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

A. 510(k) Number:

k112310

B. Purpose for Submission:

New device

C. Measurand:

Methadone, Morphine

D. Type of Test:

Qualitative lateral flow chromatographic immunoassay

E. Applicant:

Guangzhou Wondfo Biotech Co., Ltd.

F. Proprietary and Established Names:

Wondfo Methadone Urine Test
Wondfo Morphine (2000) Urine Test

G. Regulatory Information:

1. Regulation section:

   21 CFR §862.3620, Methadone Test System
   21 CFR §862.3650, Morphine Test System

2. Classification:

   All are Class II

3. Product code:

   DJR, DJG

4. Panel:

Toxicology (91)

H. Intended Use:

1. Intended use(s):

   See indications for use below.

2. Indications(s) for use:

   Wondfo Methadone Urine Test:
   Wondfo Methadone Urine Test is an immunochromatographic assay for the qualitative determination of methadone in human urine at a cutoff concentration of 300 ng/mL. The test is available in a dip card format and a cup format. It is intended for prescription use and over the counter 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 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 Morphine (2000) Urine Test:

   Wondfo Morphine (2000) Urine Test is an immunochromatographic assay for the qualitative determination of Morphine in human urine at a cutoff concentration of 2000 ng/mL. The test is available in a dip card format and a cup format. It is intended for prescription use and over the counter 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 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 and over-the counter use.

4. Special instrument requirements:

   Not Applicable

I. Device Description:

The tests 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 Methadone and Morphine. 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. When sample drug levels are zero or below the target cut off (the detection sensitivity of the test), antibody-dye conjugate binds to the drug-protein conjugate immobilized in the Test Region (T) of the device. This produces a colored Test line, which regardless of its intensity, indicates a negative result.

When sample drug levels are at or above the target cutoff, the free drug in the binding sample binds to the antibody-dye conjugate preventing the antibody-dye conjugate from binding to the drug-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), if the test has been performed properly because of the antibody-dye conjugate binding to anti-mouse IgG immobilized in the Control Region of the device.

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. When sample drug levels are zero or below the target cut off (the detection sensitivity of the test), antibody-dye conjugate binds to the drug-protein conjugate immobilized in the Test Region (T) of the device. This produces a colored Test line, which regardless of its intensity, indicates a negative result.

When sample drug levels are at or above the target cutoff, the free drug in the binding sample binds to the antibody-dye conjugate preventing the antibody-dye conjugate from binding to the drug-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), if the test has been performed properly because of the antibody-dye conjugate binding to anti-mouse IgG immobilized in the Control Region of the device.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   ACON One Step Drug Screen Test Card

2. Predicate 510(k) number(s):

   k020771

3. Comparison with predicate:

Reagent Similarities and Differences		
Feature	**Candidate Device: Wondfo Methadone Urine Test and Wondfo Morphine (2000) Urine Test (k112310)**	**Predicate Device: ACON One Step Drug Screen Card (k020771)**
Intended Use /Indications for Use	For the qualitative determination of Methadone, Morphine in individual human urine.	Same (different number of drugs detected)
Methodology	Competitive binding, lateral flow immunochromatographic assays based on the principle of antigen-antibody immunochemistry	Same
Type of Test	Immunoassay principles that rely on antigen-antibody interactions to indicate positive or negative result	Same
Results	Qualitative	Same
Specimen Type	Human Urine	Same
Cut Off Value	Methadone: 300 ng/ml Morphine: 2000 ng/ml	Same
Configurations	Cup, Dip Card	Card, dip card with integrated cup (same)
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

L. Test Principle:

Immunochromatograph assay using a lateral flow, one step system for the qualitative detection of Methadone and Morphine in human urine. Each assay uses a mouse monoclonal antibody-dye conjugate against drug with gold chloride and fixed drug-protein conjugate and anti-mouse IgG polyclonal antibody in membrane.

