510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY TEMPLATE

A. 510(k) Number:

k113624

B. Purpose for Submission:

New device

C. Measurand:

Buprenorphine, Oxycodone in human urine

D. Type of Test:

Qualitative lateral flow chromatographic immunoassay

E. Applicant:

Guangzhou Wondfo Biotech Co., Ltd.

F. Proprietary and Established Names:

Wondfo Buprenorphine Urine Test
Wondfo Oxycodone Urine Test

G. Regulatory Information:

1. Regulation section:
   21 CFR §862.3650, Opiate Test System

2. Classification:
   All are Class II

3. Product code(s):
   DJG

4. Panel:
   Toxicology (91)

H. Intended Use:

1. Intended use(s):

   See indications for use below.

2. Indications(s) for use:

   Wondfo Buprenorphine Urine Test:

   Wondfo Buprenorphine Urine Test is an immunochromatographic assay for the qualitative determination of Buprenorphine in human urine at a cutoff concentration of 10 ng/mL. The test is available in a dip card format and a cup format. For in vitro diagnostic use only. This product is only intended for prescription use and is not intended for point-of-care use.

   The test provides only preliminary test results. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. GC/MS or LC/MS is the preferred confirmatory method. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive.

   Wondfo Oxycodone Urine Test:

   Wondfo Oxycodone Urine Test is an immunochromatographic assay for the qualitative determination of Oxycodone in human urine at a cutoff concentration of 100 ng/mL. The test is available in a dip card format and a cup format. For in vitro diagnostic use only. This product is intended for over-the-counter and prescription use.

   The test provides only preliminary test results. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. GC/MS or LC/MS is the preferred confirmatory method. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive.

3. Special conditions for use statement(s):

   For prescription (buprenorphine and oxycodone) and over-the counter use (oxycodone).

4. Special instrument requirements:

   Not applicable.

I. Device Description:

The tests, to be used with human urine samples, are in different formats: dip card and cup.

The Dip Card format is a test with an integrated cup. It is a rapid test for the qualitative detection of buprenorphine and oxycodone in human urine. It is a lateral flow chromatographic immunoassay. When the absorbent end of the test device is immersed into the urine sample, the urine is absorbed into the device by capillary action, mixes with the antibody-dye conjugate, and flows across the pre-coated membrane. The absence of sample drug produces a colored test line, which regardless of its intensity, indicates a negative result. The presence of sample drug prevents the development of a distinct colored band in the test region, indicating a potentially positive result.

A colored line will appear in the control region to indicate that the test has been performed properly.

The Cup format is the same function or performance specification of dip card. It is composed of an integrated cup and a functional dip card. When the key is inserted to the cup and rotated to activate the test, the urine is absorbed into the device by capillary action, mixes with the antibody-dye conjugate, and flows across the pre-coated membrane. The presence or absence of a sample drug is the same as the dip card format.

J. Substantial Equivalence Information:

1. Predicate device name(s):

Predicate Device Name	Predicate 510(k) numbers(s)
Acon Laboratories, Inc. Acon BUP One Step Buprenorphine Test Strip and Acon BUP One Step Buprenorphine Test Device	k060466
Acon Laboratories, Inc. Acon BUP One Step Oxycodone Test Strip and Acon BUP One Step Oxycodone Test Device	k033047

2. Comparison with predicate

Similarities and Differences		
Item	**Candidate Device: Wondfo Buprenorphine Urine Test and Wondfo Oxycodone Urine Test**	**Predicate Device: ACON One Step BUP (k060466) and OXY (k033047) Test Strip**
Indications for Use	Same	For the qualitative determination of buprenorphine or oxycodone in human urine
Methodology	Same	Competitive binding, lateral flow immunochromatographic assays based on the principle of antigen-antibody immunochemistry
Type of Test	Same	Immunoassay principles that rely on antigen-antibody interactions to indicate positive or negative result
Calibrator	Same	Buprenorphine, Oxycodone
Results	Same	Qualitative
Specimen Type	Same	Human Urine
Cut Off Value	Same	Buprenorphine: 10 ng/ml Oxycodone: 100 ng/ml
Configurations	Cup, Dip Card	Strip, Device
Intended Use	OTC Use & Prescription Use	Prescription Use

K. Standard/ Guidance Document Referenced (if applicable):

- In Vitro Diagnostic Devices; Guidance for the Preparation of 510(k) Submission
- Premarket Submission and Labeling Recommendations for Drugs of Abuse Screening Tests, Draft Guidance (December 2, 2003).

