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

A. 510(k) Number:

k182701

B. Purpose for Submission:

New device

C. Measurands:

Amphetamine, Buprenorphine, Secobarbital, Oxazepam, Cocaine, 2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine, Methamphetamine, Methylenedioxymethamphetamine, Morphine, Methadone, Oxycodone, Phencyclidine, Propoxyphene, Nortriptyline and Cannabinoids

D. Type of Test:

Qualitative, lateral flow immunoassay

E. Applicant:

Guangzhou Wondfo Biotech Co., Ltd.

F. Proprietary and Established Names:

Wondfo T-Cup® Multi-Drug Urine Test Cup

G. Regulatory Information:

Product Code	Classification	Regulation	Panel
NFT	Class II	21 CFR 862.3100, Amphetamine Test System	Toxicology (91)
NGL	Class II	21 CFR 862.3650, Opiate Test System	Toxicology (91)
PTH	Class II	21 CFR 862.3150, Barbiturate Test System	Toxicology (91)
NFV	Class II	21 CFR 862.3170, Benzodiazepine Test System	Toxicology (91)
NFY	Class II	21 CFR 862.3250, Cocaine and Cocaine Metabolites	Toxicology (91)

PTG	Class II	21 CFR 862.3620, Methadone Test System	Toxicology (91)
NGG	Class II	21 CFR 862.3610, Methamphetamine Test System	Toxicology (91)
LCK	N/A	Unclassified	Toxicology (91)
QBF	Class II	21 CFR 862.3700, Propoxyphene test system	Toxicology (91)
QAW	Class II	21 CFR 862.3910, Tricyclic antidepressant drugs test	Toxicology (91)
NFW	Class II	21 CFR 862.3870 Cannabinoids Test System	Toxicology (91)

H. Intended Use:

1. Intended use(s):

   Refer to Indications for Use below.

2. Indication(s) for use:

   Wondfo T-Cup® Multi-Drug Urine Test Cup tests are competitive binding, lateral flow immunochromatographic assays for qualitative and simultaneous detection of Amphetamine, Buprenorphine, Secobarbital, Oxazepam, Cocaine, 2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine, Methamphetamine, Methylenedioxymethamphetamine, Morphine, Methadone, Oxycodone, Phencyclidine, Propoxyphene, Nortriptyline and Cannabinoids in human urine at the cutoff concentrations of:

Analyte	Cutoff (ng/mL)
Amphetamine (AMP)	1000 ng/mL or 500 ng/mL
Buprenorphine (BUP)	10 ng/mL
Secobarbital (BAR)	300 ng/mL
Oxazepam (BZO)	300 ng/mL
Cocaine (COC)	300 ng/mL or 150 ng/mL
2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP)	300 ng/mL
Methamphetamine (MET)	1000 ng/mL or 500 ng/mL
Methylenedioxymethamphetamine (MDMA)	500 ng/mL
Morphine (MOP 300/OPI 2000)	2000 ng/mL or 300 ng/mL
Methadone (MTD)	300 ng/mL
Oxycodone (OXY)	100 ng/mL
Phencyclidine (PCP)	25 ng/mL
Propoxyphene (PPX)	300 ng/mL

Analyte	Cutoff (ng/mL)
Nortriptyline (TCA)	1000 ng/mL
Cannabinoids (THC)	50 ng/mL

Wondfo T-Cup® Multi-Drug Urine Test Cup offers any combinations from 2 to 15 drugs of abuse tests but only one cutoff concentration under same drug condition will be included per device. It is for in vitro diagnostic use only.

The tests may yield positive results for the prescription drugs Buprenorphine, Nortriptyline, Oxazepam, Secobarbital, Propoxyphene, and Oxycodone when taken at or above prescribed doses. It is not intended to distinguish between prescription use or abuse of these drugs. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly in evaluating a preliminary positive result.

The tests provide only preliminary results. To obtain a confirmed analytical result, a more specific alternate chemical method must be used. GC/MS or LC/MS is the recommended confirmatory method.

3. Special conditions for use statement(s):

   For over the counter use.

4. Special instrument requirements:

   Not applicable.