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 with: 600, 525, 450, 375, 300, 225, 150, 75 and 0 ng/ml of methadone, corresponding to ± 25, 50, 75, and 100% of the 300 ng/ml cut-off value; and 4000, 3500, 300, 2500, 2000, 1500, 1000, 500 and 0 ng/ml of morphine, corresponding to ± 25, 50, 75, and 100% of the 2000 ng/ml cut-off value. Two sets of operators performed the testing (group A ran the cup format and group B ran the dip card format) and 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 Methadone Urine Test and Wondfo Morphine (2000) 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

Methadone

Lot	**-100% Cut-off**	**-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	Ne/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	5/45	0/50	0/50	0/50	0/50

Morphine

Lot	**-100% Cut-off**	**-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	Ne/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

b. Dip Card Format

Methadone

Lot	-100% Cut-off	-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	Ne/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	7/43	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

Morphine

Lot	-100% Cut-off	-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	Ne/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

b. Linearity/assay reportable range:

Not Applicable, the assay is intended for qualitative use

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 have been conducted. Protocols and acceptance criteria were described and found to be acceptable. The manufacturer claims an 18 month shelf life.

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 Methadone Urine Test and Wondfo Morphine (2000) 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 the same class 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.

Methadone

MTD (Methadone) (Methadone, Cutoff = 300 ng/ml)	**Result** (Positive at 300 ng/ml**)**	**% Cross Reactivity** 100%
Doxylamine	Positive at 50000 ng/ml	0.6%

Morphine

MOR(Morphine) (Morphine, Cutoff= 2000 ng/ml)	**Result** (Positive at 2000 ng/ml)	**% Cross Reactivity** 100%
Codeine	Positive at 2000 ng/mL	100%
Ethylmorphine	Positive at 5000 ng/mL	40%
Hydrocodone	Positive at 12,500 ng/mL	16%
Hydromorphine	Positive at 5000 ng/mL	40%
Levorphanol	Positive at 75000 ng/mL	2.7%
s-Monoacetylmorphine	Positive at 5000 ng/mL	40%
Morphine 3-b-glucuronide	Positive at 2000 ng/mL	100%
Norcodeine	Positive at 12500 ng/mL	16%
Normorphone	Positive at 50000 ng/mL	4%
Oxycodone	Positive at	8%

	25000 ng/mL	
Oxymorphine	Positive at 25000 ng/mL	8%
Procaine	Positive at 150000 ng/mL	1.3%
Thebaine	Positive at 100000 ng/mL	2%

The following unrelated compounds were found not to cross-react when tested spiked (100 µg/mL) into drug-free urine, as well as into urine spiked with ± 25% of the cut-off concentration of methadone or Morphine individually:

Methadone

Acetaminophen
Acetophenetidin
N-Acetylprocainamide
Acetylsalicylic Acid
Aminopyrine
Amitryptyline
Amobarbital
Amoxicillin
Ampicillin
L-Ascorbic Acid
DL-Amphetamine Sulfate
Apomorphine
Aspartame
Atropine
Benzilic Acid
Benzoic Acid
Benzoylecgonine
Benzphetamine
Bilirubin
(+/-) Brompheniramine
Caffeine
Cannabidiol
Cannabinol
Chloralhydrate
Chloramphenicol
Chlorothiazide
(+/-) Chlorpheniramine
Chlorpromazine
Chlorquine
Cholesterol
Clomipramine
Deoxycorticosterone
Dextrmethorphan
Diazepam
Diclofenac
Diflunisal
Digoxin
Diphenydramine
Ecgonine Hydrochloride
Ecgonine Methyl Ester
(-)-Ephedrine
[1R,2S]-(-)-Ephedrine
(L)-Epinephrine
Erythromycin
-Estradiol
Estrone-3-Sulfate
Ethyl-p-aminobenzoate
Fenoprofen
Furosemide
Gentisic acid
Hemoglobin
Hydralazine
Hydrochlorothiazide
Hydrocodone
Hydrocortisone
O-Hydroxylhippuric Acid
p-Hydroxylamphetamine
p-Hydroxymethamphetamine
3-Hydroxytyramine
Ibuprofen
Imipramine
Iproniazid
Meprobamate
Methamphetamine
Methoxyphenamine
(+/-)-3,4-Methylenedioxy-amphetamine Hydrochloride
(+/-)-3,4-Methylenedioxy-methamphetamine Hydrochloride
Morphine-3--D-glucoronide
Morphine Sulfate
Nalidixic Acid
Naloxone
Naltrexone
Naproxen
Niacinamide
Nifedipine
Norcodein
Norethindrone
D-Norpropoxyphene
Noscapine
D,L-Octopamine
Oxalic Acid
Oxazepam
Oxolinic Acid
Oxycodone
Oxymetazoline
Papaverine
Penicillin-G
Petazocine Hydrochloride
Pentobarbital
Perphenazine
Phencyclidine
DL-Propranolol
D-Propoxyphene
D-Pseudoephedrine
Quinacrine
Quinidine
Quinine
Ranitidine
Salicylic Acid
Secobarbital
Serotonin
Sulfamethazine
Sulindac
Tetracycine
Tetrahydrocortisone, 3-acetate
Tetreahydrocortisone 3-(-D-glucoronide)
Tetrahydrozoline
Thebaine
Thiamine
Thioridazine
DL-Tyrosine
Tolbutamide
Triamterene
Trifluoperazine
Trimethoprim
Trimipramine
Tryptamine
DL-Tryptophan
Tyramine
Uric acid