L. Test Principle:

Wondfo Buprenorphine and Oxycodone Urine Tests are competitive immunoassays that are used to screen for the presence of buprenorphine or oxycodone in urine. Both entail a chromatographic absorbent end where urine is absorbed into the device by capillary action, mixes with the buprenorphine or oxycodone monoclonal antibody conjugate, and flows across the pre-coated membrane. When sample drug levels are zero or below the target cut off (the detection sensitivity of the test), the anti-buprenorphine or anti-oxycodone monoclonal antibody (mouse) conjugate binds to the buprenorphine-protein or oxycodone-protein (duck egg) conjugate immobilized in the Test Region (T) of the device. This produces a colored Test line that, regardless of its intensity, indicates a negative result. When sample drug levels are at or above the target cutoff, the free drug in the sample binds

to the buprenorphine or oxycodone monoclonal antibody conjugate preventing it from binding to the buprenorphine-protein or oxycodone-protein conjugate immobilized in the Test Region (T) of the device. This prevents the development of a distinct colored band in the test region, indicating a potentially positive result. To serve as a procedure control, a colored line will appear at the Control Region (C), where the Goat anti mouse IgG polyclonal antibody is immobilized, if the test has been performed properly.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

The precision study was performed by taking negative urine samples and spiking these to: 20.0, 17.5, 15.0, 12.5, 10, 7.5, 5.0, 2.5 and 0 ng/mL of buprenorphine, corresponding to (%) 100, 75, 50, 25, cut-off, -25, -50, -75, and negative of the 10 ng/mL buprenorphine cut-off value; and 200, 175, 150, 125, 100, 75, 50, 25 and 0 ng/mL of oxycodone, corresponding to (%) 100, 75, 50, 25, cut-off, -25, -50, -75, and negative of the 100 ng/mL oxycodone cut-off value. The levels of buprenorphine and oxycodone were confirmed by GC/MS. Two sets of operators performed the testing (group A ran the cup format and group B ran the dip card format) and each concentration of the samples were divided into 12 sets of 25 (one set per lot per run for each format). Three lots of the cup and three lots of the dip card formats of the Wondfo Buprenorphine Urine Test and Wondfo Oxycodone Urine Test were used. Each of three operators tested 2 aliquots at each concentration for each lot per day (2 runs per day for 25 days), resulting in a total of 50 determinations by each operator at each concentration. The operators were blinded. A summary of the results is presented in the tables below.

a. Cup Format

Buprenorphine

Lot	**Negative**	**-75% Cut-off**	**-50% Cut-off**	**-25% Cut-off**	**Cut-off**	**+25% Cut-off**	**+50% Cut-off**	**+75% Cut-off**	**+ 100% Cut-off**
	Neg/Pos	Neg/Pos	Neg/Pos	Neg/Pos	Neg/Pos	Neg/Pos	Neg/Pos	Neg/Pos	Neg/Pos
Lot 1	50/0	50/0	50/0	50/0	6/44	0/50	0/50	0/50	0/50
Lot 2	50/0	50/0	50/0	50/0	4/46	0/50	0/50	0/50	0/50
Lot 3	50/0	50/0	50/0	50/0	4/46	0/50	0/50	0/50	0/50