I. Device Description:

The Wondfo T-Cup® Multi-Drug Urine Test Cup is a rapid, single-use in vitro diagnostic device. Each test kit contains a test device in one pouch. One pouch contains a test T-Cup and two desiccants, a package insert, and a urine cup for sample collection.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   Advin Multi-Drug Screen Test Cup

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

   k122809

3. Comparison with predicate:

Similarities		
Item	Candidate Device	Predicate Device (k122809)
Intended Use	Qualitative detection of drugs of abuse in urine	Same
Test Principle	Competitive binding, lateral flow immunochromatographic assay	Same
Matrix	Urine	Same
Test drug cutoffs (ng/mL)	Amphetamine (AMP) – 1000 or 500 Buprenorphine (BUP) – 10 Secobarbital (BAR) – 300 Oxazepam (BZO) - 300 Cocaine (COC) – 300 or 150 diphenylpyrrolidine (EDDP) - 300 Methamphetamine (MET) – 1000 or 500 Methylenedioxymethamphetamine (MDMA) - 500 Methadone (MTD) - 300 Morphine (MOP 300/OPI 2000) – 2000 or 300 Oxycodone (OXY) - 100 Phencyclidine (PCP) - 25 Propoxyphene (PPX) - 300 Nortriptyline (TCA) - 1,000 Cannabinoids (THC) - 50	Same

Differences		
Item	Candidate Device	Predicate Device (k122809)
Indications for Use	For over-the-counter use	Prescription use and over-the-counter use
Test formats	Test cup	Cup, dip card, cassette
Number of drugs detected	15	16

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

None referenced.

L. Test Principle:

Wondfo T-Cup® Multi-Drug Urine Test Cup is a lateral flow chromatographic immunoassay. When urine sample is added to the cup device, urine is absorbed into the test strip and migrates upwards by capillary action. If the concentration of target drug presented

in the urine sample is below the cutoff level, the target drug will not saturate the binding sites of its specific monoclonal antibody-coated particles. The antibody-coated particles will then be captured by immobilized drug-conjugate and a visible colored band will be formed on the test line region. If the concentration of target is beyond the cutoff level, the target drug will saturate the binding sites of its specific monoclonal antibody-particles, thus the antibody-coated particles will not be captured by immobilized drug-conjugate hence no colored band will be formed on the test line region. A band should be formed on the control line region regardless of the presence of target drug or metabolite in the sample to indicate that the tests have been performed properly.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

Precision studies were carried out for samples with concentrations of -100% cutoff, -75% cut off, -50% cutoff, -25% cutoff, cutoff, +25% cutoff, +50% cutoff, +75% cutoff and +100% cutoff. Samples with concentration of -100% cutoff were drug-free urines samples. Other samples were prepared by spiking target drug in drug-free urine samples. Each drug concentration was confirmed by LC/MS or GC/MS. For each concentration, tests were performed two runs per day for 25 days using three lots of test cups. The results of a representative lot are summarized in the following tables:

Precision Study Results of a representative lot:

Drug	Result	+100% Cutoff	+75% Cutoff	+50% Cutoff	+25% Cutoff	Cutoff	-25% Cutoff	-50% Cutoff	-75% Cutoff	-100% Cutoff
BUP 10	Neg	0	0	0	0	9	50	50	50	50
	Pos	50	50	50	50	41	0	0	0	0
	Total	50	50	50	50	50	50	50	50	50
PCP 25	Neg	0	0	0	0	7	50	50	50	50
	Pos	50	50	50	50	43	0	0	0	0
	Total	50	50	50	50	50	50	50	50	50
THC 50	Neg	0	0	0	0	10	50	50	50	50
	Pos	50	50	50	50	40	0	0	0	0
	Total	50	50	50	50	50	50	50	50	50
OXY 100	Neg	0	0	0	0	9	50	50	50	50
	Pos	50	50	50	50	41	0	0	0	0
	Total	50	50	50	50	50	50	50	50	50
BAR 300	Neg	0	0	0	0	8	50	50	50	50
	Pos	50	50	50	50	42	0	0	0	0
	Total	50	50	50	50	50	50	50	50	50
BZO 300	Neg	0	0	0	0	7	50	50	50	50
	Pos	50	50	50	50	43	0	0	0	0
	Total	50	50	50	50	50	50	50	50	50
EDDP 300	Neg	0	0	0	0	9	50	50	50	50
	Pos	50	50	50	50	41	0	0	0	0