Clonidine
Cocathylene
Temazepam
Cocaine Hydrochloride
Codeine
Cortisone
(-) Cotinine
Creatinine

(+/-)-Isoproterenol
Isoxsuprine
Ketamine
Ketoprofen
Labetalol
Levorphanol
Loperamide
Mephentermine
Maprotiline
Meperidine

Phenelzine
Phenobarbital
Phentermine
Trans-2-phenylcyclo
-propylamine hydrochloride
L-Phenylephrine
□-Phenylethylamine
Phenylpropanolamine
Prednisolone
Prednisone
Procaine
Promazine
Promethazine

Verapamil
Zomepirac

Morphine

4-Acetamidophenol
Acetophenetidin
N-Acetylprocainamide
Acetylsalicylic Acid
Aminopyrine
Amitryptyline
Amobarbital
Amoxicillin
Ampicillin
L-Ascorbic Acid
DL-Amphetamine
Apomorphine
Aspartame
Atropine
Benzilic Acid
Benzoic Acid
Benzoylecgonine
Benzphetamine

Deoxycorticosterone
Dextrmethorphan
Diazepam
Diclofenac
Diflunisal
Digoxin
Diphenydramine
Doxylamine
Ecgonine Hydrochloride
Ecgonine Methyl Ester
(-)-□Ephedrine
Erythromycin
□-Estradiol
Estrone-3-Sulfate
Ethyl-p-aminobenzoate
Fenoprofen
Furosemide
Gentisic acid

Meprobamate
Methadone
Methoxyphenamine
(+)-3,4-Methylenedioxy-
amphetamine Hydrochloride
(+)-3,4-Methylenedioxy-
methamphetamine Hydrochloride
Nalidixic Acid
Nalorphine
Naloxone
Naltrexone
Naproxen
Niacinamide
Nifedipine
Norethindrone
D-Norpropoxyphene
Noscapine
D,L-Octopamine

DL-Propranolol
D-Propoxyphene
D-Pseudoephedrine
Quinidine
Quinine
Ranitidine
Salicylic Acid
Secobarbital
Serotonin
Sulfamethazine
Sulindac
Temazepam
Tetracycine
Tetrahydrocortisone,
3-acetate
Tetreahydrocortisone
3-(□-D-
glucoronide

Bilirubin
(+/-) Brompheniramine
Caffeine
Cannabidiol
Chloralhydrate
Chloramphenicol
Chlordiazepoxide
Chlorothiazide
(+/-) Chlorpheniramine
Chlorpromazine
Chlorquine
Cholesterol
Clomipramine

Hemoglobin
Hydralazine
Hydrochlorothiazide
Hydrocortisone
O-Hydroxylhippuric Acid
p-Hydroxymethamphetamine
3-Hydroxytyramine
Ibuprofen
Imipramine
Iproniazid
(+/-)-Isoproterenol
Isoxsuprine
Ketamine

Oxalic Acid
Oxazepam
Oxolinic Acid
Oxymetazoline
Papaverine
Penicillin-G
Petazocine
Pentobarbital
Perphenazine
Phencyclidine
Phenelzine
Phenobarbital
Phentermine

Tetrahydrozoline
Thiamine
Thioridazine
DL-Tyrosine
Tolbutamide
Triamterene
Trifluoperazine
Trimethoprim
Trimipramine
Tryptamine
DL-Tryptophan
Tyramine

Clonidine	Ketoprofen	L-Phenylephrine	Uric acid
Cocaine Hydrochloride	Labetalol	□-Phenylethylamine	Verapamil
Cortisone	Loperamide	Phenylpropanolamine	Zomepirac
(-) Cotinine	Maprotiline	Prednisone	
Creatinine	Meperidine		

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 methadone or morphine, individually and tested using three batches of cup and three batches of dip card of the Wondfo Methadone Urine Test and Wondfo Morphine (2000) Urine Tests, respectively. The spiked, pH-adjusted urine was tested in triplicate. Altering the pH of the urine sample did not affect the accuracy of any of the test results.

