	Oxycodone	70,000 (2.9%)
Codeine	1,800 (111.1%)	Morphine-3-glucuronide	2,600 (76.9%)
Ethylmorphine	1500 (133.3%)	Hydrocodone	5,000 (40%)
Hyrdromorphone	5,000 (40%)	Thebaine	95,000 (2.1%)
Heroine	11,000 (18.2%)		
OXY			
Oxycodone	100 (100%)	Hydromorphone	25,000 (0.4%)
Hydrocodone	5,000 (2%)	Oxymorphone	12,500 (0.8)
Ethymorphine	50,000 (0.2%)	Codeine	50,000 (0.2%)

PPX			
Propoxyphene	300 (100%)	Nor-propoxyphen	300 (100%)
TCA			
Nortriptyline	1,000 (100%)	Amitriptyline	4,000 (25%)
Clomipramine	2,000 (50%)	Doxepine	1,000 (100%)
Desipramine	500 (200%)	Imipramine	1,000 (100%)
Promethazine	1,000 (100%)	Trimipramine	5,000 (20%)
THC			
11-nor-Δ9-THC-9-COOH	50 (100%)	(+/-)11-hydroxy-Δ9-THC	5,000 (1%)
(-)- Δ8-THC	20,000 (0.3%)	(-)-Δ9-THC	20,000 (0.3%)

Precision:

The precision of Advin Multi-Drug Screen Test was evaluated at 3 Physician's Office Laboratory sites and 100 lay persons. Data obtained from these sites indicate that correct test results can be obtained when urine specimen with drug concentrations at +/-50% cutoff levels are tested with Advin Multi-Drug Test Cassette, Dipcard, and Cup.

Lay-Users Study

A total of over one hundred male and female persons age 18 or older participated in the lay person user study with Advin Multi -Drug Screen Test following product package insert. The drug-free urine specimens together with spiked urine specimens with different drug concentrations at +/- 50% cutoff and +/- 25% cutoff were tested by the participants. Each level of the drug solutions was randomly tested with at least 20 replicates.

The lay person user study results indicates that the agreement between the testing results from lay person and GC/MS analysis results is from over 99% for the concentrations at +/- 50% cutoff levels and 65% to 86% for the concentrations near the cutoff levels and. The statistic analysis indicates that a lay person can follow the product package insert and perform Advin Multi-Drug Screen Test Cassette, Dip Card and Cup similar to professionals at POL sites with reasonable accuracy.

A Summary of the lay person user study results are listed in the tables below:

Analysis of Discordant Results with Advin Multi–drug Screen Cassette by Lay Person vs. GC/MS Analysis

Drug test cutoff (ng/mL)	Number of tests (discordant results/total results)	Result of Advin Multi-drug Test Cassette	GC/MS or LCMS (ng/mL)
AMP 500	12 /136	Positive	366
	7/86	Negative	555
BAR 300	5/65	Positive	227
	4/44	Negative	394
BUP 10	6/66	Positive	6.9
	6/44	Negative	11.3

BZO 300	6/65	Positive	209
	4/41	Negative	374
COC 150	6/68	Positive	113
	4/42	Negative	186
EDDP	5/66	Positive	212
	6/42	Negative	406
MET 500	6/62	Positive	394
	5/44	Negative	646
MDMA 500	6/62	Positive	368
	6/46	Negative	624
MTD 300	7/64	Positive	218
	3/44	Negative	412
MOR 300	5/62	Positive	255
	6/47	Negative	318
OPI 2000	5/64	Positive	1465
	4/44	Negative	2135
OXY	6/70	Positive	67
	3/42	Negative	112
PCP 25	7/68	Positive	17.2
	3/41	Negative	35.2
TCA 1000	6/68	Positive	784
	4/42	Negative	1210
THC 50	6/62	Positive	34.1
	5/48	Negative	57.1

Analysis of Discordant Result with Advin Multi–drug Screen Dipcard by Lay Person vs. GC/MS Analysis

Drug test cutoff (ng/mL)	Number of tests (discordant results/total results)	Result of Advin Multi-drug Test Dipcard	GC/MS or LCMS (ng/mL)
AMP 500	12/126	Positive	366
	7/86	Negative	555
BAR 300	5/66	Positive	227
	6/40	Negative	394
BUP 10	4/63	Positive	6.9
	4/42	Negative	11.3
BZO 300	4/63	Positive	209
	4/42	Negative	374
COC 150	5/64	Positive	113
	4/45	Negative	186
EDDP 300	5/62	Positive	212
	6/43	Negative	406
MET 500	6/65	Positive	394
	4/40	Negative	646
MDMA 500	5/63	Positive	368
	6/41	Negative	624
MTD 300	6/63	Positive	218
	5/42	Negative	412
MOR 300	5/65	Positive	255

	4/44	Negative	318
OPI 2000	5/63	Positive	1465
	5/41	Negative	2125
OXY 100	5/62	Positive	67
	4/41	Negative	112
PCP 25	5/64	Positive	17.2
	4/42	Negative	35.2
TCA 1000	5/62	Positive	784
	4/43	Negative	1210
THC 50	6/65	Positive	34.1
	4/44	Negative	57.1

Analysis of Discordant Result with Advin Multi–drug Screen Cup by Lay Person vs. GC/MS Analysis