Drug	Result	+100% Cutoff	+75% Cutoff	+50% Cutoff	+25% Cutoff	Cutoff	-25% Cutoff	-50% Cutoff	-75% Cutoff	-100% Cutoff
	Total	50	50	50	50	50	50	50	50	50
MTD 300	Neg	0	0	0	0	9	50	50	50	50
	Pos	50	50	50	50	41	0	0	0	0
	Total	50	50	50	50	50	50	50	50	50
MOP 300	Neg	0	0	0	0	9	50	50	50	50
	Pos	50	50	50	50	41	0	0	0	0
	Total	50	50	50	50	50	50	50	50	50
PPX 300	Neg	0	0	0	0	11	50	50	50	50
	Pos	50	50	50	50	40	0	0	0	0
	Total	50	50	50	50	50	50	50	50	50
COC 150	Neg	0	0	0	0	10	50	50	50	50
	Pos	50	50	50	50	41	0	0	0	0
	Total	50	50	50	50	50	50	50	50	50
MDMA 500	Neg	0	0	0	0	11	50	50	50	50
	Pos	50	50	50	50	39	0	0	0	0
	Total	50	50	50	50	50	50	50	50	50
TCA 1000	Neg	0	0	0	0	10	50	50	50	50
	Pos	50	50	50	50	40	0	0	0	0
	Total	50	50	50	50	50	50	50	50	50
AMP 500	Neg	0	0	0	0	11	50	50	50	50
	Pos	50	50	50	50	39	0	0	0	0
	Total	50	50	50	50	50	50	50	50	50
MET 500	Neg	0	0	0	0	10	50	50	50	50
	Pos	50	50	50	50	40	0	0	0	0
	Total	50	50	50	50	50	50	50	50	50
OPI 2000	Neg	0	0	0	0	10	50	50	50	50
	Pos	50	50	50	50	40	0	0	0	0
	Total	50	50	50	50	50	50	50	50	50
COC 300	Neg	0	0	0	0	10	50	50	50	50
	Pos	50	50	50	50	40	0	0	0	0
	Total	50	50	50	50	50	50	50	50	50
AMP 1000	Neg	0	0	0	0	8	50	50	50	50
	Pos	50	50	50	50	42	0	0	0	0
	Total	50	50	50	50	50	50	50	50	50
MET 1000	Neg	0	0	0	0	7	50	50	50	50
	Pos	50	50	50	50	43	0	0	0	0
	Total	50	50	50	50	50	50	50	50	50

b. *Linearity/assay reportable range:*

Not applicable.

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

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. There are no external controls supplied with the device.

Device stability has been evaluated through accelerated and long-term studies. Protocols and acceptance criteria were described and found to be acceptable. The manufacturer claims that the devices are stable for two years (24 months) when stored at 4–30º C.

d. *Detection limit:*

Not applicable.

e. *Analytical specificity:*

Analytical specificity for this device was determined through adding the potential interfering substances to drug-free urine samples. The relative cross-reactivity represents the minimum concentration necessary to yield a result similar to the cutoff level of the respective assay. Percent cross-reactivity, provided in the below table, was calculated as the concentration of analyte tested that yielded a positive result, divided by the cutoff concentration, multiplied by 100; compounds that did not yield a positive result at the highest concentration tested have relative cross reactivity results represented by a dash in the table below.

Drug/Cutoff	Compound	Concentration (ng/mL)	Relative cross-reactivity (%)
BUP 10	Buprenorphine -3-D-Glucuronide	15	66.7%
	Norbuprenorphine	20	50%
	Norbuprenorphine-3-D-Glucuronide	200	5%
	Morphine	>100,000	--
	Oxymorphone	>100,000	--
	Hydromorphone	>100,000	--
PCP 10	4-Hydroxyphencyclidine	12500	0.2%
THC 50	11-nor-Δ8-THC 50-9-COOH	30	167%
	(-)-11-nor-9-carboxy-Δ 9-THC 50	50	100%
	11-nor-Δ9-THC 50-carboxy glucuronide	100	50%