Oxycodone

Lot	Negative	-75% Cut-off	-50% Cut-off	-25% Cut-off	Cut-off	+25% Cut-off	+50% Cut-off	+75% Cut-off	+ 100% Cut-off
	Neg/Pos	Neg/Pos	Neg/Pos	Neg/Pos	Neg/Pos	Neg/Pos	Neg/Pos	Neg/Pos	Neg/Pos
Lot 1	50/0	50/0	50/0	50/0	6/44	0/50	0/50	0/50	0/50
Lot 2	50/0	50/0	50/0	50/0	6/44	0/50	0/50	0/50	0/50
Lot 3	50/0	50/0	50/0	50/0	5/45	0/50	0/50	0/50	0/50

b. Dip Card Format

Buprenorphine

Lot	Negative	-75% Cut-off	-50% Cut-off	-25% Cut-off	Cut-off	+25% Cut-off	+50% Cut-off	+75% Cut-off	+ 100% Cut-off
	Neg/Pos	Neg/Pos	Neg/Pos	Neg/Pos	Neg/Pos	Neg/Pos	Neg/Pos	Neg/Pos	Neg/Pos
Lot 1	50/0	50/0	50/0	50/0	5/45	0/50	0/50	0/50	0/50
Lot 2	50/0	50/0	50/0	50/0	5/45	0/50	0/50	0/50	0/50
Lot 3	50/0	50/0	50/0	50/0	6/44	0/50	0/50	0/50	0/50

Oxycodone

Lot	Negative	-75% Cut-off	-50% Cut-off	-25% Cut-off	Cut-off	+25% Cut-off	+50% Cut-off	+75% Cut-off	+ 100% Cut-off
	Neg/Pos	Neg/Pos	Neg/Pos	Neg/Pos	Neg/Pos	Neg/Pos	Neg/Pos	Neg/Pos	Neg/Pos
Lot 1	50/0	50/0	50/0	50/0	4/46	0/50	0/50	0/50	0/50
Lot 2	50/0	50/0	50/0	50/0	4/46	0/50	0/50	0/50	0/50
Lot 3	50/0	50/0	50/0	50/0	5/45	0/50	0/50	0/50	0/50

b. Linearity/assay reportable range:

Not applicable; the assay is intended for qualitative use only.

c. Traceability, Stability, Expected values (controls, calibrators, or methods):

Control standards are not supplied with this device; however, this device has internal process controls. A colored line appearing in the control region confirms sufficient sample volume and adequate membrane wicking. Users are informed that the test is invalid if a line fails to appear in the control region.

Stability

Accelerated and real time studies were performed on three lots of cup and dip card Wondfo Buprenorphine and Wondfo Oxycodone Urine Test formats. Accelerated stability was performed at 50°C to support an 18 month shelf life. Real-time studies were performed by storing three lots of cup and dip card formats at 4°C and 30°C respectively. Performance tests were completed at defined intervals and the results support a 23 month shelf life at 4°C-30°C for the Wondfo Buprenorphine and Wondfo Oxycodone Urine Tests. This data supports their claimed 18 month shelf life for both devices.

d. Detection limit:

Analytical performance of the device around the cutoff is described in Section f. (Assay cut-off) below.

e. Analytical specificity:

Specificity and cross-reactivity was performed by using three batches of both the cup and dip card formats of the Wondfo Buprenorphine and Wondfo Oxycodone Urine Tests. The samples were split into two aliquots and one group of operators ran the cup format on one set of aliquots and a separate group of operators ran the dip card format on the other set of aliquots. Thirty drug-free urine samples were tested and all were found to be negative, five were confirmed by GC/MS to have a concentration of zero. Cross-reactivity was determined by spiking the target drug, drug metabolites and related compounds that may cross-react with the target drugs into drug-free urine at three different concentrations and measuring the samples in triplicate using three batches of cups and three batches of dip cards. Percent cross reactivity was calculated by dividing the cut-off concentration by the minimum concentration required to obtain a positive result and multiplying 100%. A summary of the results are as follows:

Buprenorphine

BUP (Buprenorphine) (Cutoff=10 ng/mL)	**Result** Positive at 10 ng/mL	**% Cross-Reactivity** 100
Buprenorphine -3-D-Glucuronide	Positive at 15 ng/mL	66.67
Norbuprenorphine	Positive at 20 ng/mL	50
Norbuprenorphine 3-D-Glucuronide	Positive at 200 ng/mL	5