The specific gravity of a drug-free urine pool was measured by obtaining urine samples with specific gravities of 1.000-1.035 and spiking with ± 25% of the cut-off concentration of methadone and morphine, individually using three batches of cup and three batches of dip card of the Wondfo Methadone Urine Test and Wondfo Morphine (2000) 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 Methadone Urine Test and Wondfo Morphine Urine Tests 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 Methadone Urine Test and Wondfo Morphine (2000) Urine Test to test 150 urine samples each. These samples came from the Shezhen Drug Addiction Recovery Center (25 Drug urine samples each with Methadone or morphine) and from drug-free urine samples (125 samples) spiked with methadone or morphine (125 samples for each drug) diluted from the International Drug Standard (Sigma) to concentrations that are plus and minus 25% and 50 % of the cutoff concentrations. Drug concentrations were confirmed by GC/MS. Results were read by three laboratory assistants with relevant experience. The cutoff studies were performed by two separate groups of operators (one for the strip format and one for the cassette 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.

a. Cup

Methadone

[Drug] (ng/ml)	**Cut-off range**	**Batch 1**		**Batch 2**		**Batch 3**		**Total**	
		-	**+**	**-**	**+**	**-**	**+**	**-**	**+**
~150	-50% Cutoff	90	0	90	0	90	0	270	0
~225	-25% Cutoff	90	0	90	0	90	0	270	0

~300	Cut-off	13	77	12	78	10	80	35	235
~375	+25% Cut-off	0	90	0	90	0	90	0	270
~450	+50% Cut-off	0	90	0	90	0	90	0	270

Morphine

[Drug] (ng/ml)	Cut-off range	Batch 1		Batch 2		Batch 3		Total	
		-	+	-	+	-	+	-	+
~1000	-50% Cutoff	90	0	90	0	90	0	270	0
~1500	-25% Cutoff	90	0	90	0	90	0	270	0
~2000	Cut-off	10	80	10	80	12	78	32	238
~2500	+25% Cut-off	0	90	0	90	0	90	0	270
~3000	+50% Cut-off	0	90	0	90	0	90	0	270

b. Dip Strip:

Methadone

[Drug] (ng/ml)	Cut-off range	Batch 1		Batch 2		Batch 3		Total	
		-	+	-	+	-	+	-	+
~150	-50% Cutoff	90	0	90	0	90	0	270	0
~225	-25% Cutoff	90	0	90	0	90	0	270	0
~300	Cut-off	11	79	12	78	8	82	31	239
~375	+25% Cut-off	0	90	0	90	0	90	0	270
~450	+50% Cut-off	0	90	0	90	0	90	0	270

Morphine

[Drug] (ng/ml)	Cut-off range	Batch 1		Batch 2		Batch 3		Total	
		-	+	-	+	-	+	-	+
~1000	-50% Cutoff	90	0	90	0	90	0	270	0
~1500	-25% Cutoff	90	0	90	0	90	0	270	0
~2000	Cut-off	13	77	11	79	10	80	34	236
~2500	+25% Cut-off	0	90	0	90	0	90	0	270

~3000	+50% Cut-off	0	90	0	90	0	90	0	270

The cut-off values were determined to be:

Test	Calibrator	Cut-off (ng/ml)
Methadone	Methadone	300
Morphine	Morphine	2000

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

   1. Performance of the Wondfo Methadone Urine Test and Wondfo Morphine (2000) Urine Test (cup and dip stick formats) was established by comparing 80 samples of each analyte against GC/MS. These samples came from drug-free urine (10 samples each), the Shezhen Drug Addiction Recovery Center (70 samples for each analyte) and from clinical samples with concentrations ranges as follows: 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, and > +50% of the Cut-off. There were two groups of operators (one for the cup format and one for the dip stick format) and they were blinded to the samples. Each result was read by three laboratory assistants with relevant experience and a lay person with no experience other than reading the instructions for use.

      a. Cup

      Methadone:

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	12	16	0	0
Viewer B	+	0	0	1	19	21
	-	10	12	17	0	0
Viewer C	+	0	0	2	19	21
	-	10	12	16	0	0
Lay Person	+	0	0	3	19	21
	-	10	12	15	0	0