Drug/Cutoff	Compound	Concentration (ng/mL)	Relative cross-reactivity (%)
	11-hydroxy-Δ9-Tetrahydrocannabinol	5000	1%
	Δ8- Tetrahydrocannabinol	1300	4%
	Δ9- Tetrahydrocannabinol	5000	1%
	Cannabinol	20000	0.25%
	Cannabidiol	100000	0.05%
OXY 100	Dihydrocodeine	20000	0.5%
	Hydrocodone	10000	1%
	Oxymorphone	1000	10%
	Codeine	100000	0.1%
	Hydromorphone	32000	0.3125%
	Morphine	>100,000	--
	Acetylmorphine	>100,000	--
	Buprenorphine	>100,000	--
	Ethylmorphine	>100,000	--
	Thebaine	>100,000	--
COC 150	Cocaine	375	40%
	Cocaethylene	6250	2.4%
	Ecgonine	16000	<1%
	Ecgonine methyl ester	>100,000	--
BAR 300	Amobarbital	10000	3%
	Alphenol	150	200%
	Aprobarbital	200	150%
	Butabarbital	75	400%
	Butathal	100	300%
	Butalbital	2500	12%
	Cyclopentobarbital	600	50%
	Pentobarbital	2500	12%
	Phenobarbital	10000	3%
BZO 300	Alprazolam	200	150%
	a-Hydroxyalprazolam	1500	20%
	Bromazepam	500	60%
	Chlordiazepoxide	1500	20%
	Clobazam	100	300%
	Clonazepam	800	37.5%
	Clorazepate dipotassium	200	150%
	Delorazepam	1500	20%
	Desalkylflurazepam	400	75%
	Diazepam	200	150%
	Estazolam	1000	30%
	Flunitrazepam	2500	12%
	Midazolam	12500	2.4%

Drug/Cutoff	Compound	Concentration (ng/mL)	Relative cross-reactivity (%)
	Nitrazepam	4000	7.5%
	Norchlordiazepoxide	200	150%
	Nordiazepam	500	60%
	Temazepam	250	120%
	Triazolam	1200	25%
	Demoxepam	2000	15%
	Flurazepam	500	60%
	D,L-Lorazepam	1500	20%
EDDP 300	Methadone	300000	0.1%
	EMDP	300000	0.1%
	Doxylamine	>100,000	--
MTD 300	Doxylamine	50000	0.6%
	EDDP	>100,000	--
MOP 300	Normorphine	300	100%
	s-Monoacetylmorphine	300	100%
	Codeine	300	100%
	Ethyl Morphine	100	300%
	Heroin	300	100%
	Hydrocodone	5000	6%
	Hydromorphone	1000	30%
	Morphinie-3-β-d-glucuronide	1000	30%
	Oxycodone	>100000	--
	Oxymorphone	100000	0.3%
	Thebaine	3000	10%
	Levorphanol	10000	3%
	6-Monoacetylmorphine (6-MAM)	150	200%
	Norcodeine	6250	4.8%
	Procaine	150000	0.2%
	d-Norpropoxyphene	300	100%
MDMA 500	3,4-Methylenedioxyamphetamine HCl (MDA)	3000	17%
	3,4-Methylenedioxyethylamphetamine (MDEA)	300	167%
	d-methamphetamine	>100,000	--
	d-amphetamine	>100,000	--
	l-methamphetamine	50,000	1%
	l-amphetamine	>100,000	--
AMP 500	l-Amphetamine	25000	2%
	dl- Amphetamine	1500	33%
	（+/-）3,4-Methylenedioxyamphetamine	2500	20%

Drug/Cutoff	Compound	Concentration (ng/mL)	Relative cross-reactivity (%)
	(MDA)		
	Phentermine	1500	33%
	Hydroxyamphetamine	8000	6.25%
	d-Methamphetamine	>100,000	--
	l-Methamphetamine	>100,000	--
	（+/-)3,4-Methylenedioxyethylamphetamine (MDE)	>100,000	--
	（+/-）3,4-Methylenedioxymethamphetamine (MDMA)	>100,000	--
	Ephedrine	>100,000	--
	β-Phenylethylamine	100000	0.5%
	Tyramine	100000	0.5%
	p-Hydroxynorephedrine	100000	0.5%
	Phenylpropanolamine	>100,000	--
	(±)Phenylpropanolamine	>100,000	--
	p-Hydroxyamphetamine	100000	0.5%
	d/l-Norephedrine	100000	0.5%
	Benzphetamine	>100,000	--
	l-Ephedrine	>100,000	--
	l-Epinephrine	>100,000	--
	d/l-Epinephrine	>100,000	--
MET 500	D-Amphetamine	25000	2%
	L- Amphetamine	37500	1.3%
	Chloroquine	10000	5%
	(+/-)-Ephedrine	25000	2%
	D/L-Methamphetamine	500	100%
	L-Methamphetamine	10000	5%
	(+/-)3,4-Methylenedioxy-n-ethylamphetamine (MDEA)	500	100%
	(+/-)3,4-Methylenedioxyamphetamine (MDA)	500	100%
	（+/-）3,4-Methylenedioxymethamphetamine (MDMA)	2000	25%
	β-Phenylethylamine	25000	2%
	Trimethobenzamide	5000	10%
	d/l-Amphetamine	75000	0.7%
	p-Hydroxymethamphetamine	15000	3.3%
	Mephentermine	25000	2%