Oxycodone

OXY (Oxycodone) (Cutoff=100 ng/mL)	**Result** Positive at 100 ng/mL	**% Cross-Reactivity** 100
Dihydrocodeine	Positive at 20,000 ng/mL	0.5
Codeine	Positive at 100,000 ng/mL	0.5
Hydromorphone	Positive at 100,000 ng/mL	0.1
Morphine	Negative at 100,000 ng/mL	Not detected
Acetylmorphine	Negative at 100,000 ng/mL	Not detected
Buprenorphine	Negative at 100,000 ng/mL	Not detected
Ethylmorphine	Negative at 100,000 ng/mL	Not detected

Interference studies were performed using 3 batches of the buprenorphine and oxycodone cup and dip card tests, with structurally unrelated interfering compounds added in either drug-free urine or urine containing buprenorphine or oxycodone at ±25% of each analyte cut-off concentration. The following compounds were found not to cross react when tested at a high target concentration of 100 µg/mL.

3-Hydroxytyramine	D,L-Propanolol	L-Ephedrine	Ranitidine
Acetophenetidin	D,L-Tryptophan	Loperamide	Salicylic acid
Acetylsalicylic acid	D,L-Tyrosine	L-Phenylephrine	Serotonin
Aminopyrine	Deoxycorticosterone	Meprobamate	Sulfamethazine
Amoxicillin	Dextromethorphan	Methoxyphenamine	Sulindac
Ampicillin	Diclofenac	Morphine-3-β-D-glucuronide	Tetracycline
Apomorphine	Diflunisal	Nalidixic acid	Tetrahydrocortisone
Aspartame	Digoxin	Naloxone	Tetrahydrozoline
Atropine	Diphenhydramine	Naltrexone	Thiamine
Benzilic acid	D-Norpropoxyphene	Naproxen	Thioridazine
Benzoic acid	D-Pseudoephedrine	Niacinamide	Tolbutamide
Benzphetamine	Ecgonine methylester	Nifedipine	Tramadol (Buprenorphine only)
Bilirubin	Erythromycin	Norethindrone	Triamterene
Caffeine	Estrone-3-sulfate	Noscapine	Trifluoperazine
Chloralhydrate	Ethyl-p-aminobenzoate	O-Hydroxyhippuric acid	Trimethoprim
Chloramphenicol	Fenoprofen	Oxalic acid	Tyramine
Chlorothiazide	Furosemide	Oxolinic acid	Urine acid
Chlorpromazine	Gentisic acid	Oxymetazoline	Verapamil
Chlorquine	Hemoglobin	Papaverine	Zomepirac
Cholesterol	Hydralazine	Penicillin-G	β-Dglucuronide
Clonidine	Hydrochlorothiazide	Perphenazine	β-Estradiol
Cortisone	Hydrocortisone	Phenelzine	β-Phenylethylamine
Creatinine	Isoxsuprine	Phenylpropanolamine	
D, L-Isoproterenol	Ketoprofen	Prednisone	
D,L-Chlolrpheniramine	Labetalol	Quinidine	
D,L-Octopamine	L-Cotinine	Quinine	

pH:

The pH of a drug-free urine pool was adjusted to pH 4, pH 5, pH 6, pH 7, pH 8 or pH 9; the urine was spiked with ± 25% of the cut-off concentration of buprenorphine or oxycodone, individually and tested using three batches/lots of cup and three batches of dip card of the Wondfo Buprenorphine Urine Test and Wondfo Oxycodone Urine Tests, respectively. The spiked, pH-adjusted urine was tested in triplicate. Altering the pH levels to 4.0 to 9.0 of the urine sample did not affect the accuracy of the test results for any format.

