



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

I Background Information:

A 510(k) Number

K252550

B Applicant

Guangzhou Wondfo Biotech Co., Ltd.

C Proprietary and Established Names

SAFElife T-Cup Multi-Drug Urine Test Cup; SAFElife T-Cup Multi-Drug Urine Test Cup Dx

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
NFT	Class II	21 CFR 862.3100 - Amphetamine Test System	TX - Clinical Toxicology
PTH	Class II	21 CFR 862.3150 - Barbiturate test system	TX - Clinical Toxicology
NFV	Class II	21 CFR 862.3170 - Benzodiazepine test system	TX - Clinical Toxicology
NFY	Class II	21 CFR 862.3250 - Cocaine and cocaine metabolite test system	TX - Clinical Toxicology
PTG	Class II	21 CFR 862.3620 - Methadone test system	TX - Clinical Toxicology

NGG	Class II	21 CFR 862.3610 - Methamphetamine test system	TX - Clinical Toxicology
LCM	Unclassified		
QBF	Class II	21 CFR 862.3700 - Propoxyphene test system	TX - Clinical Toxicology
QAW	Class II	21 CFR 862.3910 - Tricyclic antidepressant drugs test system	TX - Clinical Toxicology
NFW	Class II	21 CFR 862.3870 - Cannabinoid test system	TX - Clinical Toxicology
NGL	Class II	21 CFR 862.3650 - Opiate test system	TX - Clinical Toxicology

II Submission/Device Overview:

A Purpose for Submission:

New Device (adding four additional analytes and a new cutoff of 20ng/mL for THC-COOH (Marijuana 20) to the previously cleared device under K182701).

B Measurand:

Amphetamine, Buprenorphine, Secobarbital, Oxazepam, Cocaine, 2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine, Methamphetamine, Methylenedioxymethamphetamine, Morphine, Opiates, Methadone, Oxycodone, Phencyclidine, Propoxyphene, Nortriptyline and Cannabinoids, 6-Monoacetylmorphine, Fentanyl, Norfentanyl, and Tramadol.

C Type of Test:

Qualitative, lateral flow immunoassay

III Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) for Use:

SAFElife™ T-Cup Multi-Drug Urine Test Cup:

SAFElife™ T-Cup Multi-Drug Urine Test Cup is a competitive binding, lateral flow immunochromatographic assay for qualitative and simultaneous detection of 6-Monoacetylmorphine, Amphetamine, Buprenorphine, Secobarbital, Oxazepam, Cocaine, 2-

ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP), Fentanyl, Methamphetamine, Methylenedioxymethamphetamine, Morphine, Opiates, Methadone, Norfentanyl, Oxycodone, Phencyclidine, Propoxyphene, Nortriptyline, Cannabinoids and Tramadol in human urine at the cutoff concentrations of:

Drug (Identifier)	Cutoff Level
6-Monoacetylmorphine (6-MAM)	10 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
Fentanyl (FTY)	1 ng/mL
Methamphetamine (MET/mAMP)	1000 ng/mL or 500 ng/mL
Methylenedioxymethamphetamine (MDMA)	500 ng/mL
Morphine (MOP)	300 ng/mL
Opiates (OPI)	2000 ng/mL
Methadone (MTD)	300 ng/mL
Norfentanyl (NFTY)	5 ng/mL
Oxycodone (OXY)	100 ng/mL
Phencyclidine (PCP)	25 ng/mL
Propoxyphene (PPX)	300 ng/mL
Nortriptyline (TCA)	1000 ng/mL
Cannabinoids (THC)	50 ng/mL or 20 ng/mL
Tramadol (TRA)	100 ng/mL

SAFElife™ T-Cup Multi-Drug Urine Test Cup offers any combinations from 1 to 19 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.

The tests may yield positive results for the prescription drugs Buprenorphine, Fentanyl, Nortriptyline, Oxazepam, Secobarbital, Oxycodone and Tramadol 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. Gas Chromatography/Mass Spectrometry (GC/MS) or Liquid Chromatography/Mass Spectrometry (LC/MS) is the recommended confirmatory method.

SAFElife™ T-Cup Multi-Drug Urine Test Cup Dx:

SAFElife™ T-Cup Multi-Drug Urine Test Cup Dx is a competitive binding, lateral flow immunochromatographic assay for qualitative and simultaneous detection of 6-Monoacetylmorphine, Amphetamine, Secobarbital, Buprenorphine, Oxazepam, Cocaine, 2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP), Fentanyl, Methylenedioxymethamphetamine, Methamphetamine, Morphine, Opiates, Methadone, Norfentanyl, Oxycodone, Phencyclidine, Propoxyphene, Nortriptyline, Cannabinoids and Tramadol in human urine with below cutoff concentrations and approximate detection time:

Drug (Identifier)	Calibrator	Cut-off Level
6-Monoacetylmorphine (6-MAM)	6-Monoacetylmorphine	10 ng/mL
Amphetamine (AMP500)	d-Amphetamine	500 ng/mL

Amphetamine (AMP1000)	d-Amphetamine	1000 ng/mL
Secobarbital (BAR)	Secobarbital	300 ng/mL
Buprenorphine (BUP)	Buprenorphine	10 ng/mL
Oxazepam (BZO)	Oxazepam	300 ng/mL
Cocaine (COC150)	Benzoylcegonine	150 ng/mL
Cocaine (COC300)	Benzoylcegonine	300 ng/mL
2-ethylidene-1,5-dimethyl-3, 3-diphenylpyrrolidine (EDDP)	2-ethylidene-1,5-dimethyl-3, 3-diphenyl-pyrrolidine	300 ng/mL
Fentanyl (FTY)	Fentanyl	1 ng/mL
Methylenedioxymethamphetamine (MDMA)	3,4-Methylenedioxymethamphetamine	500 ng/mL
Methamphetamine (MET500/mAMP500)	D(+)-Methamphetamine	500 ng/mL
Methamphetamine (MET1000/mAMP1000)	D(+)-Methamphetamine	1000 ng/mL
Morphine (MOP300)	Morphine	300 ng/mL
Opiates (OPI2000)	Morphine	2000 ng/mL
Methadone (MTD)	Methadone	300 ng/mL
Norfentanyl (NFTY)	Norfentanyl	5 ng/mL
Oxycodone (OXY)	Oxycodone	100 ng/mL
Phencyclidine (PCP)	Phencyclidine	25 ng/mL
Propoxyphene (PPX)	d-Propoxyphene	300 ng/mL
Nortriptyline (TCA)	Nortriptyline	1000 ng/mL
Cannabinoids (THC20)	11-nor- Δ^9 -THC-9-COOH	20 ng/mL
Cannabinoids (THC50)	11-nor- Δ^9 -THC-9-COOH	50 ng/mL
Tramadol (TRA)	Tramadol	100 ng/mL

SAFElife™ T-Cup Multi-Drug Urine Test Cup Dx offers any combinations from 1 to 19 drugs of abuse tests with or without on-board adulteration/specimen validity test (SVT) but only one cutoff concentration under same drug condition will be included per device. It is for in vitro diagnostic use.

The tests may yield positive results for the prescription drugs Buprenorphine, Fentanyl, Nortriptyline, Oxazepam, Secobarbital, Oxycodone and Tramadol 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. Gas Chromatography/Mass Spectrometry (GC/MS) or Liquid Chromatography/Mass Spectrometry (LC/MS) is the recommended confirmatory method.

C Special Conditions for Use Statement(s):

OTC - Over The Counter

D Special Instrument Requirements:

Not Applicable.

IV Device/System Characteristics:

A Device Description:

The SAFElife™ T-Cup Multi-Drug Urine Test Cup and the SAFElife™ T-Cup Multi-Drug Urine Test Cup Dx are lateral flow immunochromatographic assays for the qualitative detection of the claimed analytes in human urine at the associated cut-off concentrations. This submission (K252550) represents the following claimed analytes and associated cut off concentrations; 6-Monoacetylmorphine at 10 ng/ml, Fentanyl at 1 ng/mL, Norfentanyl at 5 ng/mL, Tramadol at 100 ng/mL, and Cannabinoids (THC) at 20 ng/mL. Each SAFElife™ T-Cup Multi-Drug Urine Test Cup or SAFElife™ T-Cup Multi-Drug Urine Test Cup Dx device consists of a test cup and a package insert. Each test cup is sealed with one sachet of desiccant in an aluminum pouch.

B Principle of Operation:

SAFElife 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.

V Substantial Equivalence Information:**A Predicate Device Name(s):**

Wondfo T-Cup Multi-Drug Urine Test Cup

B Predicate 510(k) Number(s):

K182701

C Comparison with Predicate(s):

Device & Predicate Device(s):	<u>K252550</u>	<u>K182701</u>
Device Trade Name	SAFElife™ T-Cup Multi-Drug Urine Test Cup SAFElife™ T-Cup Multi-Drug Urine Test Cup Dx	Wondfo T-Cup Multi-Drug Urine Test Cup
General Device Characteristic Similarities		
Intended Use/Indications For Use	For the qualitative determination of drugs and drug metabolites in human urine.	Same