Drug/Cutoff	Compound	Concentration (ng/mL)	Relative cross-reactivity (%)
	(1R,2S)-(-)-Ephedrine	50000	1%
	l-Phenylephrine	100000	0.5%
	(-)-Methamphetamine	12500	4%
TCA 1000	Nordoxepine	1000	100%
	Trimipramine	3000	33.3%
	Amitriptyline	1500	66.7%
	Promazine	1500	66.7%
	Desipramine	200	500%
	Imipramine	400	250%
	Clomipramine	12500	8%
	Doxepine	2000	50%
	Maprotiline	2000	50%
	Promethazine	25000	4%
	Cyclobenzaprine	800	125%
	Norclomipramine	12500	8%
COC 300	Cocaine	750	40%
	Cocaethylene	12500	2.4%
	Ecgonine	32000	<1%
	Ecgonine methyl Ester	>100000	--
Amp 1000	1-Amphetamine	50000	2%
	d1-Amphetamine	3000	33.3%
	Phentermine	3000	33.3%
	(+/-) 3,4-Methylenedioxyamphetamine (MDA)	5000	20%
	Hydroxyamphetamine	>100000	--
	d-Methamphetamine	>100000	--
	l-Methamphetamine	>100000	--
	Ephedrine	>100000	--
	（+/-）3,4-Methylenedioxymethamphetamine (MDMA)	100000	20%
	β-Phenylethylamine	100000	1%
	Tyramine	100000	1%
	p-Hydroxynorephedrine	100000	1%
	Phenylpropanolamine	>100000	--
	(±)Phenylpropanolamine	>100000	--
	p-Hydroxyamphetamine	100000	1%
	d/l-Norephedrine	100000	1%
	Benzphetamine	>100000	--
	l-Ephedrine	>100000	--
	l-Epinephrine	>100000	--

Drug/Cutoff	Compound	Concentration (ng/mL)	Relative cross-reactivity (%)
	d/l-Epinephrine	>100000	--
	Hydroxyamphetamine	8000	12.5%
MET 1000	(+/-)3,4-Methylenedioxy-n-ethylamphetamine (MDEA)	1000	100%
	D/L-Methamphetamine	1000	100%
	p-Hydroxymethamphetamine	30000	3.3%
	D-Amphetamine	>100000	--
	L-Amphetamine	75000	1.3%
	Chloroquine	50000	2%
	(+/-)-Ephedrine	50000	2%
	(-)-Methamphetamine	25000	4%
	(+/-) 3,4-Methylenedioxyamphetamine (MDA)	1000	100%
	（+/-）3,4-Methylenedioxymethamphetamine (MDMA)	4000	25%
	β-Phenylethylamine	50000	2%
	Trimethobenzamide	10000	10%
	d,l-Amphetamine	100000	1%
	Mephetermine	50000	2%
	(1R,2S)-(-)-Ephedrine	>100000	--
	l-phenylephrine	>100000	--
	L-Methamphetamine	25000	4%
OPI 2000	Codeine	2000	100%
	Ethyl Morphine	1500	133%
	Hydrocodone	12500	16%
	Hydromorphone	3500	57%
	Levorphanol	75000	2.7%
	6-Monoacetylmorphine（6-MAM）	1500	133%
	Morphine 3-β-D-glucuronide	2000	100%
	Norcodeine	12500	16%
	Normorphine	50000	4%
	Oxycodone	25000	8%
	Oxymorphone	25000	8%
	Procaine	150000	1.3%
	Thebaine	5000	40%
	Heroin	2000	100%
	s-Monoacetylmorphine	2000	100%

Potential interference from compounds chemically dissimilar to the target drugs and

from endogenous agents was performed by spiking the substances into pooled urine containing target drugs at near-cutoff concentrations (at +25% and -25% of cutoff). Unless otherwise indicated, substances were tested for potential interference at concentrations of 100 µg/mL.

The following substances demonstrated no positive or negative interference on the assays encompassed in this submission.