Drug test cutoff (ng/mL)	Number of tests (discordant results/total results)	Result of Advin Multi-drug Test Cup	GC/MS or LCMS (ng/mL)
AMP 500	23/256	Positive	366
	22/176	Negative	555
BAR 300	5/193	Positive	227
	6/42	Negative	394
BUP 10	4/191	Positive	6.9
	6/44	Negative	11.3
BZO 300	6/196	Positive	209
	6/41	Negative	374
COC 150	6/194	Positive	113
	5/43	Negative	186
EDDP 300	6/194	Positive	212
	5/43	Negative	406
MET 500	6/195	Positive	394
	5/42	Negative	646
MDMA 500	5/191	Positive	368
	6/43	Negative	624
MTD 300	5/193	Positive	218
	6/44	Negative	412
MOR 300	6/127	Positive	255
	5/42	Negative	381
OPI 2000	5/129	Positive	1465
	4/41	Negative	2125
OXY 100	7/194	Positive	67
	5/43	Negative	112
PCP 25	6/194	Positive	17.2
	4/41	Negative	35.2
TCA 1000	5/192	Positive	784
	6/43	Negative	1210
THC 50	6/195	Positive	34.1
	5/42	Negative	57.1

Conclusion:

From data collected in the accuracy and precision studies, it was demonstrated that Advin Multi-Drug Screen Test is safe and effective to use when compared to predicate devices already marketed in the United States.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 17, 2013

Advin Biotech
C/O Edward Tung
6861 Nancy Ridge Dr., Suite #D
SAN DIEGO CA 92121

Re: K122809
Trade/Device Name: Advin Multi-Drug Screen Test Cassette
Advin Multi-Drug Screen Test Dipcard
Advin Multi-Drug Screen Test Cup
Regulation Number: 21 CFR 862.3100
Regulation Name: Amphetamine test system
Regulatory Class: II
Product Code: DKZ, DJC, DIS, JXM, DJG, LDJ, DIO, DJR, LFG, JXN, LCM
Dated: June 03, 2013
Received: June 06, 2013

Dear Dr. Tung:

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); 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 regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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, Ph.D.

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

Indications for Use

510(k) Number (if known): k122809

Device Name: Advin Multi-Drug Screen Test Cassette
Advin Multi-Drug Screen Test Dip Card
Advin Multi-Drug Screen Test Cup

Indications for Use:
The Advin Multi-Drug Screen Test is a one-step immunoassay for the qualitative detection of multiple drugs of abuse and/or their metabolites in human urine at the following cutoff levels:

Drug Test	Calibrator	Cutoff Level
Amphetamine (AMP)	d-Amphetamine	500 ng/mL
Barbiturates (BAR)	Secobarbital	300 ng/mL
Benzodiazepines (BZO)	Oxazepam	300 ng/mL
Buprenorphine (BUP)	Buprenorphine	10 ng/mL
Cocaine (COC)	Benzoylecgnine	150 ng/mL
EDDP	2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine	300 ng/mL
Ecstasy (MDMA)	Methylenedioxymethamphetamine	500 ng/mL
Methamphetamine (MET)	d-Methamphetamine	500 ng/mL
Methadone (MTD)	Methadone	300 ng/mL
Morphine (MOR300)	Morphine	300 ng/mL
Opiates (OPI)	Morphine	2,000 ng/mL
Oxycodone (OXY)	Oxycodone	100 ng/mL
Phencyclidine (PCP)	Phencyclidine	25 ng/mL
Propoxyphene (PPX)	Propoxyphene	300 ng/mL
Tricyclic-antidepressant (TCA)	Nortriptynine	1,000 ng/mL
Marijuana (THC)	11-nor-Δ9-THC-9-COOH	50 ng/mL

Prescription Use __X__ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use __X__ (21 CFR Part 801 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Ruth A. Chesler -S

Division Sign-Off
Office of In Vitro Diagnostics and Radiological Health
510(k) k122809

Indications for Use

510(k) Number (if known): k122809

Device Name: Advin Multi-Drug Screen Test Cassette
Advin Multi-Drug Screen Test Dip Card
Advin Multi-Drug Screen Test Cup

Indications for Use:
The Advin Multi-Drug Screen Test consists of three formats: a Cassette, a Dip Card and a Cup, which may be configured in any combination of the drug analytes listed in the above table.

Advin Multi-Drug Screen Test is used to obtain a visual, qualitative, preliminary test result for prescription use in point of care sites, laboratory settings and is also intended for workplace and over-the-counter use. The Propoxyphene test strip is not intended for over-the-counter use.

The Advin Multi-Drug Screen Test will yield preliminary positive results when prescription drugs TCA, Barbiturates and Benzodiazepine, Methadone, Buprenorphine and Opiates are ingested, even at or above therapeutic doses. There are no uniformly recognized drug levels for TCA, Barbiturates and Benzodiazepine in urine.

The Advin Multi-Drug Screen Test provides only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical test result. Gas chromatography/mass spectrometry (GC/MS), Liquid Chromatography / Mass Spectrometry/Mass (LC/MS/MS) and High Performance Liquid Chromatography (HPLC) are the preferred confirmatory methods. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly in the evaluation of a preliminary positive test result.

Prescription Use __X__ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use __X__ (21 CFR Part 801 Subpart C)

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

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