Morphine

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	18	22
	-	10	20	9	0	0
Viewer B	+	0	0	1	18	22
	-	10	20	9	0	0
Viewer C	+	0	0	1	18	22
	-	10	20	9	0	0
Lay Person	+	0	0	2	18	22
	-	10	20	8	0	0

b. Dip Card

Methadone:

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	12	17	0	0
Viewer B	+	0	0	2	19	21
	-	10	12	16	0	0
Viewer C	+	0	0	1	19	21
	-	10	12	17	0	0
Lay Person	+	0	0	2	19	21
	-	10	12	16	0	0

Morphine

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	18	22
	-	10	20	9	0	0
Viewer	+	0	0	1	18	22

B	-	10	20	9	0	0
Viewer C	+	0	0	1	18	22
	-	10	20	9	0	0
Lay Person	+	0	0	1	18	22
	-	10	20	9	0	0

The discordant results are listed in the table below.

a. Cup:

Viewer	**Sample Number**	**GC/MS result**	**Viewer Result**
Viewer A	MTDC63	278	positive
Viewer A	MTD 212	280	positive
Viewer B	MTD 212	280	positive
Viewer C	MTD 212	280	positive
Viewer C	MTD 216	280	positive
Lay person	MTDC63	278	positive
Lay person	MTD 212	280	positive
Lay person	MTD 216	280	positive
Viewer A	OPIC61	1906	positive
Viewer B	OPIC65	1923	positive
Viewer C	OPIC61	1906	positive
Lay person	OPIC61	1906	positive
Lay person	OPIC65	1923	positive

b. Dip Card:

Viewer	Sample Number	GC/MS result	Viewer Result
Viewer A	MTD 212	280	positive
Viewer B	MTDC63	278	positive
Viewer B	MTD 216	280	positive
Viewer C	MTD 212	280	positive
Lay person	MTDC63	278	positive
Lay person	MTD 212	280	positive
Viewer A	OPIC65	1923	positive
Viewer B	OPIC61	1906	positive
Viewer C	OPIC61	1906	positive
Lay person	OPIC65	1923	positive

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

% Agreement	MTD (Cup)	MTD (Dip Card)	MOR (Cup)	MOR (Dip Card)
Positive	100%	100%	100%	100%
Negative	95.8%	96.7%	97.5%	97.5%
Overall	97.9%	98.4%	98.8%	98.8%

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

% Agreement	MTD (Cup)	MTD (Dip Card)	MOR (Cup)	MOR (Dip Card)
Positive	100%	100%	100%	100%
Negative	96.6%	98.2%	97.4%	100%
Overall	98.3%	99.1%	98.7%	100%

B. A lay-user study was performed to assess the suitability of the device for home use. Six drug-free urine sample pools were spiked to ± 25%, ± 50%, ± 75% of the cutoff of target drug, additionally a negative urine pool with no drug was tested. These concentrations were confirmed by GC/MS and aliquoted into 40 individual containers per concentration (20 aliquots per concentration for each strip format). The testing was performed at three sites by 140 blinded consumers divided between three sites (140 users for cup, 140 for dip card for each of the Wondfo

Methadone Urine Test and Wondfo Morphine (2000) Urine Test). The lay users were chosen from likely intended users at the Guangzhou No. 8 People's Hospital, Guangzhou Mental Hospital, and Guangdong Provincial No. 2 People's Hospital. Each participant received the package inset, 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 by lay-users. The following are the results of the lay-user study pooled together from all three sites for the cup format:

Methadone

% of Cutoff	Number of Samples	Methadone GC/MS Concentration (ng/mL)	Lay person results: Pos/Neg	Percentage of Correct Results
-100% of the Cut-off	20	0	0/20	100
-75 % Cutoff	20	69.5	0/20	100
-50 % Cutoff	20	186.6	0/20	100
-25 % Cutoff	20	248.2	3/17	85.0
+25% Cutoff	20	386.7	19/1	95.0
+50 % Cutoff	20	469.8	20/0	100
+75 % Cutoff	20	550.6	20/0	100

Morphine:

% of Cutoff	Number of Samples	Morphine GC/MS Concentration (ng/mL)	Lay person results: Pos/Neg	Percentage of Correct Results
-100% of the Cut-off	20	0	0/20	100
-75 % Cutoff	20	478.7	0/20	100
-50 % Cutoff	20	1080.8	0/20	100
-25 % Cutoff	20	1409.5	2/18	90.0
+25% Cutoff	20	2625.4	19/1	95.0
+50 % Cutoff	20	2900.6	20/0	100
+75 % Cutoff	20	3605.2	20/0	100

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

Methadone:

% of Cutoff	Number of Samples	Methadone GC/MS Concentration (ng/mL)	Lay person results: Pos/Neg	Percentage of Correct Results
-100% of the Cut-off	20	0	0/20	100
-75 % Cutoff	20	86.2	0/20	100
-50 % Cutoff	20	173.5	0/20	100
-25 % Cutoff	20	203.4	2/18	90.0
+25% Cutoff	20	401.6	19/1	95.0
+50 % Cutoff	20	466.5	20/0	100
+75 % Cutoff	20	560.8	20/0	100

Morphine:

% of Cutoff	Number of Samples	Morphine GC/MS Concentration (ng/mL)	Lay person results: Pos/Neg	Percentage of Correct Results
-100% of the Cut-off	20	0	0/20	100
-75 % Cutoff	20	478.7	0/20	100
-50 % Cutoff	20	1080.8	0/20	100
-25 % Cutoff	20	1409.5	2/18	90.0
+25% Cutoff	20	2625.4	20/0	100
+50 % Cutoff	20	2900.6	20/0	100
+75 % Cutoff	20	3605.2	20/0	100

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

% Agreement	Methadone (Cup)	Methadone (Dip Card)	Morphine (Cup)	Morphine (Dip Card)
Total	97.1%	97.8%	97.8%	98.6%

C. The subject's were to fill out a questionnaire to evaluate labeling access.

i. Cup format

Methadone:
The participants's ages ranged from 23-59 and there were slightly more males than females. They come from a variety of career and education backgrounds and 2 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 to read the result within 5 minutes and how to interpret the results. Two of the participants responded that the cup test was difficult, 69/140 said the test was very easy and 69/140 said it was easy. 72/140 said the instructions were very clear and 68/140 said they were clear. 88/140 said the interpretation of the results was very clear and 52/140 said they were clear. When asked what they would do if the device failed to show a result, 109/140 said they would

repeat the test with a new test device 2/140 said they would turn to another method, and 29/140 said they would call the manufacturer if the device failed to show a result.

Morphine:
The participant's ages ranged from 22-59 and they were evenly distributed between males and females. They come from a variety of career and education backgrounds and three 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 to read the result within 5 minutes and how to interpret the results. One of the participants responded that the strip test was difficult, 70/140 said the test was very easy and 69/140 said it was easy. 66/140 said the instructions were very clear and 74/140 said they were clear. 79/140 said the interpretation of the results was very clear and61/140 said they were clear. When asked what they would do if the device failed to show a result, 105/140 said they would repeat the test with a new test device, 2/140 said they would turn to another method, and 33/140 said they would call the manufacturer if the device failed to show a result.

ii. Dip Card format

Methadone:
The participant's ages ranged from 23-64 and there were slightly more males than females. They come from a variety of career and education backgrounds and only 1 subject 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 to read the result within 5 minutes and how to interpret the results. Two of the participants responded that the strip test was difficult, 70/140 said the test was very easy and 58/140 said it was easy. 55/140 said the instructions were very clear and 85/140 said they were clear. 90/140 said the interpretation of the results was very clear and 50/140 said they were clear. When asked what they would do if the device failed to show a result, 114/140 said they would repeat the test with a new test device, 2/140 said they would turn to another method, and 24/140 said they would call the manufacturer if the device failed to show a result.

Morphine:
The participant's ages ranged from 21-62 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 to read the result within 5 minutes and how to interpret the results. One of the participants responded that the strip test was difficult, 60/140 said the test was very easy and 79/140 said it was easy. 79/140 said the instructions were very clear and 61/140 said they were clear. 92/140

said the interpretation of the results was very clear and 48/140 said they were clear. When asked what they would do if the device failed to show a result, 107/140 said they would repeat the test with a new test device, 3/140 said they would turn to another method, and 30/140 said they would call the manufacturer if the device failed to show a result.

Additionally, a Flesh-Kincaid reading analysis revealed that both package inserts had a reading grade level of 7.

b. Matrix comparison:

Not applicable.

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

Specific ranges for each analyte/methodology are listed in the package insert.

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.