Acetaminophen	Acetophenetidin	Acetylsalicylic Acid
Acyclovir	Amiodarone Hydrochloride	Apomorphine
Afrin	Albumin	Amlodipine Mesylate
Aminophylline	Amoxicillin	Aripiprazole
Aminopyrine	Ampicillin	Aspartame
Benzilic Acid	Atropine	Atomoxetine
Benzoic Acid	Carbamazepine	Atorvastatin Calcium
Bilirubin	Cefradine	Chloramphenicol
Bupropion	Cephalexin	Chlorothiazide
Captopril	Chloral Hydrate	Chloroquine
Ciprofloxacin Hydrochloride	Clonidine	Cholesterol
Citalopram	Clopidogrel Hydrogen Sulphate	(-) Cotinine
Clarithromycin	Clozapine	chlorpheniramine
Deoxy- corticosterone	D,L-Tyrosine	D,L-Octopamine
Dextromethorphan	Digoxin	D,L-Propranolol
Diclofenac	Diphenhydramine	D-Norpropoxy- phene
Diflunisal	Dirithromycin	Domperidone
D-Pseudo- ephedrine	Ecgonine Methyl Ester	Doxylamine
Duloxetine	Effexor	Epinephrine Hydrochloride
Dicyclomine	Enalapril Maleate	Erythromycin
β-Estradiol	Fentanyl Citrate	Esomeprazole Magnesium
Ethanol	Fluoxetine Hydrochloride	Furosemide
Fenofibrate	Fluvoxamine	Gabapentin
Fenoprofen	Glucose	Gentisic Acid
Glibenclamide	Haloperidol	3-Hydroxy- tyramine
Gliclazide	Hemoglobin	Isosorbide Dinitrate
Glipizide	Ketamine	Isoxsuprine
Ibuprofen	Kratom powder	Lamotrigine
Ketoconazole	Labetalol	Levofloxacin Hydrochloride

Ketoprofen	Liverite	Levonorgestrel
Lidocaine Hydrochloride	Loperamide	Levothyroxine Sodium
Lisinopril	Loratadine	Minocycline
Lithium Carbonate	Naproxen	Nalidixic Acid
Metoprolol Tartrate	Mifepristone	Niacinamide
Magnesium	Mirtazapine	Nifedipine
Meperidine	Montelukast Sodium	Nikethamide
Meprobamate	Phenelzine	Sulfamethazine
Mosapride Citrate	Pioglitazone Hydrochloride	Sulindac
Maprotiline	Piracetam	Tetrahydrocortisone 3 - acetate
Nimodipine	Pravastatin Sodium	Tetrahydrocortisone 3-(β-D-glucuronide)
Norethindrone	Prednisone	Tetrahydrozoline
N-Acetylprocain-amide	Propylthiouracil	Tetracycline
O-Hydroxyhippu-ric Acid	Promethazine	Thiamine
Olanzapine	Quetiapine Fumarate	Thioridazine
Omeprazole	Quinine	Topiramate
Oxalic Acid	Ranitidine	Tramadol Hydrochloride
Oxolinic Acid	Rifampicin	Trazodone Hydrochloride
Oxymetazoline	Risperidone	Triamterene
Ondansetran	Salicylic Acid	Trifluoperazine
Paliperidone	Serotonin	Trimethoprim
Pantoprazole	Sertraline Hydrochloride	Uric Acid
Papaverine	Sildenafil Citrate	Valproate
Paroxetine Hydrochloride	Simvastatin	Verapamil
Penfluridol	Sodium Valproate	Vitamin B2
PenicillinV Potassium	Spironolactone	Vitamin C
Penicillin-G		

Interference by pH and specific gravity were also evaluated using pooled urine specimens containing target drugs at near-cutoff concentrations (at +25% and -25% of cutoff). The results demonstrated that pH levels of 4 to 9 and specific gravity levels of 1.003 to 1.035 do not affect the results of the assays.

f. Assay cut-off:

For characterization of how the device performs analytically around the claimed cutoff concentration, please refer to section M.1.a., above.

2. Comparison studies:

a. Method comparison with predicate device:

The method comparison study of the Wondfo T-Cup® Multi-Drug Urine Test cup was performed by three operators with 80 unaltered urine samples. The samples were blind labeled and compared to LC/MS or GC/MS results. The results are shown in the table below.