Specific Gravity:

Twelve drug-free urine samples with specific gravities of 1.000-1.035 were collected and spiked with ± 25% of the cut-off concentration of buprenorphine and oxycodone using three batches of cup and three batches of dip card formats of the Wondfo Buprenorphine Urine Test and Wondfo Oxycodone Urine Test, respectively. The spiked urines of different specific gravities were tested in triplicate. The results indicate that there is stable performance of the Wondfo Buprenorphine Urine Test and Wondfo Oxycodone Urine Test (cup and dip card formats) when urine has a specific gravity between 1.00-1.035.

f. Assay cut-off:

The assay cut off was investigated by using three batches of both the cup and dip card of the Wondfo Buprenorphine Urine Test and Wondfo Oxycodone Urine Test to test 150 urine samples each. These samples came from the Shezhen Drug Addiction Recovery Center (25 clinical drug urine samples each with buprenorphine or oxycodone) and from drug-free urine samples (125 samples) spiked with buprenorphine or oxycodone (125 samples for each drug) diluted from the International Drug Standard (Sigma) to concentrations that are ± 25% and 50% of the cutoff concentrations (10 ng/mL for buprenorphine and 100 ng/mL for oxycodone). Drug concentrations were confirmed by GC/MS. Results were read by three laboratory assistants with relevant experience who were blinded to the samples. The cutoff studies were performed by two separate groups of operators (one for the cup format and one for the dip card format). Three operators in each group performed the readings and they were blinded to the sample. Each result was confirmed by at least two assistants. The results shown below represent samples that were tested at each concentration for each drug in replicates of 30 using three card or dip card lots (n=90) and three operators:

a. Cup

Buprenorphine

[Drug] (ng/mL)	Cut-off range	Batch 1		Batch 2		Batch 3		Total	
		-	+	-	+	-	+	-	+
5	-50% Cutoff	90	0	90	0	90	0	270	0
7.5	-25% Cutoff	90	0	90	0	90	0	270	0
10	Cut-off	10	80	10	80	12	78	32	238
12.5	+25% Cut-off	0	90	0	90	0	90	0	270
15	+50% Cut-off	0	90	0	90	0	90	0	270

Oxycodone

[Drug] (ng/mL)	Cut-off range	Batch 1		Batch 2		Batch 3		Total	
		-	+	-	+	-	+	-	+
50	-50% Cutoff	90	0	90	0	90	0	270	0
75	-25% Cutoff	90	0	90	0	90	0	270	0
100	Cut-off	13	77	11	79	10	80	34	236
125	+25% Cut-off	0	90	0	90	0	90	0	270
150	+50% Cut-off	0	90	0	90	0	90	0	270

b. Dip card

Buprenorphine

[Drug] (ng/mL)	Cut-off range	Batch 1		Batch 2		Batch 3		Total	
		-	+	-	+	-	+	-	+
5	-50% Cutoff	90	0	90	0	90	0	270	0
7.5	-25% Cutoff	90	0	90	0	90	0	270	0
10	Cut-off	13	77	11	79	10	80	34	236
12.5	+25% Cut-off	0	90	0	90	0	90	0	270
15	+50% Cut-off	0	90	0	90	0	90	0	270

Oxycodone

[Drug] (ng/mL)	Cut-off range	Batch 1		Batch 2		Batch 3		Total	
		-	+	-	+	-	+	-	+
50	-50% Cutoff	90	0	90	0	90	0	270	0
75	-25% Cutoff	90	0	90	0	90	0	270	0
100	Cut-off	10	80	11	79	11	79	32	238
125	+25% Cut-off	0	90	0	90	0	90	0	270
150	+50% Cut-off	0	90	0	90	0	90	0	270

2. Comparison studies:
   a. Method comparison with predicate device:

   1. Performance of the Wondfo Buprenorphine Urine Test and Wondfo Oxycodone Urine Test (cup and dip card formats) was established by comparing 80 clinical samples (40 negative and 40 positive) of each drug against GC/MS. There were two groups of operators (one for the cup format and one for the dip card format) and they were blinded to the samples. Each result was read by three laboratory assistants with relevant experience and a lay person (who is different between Groups A and B for Oxycodone only) with no experience other than reading the instructions for use. A summary of results comparing the results of the lay person to the experienced person are as follows:

      a. Cup

Buprenorphine

Wondfo Device Result		Drug-free urine	< -50% of the cut-off	-50% of the cut-off to the cut-off	cut-off to +50% of the cut-off	> +50% of the Cut-off
Viewer A	+	0	0	1	16	24
	-	10	18	11	0	0
Viewer B	+	0	0	1	16	24
	-	10	18	11	0	0
Viewer C	+	0	0	1	16	24
	-	10	18	11	0	0