Drug	Result	Drug-free by GC/MS	Low Neg by GC/MS (less than -50%)	Near Cutoff Neg by GC/MS (Between -50% and the Cutoff)	Near Cutoff Pos by GC/MS (Between the cutoff and +50%)	High Pos by GC/MS (greater than +50%)
AMP 500	Pos	0	0	2	30	10
	Neg	10	17	11	0	0
BUP 10	Pos	0	0	3	29	10
	Neg	10	18	9	1	0
BAR 300	Pos	0	0	1	28	11
	Neg	10	19	10	1	0
BZO 300	Pos	0	0	2	29	10
	Neg	10	15	13	1	0
COC 150	Pos	0	0	2	31	9
	Neg	10	18	10	0	0
EDDP 300	Pos	0	0	1	32	8
	Neg	0	0	1	32	8
MET 500	Pos	0	0	2	20	20
	Neg	10	15	13	0	0
MDMA 500	Pos	0	0	2	30	10
	Neg	10	18	10	0	0
MOP 300	Pos	0	0	0	28	10
	Neg	10	18	12	2	0
MTD 300	Pos	0	0	2	27	12
	Neg	10	18	10	1	0
OXY 100	Pos	0	0	0	29	10

Drug	Result	Drug-free by GC/MS	Low Neg by GC/MS (less than -50%)	Near Cutoff Neg by GC/MS (Between -50% and the Cutoff)	Near Cutoff Pos by GC/MS (Between the cutoff and +50%)	High Pos by GC/MS (greater than +50%)
	Neg	10	18	12	1	0
PCP 25	Pos	0	0	1	28	10
	Neg	10	20	9	2	0
PPX 300	Pos	0	0	2	31	8
	Neg	10	17	11	1	0
TCA 1000	Pos	0	0	2	29	10
	Neg	10	18	10	1	0
THC 50	Pos	0	0	3	28	10
	Neg	10	19	8	2	0
AMP 1000	Pos	0	0	2	28	10
	Neg	10	16	12	2	0
COC 300	Pos	0	0	3	27	11
	Neg	10	13	14	2	0
MET 1000	Pos	0	0	3	23	15
	Neg	10	18	9	2	0
OPI 2000	Pos	0	0	3	29	10
	Neg	10	18	9	1	0

Summary of Discordant Results:

Drug test	Sample ID	Analyte detected	LC/MS Result	Device Result
AMP 500	10062	Amphetamine	479.507	Pos
	10021	Amphetamine	480.687	Pos
BUP 10	10140	Buprenorphine	10.039	Neg
	10099	Buprenorphine	8.071	Pos
	10090	Buprenorphine	8.226	Pos
	10101	Buprenorphine	9.000	Pos
BAR 300	100177	Barbiturates	306.032	Neg
BZO 300	10279	Benzodiazepines	289.534	Pos
	10293	Benzodiazepines	307.387	Neg

Drug test	Sample ID	Analyte detected	LC/MS Result	Device Result
	10310	Benzodiazepines	274.237	Pos
COC 150	11397	Cocaine	146.311	Pos
	11414	Cocaine	145.437	Pos
EDDP 300	10359	2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine	246.613	Pos
MET 500	11452	Methamphetamine	384.376	Pos
MDMA 500	10477	3,4-Methyl enedioxy methamphetamine	409.82	Pos
	10456		417.972	Pos
MOP 300	10541	Morphine	303.693	Neg
	10514	Morphine	307.303	Neg
MTD 300	10566	Methadone	282.733	Pos
OXY 100	10688	Oxycodone	113.792	Neg
PCP 25	10797	Phencyclidine	20.203	Pos
	10736	Phencyclidine	25.049	Neg
	10725	Phencyclidine	25.105	Neg
PPX 300	10802	Propoxyphene	241.706	Pos
	10820	Propoxyphene	252.045	Pos
	10863	Propoxyphene	314.373	Neg
TCA 1000	10917	Tri-cyclic Antidepressants	796.893	Pos
	10951	Tri-cyclic Antidepressants	812.065	Pos
	10893	Tri-cyclic Antidepressants	1007.857	Neg
THC 50	11020	Marijuana	40.238	Pos
	11011	Marijuana	43.304	Pos
	10971	Marijuana	45.118	Pos
	11001	Marijuana	51.112	Neg
	10975	Marijuana	50.639	Neg
AMP 1000	11077	Amphetamine	739.221	Pos

Drug test	Sample ID	Analyte detected	LC/MS Result	Device Result
	11092	Amphetamine	797.646	Pos
	11057	Amphetamine	1025.544	Neg
	11112	Amphetamine	1017.953	Neg
COC 300	11143	Cocaine	283.934	Pos
	11126	Cocaine	292.623	Pos
	11147	Cocaine	293.871	Pos
	11160	Cocaine	309.73	Neg
	11182	Cocaine	320.007	Neg
MET 1000	11216	Methamphetamine	873.409	Pos
	11250	Methamphetamine	888.241	Pos
	11213	Methamphetamine	890.705	Pos
	11215	Methamphetamine	1036.001	Neg
	11240	Methamphetamine	1022.392	Neg
OPI 2000	11354	Opiates	1830.086	Pos
	11335	Opiates	1882.994	Pos
	11297	Opiates	1947.150	Pos
	11295	Opiates	2015.745	Neg