Oxycodone

Wondfo Device Result		Drug-free urine	< -50% of the cut-off	-50% of the cut-off to the cut-off	cut-off to +50% of the cut-off	> +50% of the Cut-off
Viewer A	+	0	0	2	19	21
	-	10	20	8	0	0
Viewer B	+	0	0	2	19	21
	-	10	20	8	0	0
Viewer C	+	0	0	1	19	21
	-	10	20	9	0	0
Lay Person	+	0	0	2	19	21
	-	10	20	8	0	0

b. Dip Card

Buprenorphine:

Wondfo Device Result		Drug-free urine	< -50% of the cut-off	-50% of the cut-off to the cut-off	cut-off to +50% of the cut-off	> +50% of the Cut-off
Viewer A	+	0	0	1	16	24
	-	10	18	11	0	0
Viewer B	+	0	0	1	16	24
	-	10	18	11	0	0
Viewer C	+	0	0	2	16	24
	-	10	18	10	0	0

Oxycodone

Wondfo Device Result		Drug-free urine	< -50% of the cut-off	-50% of the cut-off to the cut-off	cut-off to +50% of the cut-off	> +50% of the Cut-off
Viewer A	+	0	0	1	19	21
	-	10	20	9	0	0
Viewer B	+	0	0	1	19	21
	-	10	20	9	0	0
Viewer C	+	0	0	1	19	21
	-	10	20	9	0	0
Lay Person	+	0	0	2	19	21
	-	10	20	8	0	0

A summary of discordant results for buprenorphine and oxycodone are as follows:

a. Cup:

Viewer	Sample Number	GC/MS result (ng/mL)	Viewer Result
Viewer A	BUP217	9.2	positive
Viewer B	BUPC62	9.5	positive
Viewer C	BUP217	9.2	positive
Viewer A	OXYC61	91.5	positive
Viewer A	OXYC65	92.3	positive
Viewer B	OXYC62	90.8	positive
Viewer B	OXYC65	92.3	positive
Viewer C	OXYC61	91.5	positive
Lay person	OXYC61	91.5	positive
Lay person	OXYC65	92.3	positive

b. Dip Card:

Viewer	Sample Number	GC/MS result (ng/mL)	Viewer Result
Viewer A	BUPC62	9.5	positive
Viewer B	BUPC65	9.1	positive
Viewer C	BUPC65	9.1	positive
Viewer C	BUP217	9.2	positive
Viewer A	OXYC65	92.3	positive
Viewer B	OXYC61	91.5	positive
Viewer C	OXYC61	91.5	positive
Lay person	OXYC61	91.5	positive
Lay person	OXYC65	92.3	positive

The results indicate similar positive, negative, and overall agreement rates for both buprenorphine and oxycodone using the cup and dip card formats.

The overall agreement between the Wondfo devices and GC/MS is presented in the table below:

% Agreement	BUP (Cup)	BUP (Dip Card)	OXY (Cup)	OXY (Dip Card)
Positive	100%	100%	100%	100%
Negative	97.5%	96.7%	95.8%	97.5%
Overall	98.8%	98.3%	97.9%	98.8%

The overall agreement between the lay viewer and experienced viewer is presented in the table below:

% Agreement	OXY (Cup)	OXY (Dip Card)
Positive	100%	100%
Negative	99.2%	97.4%
Overall	99.6%	98.7%

b. A lay-user study was performed to assess the suitability of the device for home use. Six drug-free urine sample pools spiked to ± 25%, ± 50%, ± 75% of the cut-off of oxycodone (100 ng/mL) and a negative urine pool with no drug were tested. These concentrations were confirmed by GC/MS and aliquoted into 40 individual containers per concentration (20 aliquots per concentration for each format). The testing was performed by 140 blinded lay users divided between three sites (140 users for cup and a different group of 140 for dip card format for the Wondfo Oxycodone Urine Test). Each participant received the package insert, 1 blinded sample, and either a test cup or dip card. The lay persons test result was compared to the GC/MS result to demonstrate accuracy and precision by lay-users. The following are the results of the lay-user study pooled together from all three sites for the cup format:

Oxycodone:

% of Cutoff	Number of Samples	Oxycodone GC/MS Concentration (ng/mL)	Lay person results: Pos/Neg	% of Correct Results
Negative	20	0	0/20	100
-75 % Cutoff	20	23.9	0/20	100
-50 % Cutoff	20	54.7	0/20	100
-25 % Cutoff	20	70.8	2/18	90
+25% Cutoff	20	130.2	18/2	90
+50 % Cutoff	20	144.4	20/0	100
+75 % Cutoff	20	182.1	20/0	100

The following are the results of the lay-user study pooled together from all three sites for the dip card format:

Oxycodone:

% of Cutoff	Number of Samples	Oxycodone GC/MS Concentration (ng/mL)	Lay person results: Pos/Neg	% of Correct Results
Negative	20	0	0/20	100
-75 % Cutoff	20	23.9	0/20	100
-50 % Cutoff	20	54.7	0/20	100
-25 % Cutoff	20	70.8	3/17	85
+25% Cutoff	20	130.2	19/1	95
+50 % Cutoff	20	144.4	20/0	100
+75 % Cutoff	20	182.1	20/0	100

The overall percent agreement between the Lay person and the GC/MS method was:

% Agreement	OXY (Cup)	OXY (Dip Card)
Total	97.1%	97.1%

c. The subject's were to fill out a questionnaire to evaluate the effectiveness of the labeling. Different people tested the cup and dip card formats.

i. Cup format

Oxycodone:
The participants' ages ranged from 21-64 and there was a fairly even distribution between males and females. They come from a variety of career and education backgrounds and one participant had used a home drug kit before. They all understood the storage and expiration of the device and that the test could not be reused. They all understood that they could not insert and rotate the key until they were ready to test. They all understood to read the result at 5 minutes (none after 5 minutes) and how to interpret the results. 80/140 said the test was very easy and 60/140 said it was easy. 59/140 said the instructions were very clear and 81/140 said they were clear. 73/140 said the interpretation of the results was very clear and 67/140 said they were clear. When asked what they would do if the device failed to show a result, 98/140 said they would repeat the test with a new test device, 5/140 said they would

turn to another method, and 37/140 said they would call the manufacturer if the device failed to show a result.

ii. Dip Card format

Oxycodone:
The participant's ages ranged from 21-65 and there were slightly more males than females. They come from a variety of career and education backgrounds and none of the participants had used a home drug kit before. They all understood the storage and expiration of the device and that the test could not be reused. They all understood that the dip card couldn't be immersed in urine above the marker line and understood to read the result at 5 minutes (none after 5 minutes) and how to interpret the results. One of the participants responded that the strip test was difficult, 64/140 said the test was very easy and 75/140 said it was easy. 72/140 said the instructions were very clear and 68/140 said they were clear. 80/140 said the interpretation of the results was very clear and 60/140 said they were clear. When asked what they would do if the device failed to show a result, 110/140 said they would repeat the test with a new test device, 2/140 said they would turn to another method, and 28/140 said they would call the manufacturer if the device failed to show a result.

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

b. Matrix comparison:

Not applicable; these devices are intended for use with human urine only.

3. Clinical studies:

a. Clinical Sensitivity:

Not applicable.

b. Clinical specificity:

Not applicable.

c. Other clinical supportive data (when a. and b. are not applicable):

Not applicable.

4. Clinical cut-off:

Not applicable.

5. Expected values/Reference range

   Not applicable.

N. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

O. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.