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):

A lay user study was performed involving a total of 280 participants from 3 sites. 89 males and 51 females tested T-Cup® Multi-Drug Urine Test Cup Configuration 1 (including AMP 500, MET 500, MOP 300, COC 150) ; 84 male and 56 females tested T-Cup® Multi-Drug Urine Test Cup Configuration 2 (Group 2, including AMP 1000, MET 1000, MOP 2000 (OPI), COC 300). Each participant was provided one package insert, one blind labeled test solution, and one test device. Test solutions were randomly assigned to participants, one for each. Following testing, users completed a study questionnaire to assess usability and user comprehension, and the results from this questionnaire were found to be acceptable. Participants aged 20 and

over, with diverse educational backgrounds, were recruited. Results from the lay user testing are provided in the below table:

Drug	Result	-100% Cutoff	-75% Cutoff	-50% Cutoff	-25% Cutoff	+25% Cutoff	+50% Cutoff	+75% Cutoff
AMP 500	Neg	20	20	20	18	2	0	0
	Pos	0	0	0	2	18	20	20
	Total	20	20	20	20	20	20	20
BAR 300	Neg	40	40	40	36	4	0	0
	Pos	0	0	0	4	36	40	40
	Total	40	40	40	40	40	40	40
BZO 300	Neg	40	40	40	36	4	0	0
	Pos	0	0	0	4	36	40	40
	Total	40	40	40	40	40	40	40
BUP 10	Neg	40	40	40	35	2	0	0
	Pos	0	0	0	5	38	40	40
	Total	40	40	40	40	40	40	40
COC 150	Neg	20	20	20	18	1	0	0
	Pos	0	0	0	2	19	20	20
	Total	20	20	20	20	20	20	20
EDDP 300	Neg	40	40	40	36	2	0	0
	Pos	0	0	0	4	38	40	40
	Total	40	40	40	40	40	40	40
MDMA 500	Neg	20	20	20	18	1	0	0
	Pos	0	0	0	2	19	20	20
	Total	20	20	20	20	20	20	20
MET 500	Neg	20	20	20	17	2	0	0
	Pos	0	0	0	3	18	20	20
	Total	20	20	20	20	20	20	20
MOP 300	Neg	20	20	20	18	2	0	0
	Pos	0	0	0	2	18	20	20
	Total	20	20	20	20	20	20	20
MTD 300	Neg	40	40	40	35	5	0	0
	Pos	0	0	0	5	35	40	40
	Total	40	40	40	40	40	40	40
OXY 100	Neg	40	40	40	35	2	0	0
	Pos	0	0	0	5	38	40	40
	Total	40	40	40	40	40	40	40
PCP 25	Neg	40	40	40	35	2	0	0
	Pos	0	0	0	5	38	40	40
	Total	40	40	40	40	40	40	40
PPX 300	Neg	40	40	40	36	5	0	0
	Pos	0	0	0	4	35	40	40
	Total	40	40	40	40	40	40	40
TCA 1000	Neg	40	40	40	39	2	0	0
	Pos	0	0	0	1	38	40	40

Drug	Result	-100% Cutoff	-75% Cutoff	-50% Cutoff	-25% Cutoff	+25% Cutoff	+50% Cutoff	+75% Cutoff
	Total	40	40	40	40	40	40	40
THC 50	Neg	40	40	40	34	4	0	0
	Pos	0	0	0	6	36	40	40
	Total	40	40	40	40	40	40	40
AMP 1000	Neg	20	20	20	19	0	0	0
	Pos	0	0	0	1	20	20	20
	Total	20	20	20	20	20	20	20
COC 300	Neg	20	20	20	17	2	0	0
	Pos	0	0	0	3	18	20	20
	Total	20	20	20	20	20	20	20
MET 1000	Neg	20	20	20	20	1	0	0
	Pos	0	0	0	0	19	20	20
	Total	20	20	20	20	20	20	20
OPI 2000	Neg	20	20	20	20	1	0	0
	Pos	0	0	0	0	19	20	20
	Total	20	20	20	20	20	20	20

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 Parts 801 and 809, as applicable.

O. Conclusion:

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