Specimen Type	Human Urine	Same
Methodology	Competitive binding, lateral flow immunochromatographic assays based on the principle of antigen antibody immunochemistry.	Same
General Device Characteristic Differences		
Analytes and Cutoff	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/mAMP) 1000 ng/mL or 500 ng/mL Methylenedioxymethamphetamine (MDMA) 500 ng/mL Morphine (MOP 300) 300 ng/mL Opiates (OPI 2000) 2000 ng/mL Methadone (MTD) 300 ng/mL Oxycodone (OXY) 100 ng/mL Phencyclidine (PCP) 25 ng/mL Propoxyphene (PPX) 300 ng/mL Nortriptyline (TCA) 1000 ng/mL Cannabinoids (THC)	Same except without 6-MAM 10 ng/mL FTY 1 ng/mL NFTY 5 ng/mL TRA 100 ng/mL THC 20 ng/mL

	50 ng/mL 6-Monoacetylmorphine (6-MAM) 10 ng/mL Fentanyl (FTY) 1 ng/mL Norfentanyl (NFTY) 5 ng/mL Cannabinoids (THC) 20 ng/mL Tramadol (TRA) 100 ng/mL	
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VI Standards/Guidance Documents Referenced:

None referenced.

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

Analytical performance for Amphetamine, Buprenorphine, Secobarbital, Oxazepam, Cocaine, 2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine, Methamphetamine, Methylenedioxymethamphetamine, Morphine, Opiates, Methadone, Oxycodone, Phencyclidine, Propoxyphene, Nortriptyline and Cannabinoids were conducted on k182701.

1. 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 one replicate per run per lot (one operator per lot), two runs per day for 25 days in a randomized order. The results are summarized in the following table:

Drug	Lot Number	-100% Cutoff	-75% Cutoff	-50% Cutoff	-25% Cutoff	Cutoff	+25% Cutoff	+50% Cutoff	+75% Cutoff	+100% Cutoff
6-MAM 10	Lot 1	50-/0+	50-/0+	50-/0+	50-/0+	25-/25+	1-/49+	0-/50+	0-/50+	0-/50+
	Lot 2	50-/0+	50-/0+	50-/0+	48-/2+	25-/25+	1-/49+	0-/50+	0-/50+	0-/50+
	Lot 3	50-/0+	50-/0+	50-/0+	49-/1+	26-/24+	2-/48+	0-/50+	0-/50+	0-/50+
FTY1	Lot 1	50-/0+	50-/0+	50-/0+	48-/2+	23-/27+	0-/50+	0-/50+	0-/50+	0-/50+
	Lot 2	50-/0+	50-/0+	50-/0+	48-/2+	24-/26+	0-/50+	0-/50+	0-/50+	0-/50+
	Lot 3	50-/0+	50-/0+	50-/0+	48-/2+	25-/25+	0-/50+	0-/50+	0-/50+	0-/50+
NFTY5	Lot 1	50-/0+	50-/0+	50-/0+	49-/1+	24-/26+	2-/48+	0-/50+	0-/50+	0-/50+

	Lot 2	50-/0+	50-/0+	50-/0+	49-/1+	26-/24+	1-/49+	0-/50+	0-/50+	0-/50+
	Lot 3	50-/0+	50-/0+	50-/0+	48-/2+	24-/26+	1-/49+	0-/50+	0-/50+	0-/50+
THC20	Lot 1	50-/0+	50-/0+	50-/0+	48-/2+	26-/24+	1-/49+	0-/50+	0-/50+	0-/50+
	Lot 2	50-/0+	50-/0+	50-/0+	49-/1+	25-/25+	0-/50+	0-/50+	0-/50+	0-/50+
	Lot 3	50-/0+	50-/0+	50-/0+	48-/2+	23-/27+	2-/48+	0-/50+	0-/50+	0-/50+
TRA100	Lot 1	50-/0+	50-/0+	50-/0+	50-/0+	24-/26+	0-/50+	0-/50+	0-/50+	0-/50+
	Lot 2	50-/0+	50-/0+	50-/0+	50-/0+	27-/23+	0-/50+	0-/50+	0-/50+	0-/50+
	Lot 3	50-/0+	50-/0+	50-/0+	50-/0+	25-/25+	0-/50+	0-/50+	0-/50+	0-/50+

2. Linearity:

Not applicable.

3. Analytical Specificity/Interference:

Analytical specificity

Analytical specificity was performed for this device to determine the cross-reactivity from structurally related compounds by identifying the concentration of a compound prepared in drug-free negative urine that would produce a positive response for each 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. The results are summarized below.

Drug/Cutoff	Compound	Minimum concentration required to obtain a positive result (ng/mL)	% Cross-Reactivity
6-MAM10	Heroin	60	16.7%
	Morphine	75000	0.01%
	Normorphine	150000	Not detected
	Nalorphine HCl	150000	Not detected
	Hydrocodone	150000	Not detected
	Hydromorphone	150000	Not detected
	Chlordiazepoxide	150000	Not detected
	Clobazam	150000	Not detected
	D-Amphetamine	150000	Not detected
	(±)-Amphetamine	150000	Not detected
	Levorphanol tartrate	150000	Not detected
	Codeine	150000	Not detected
	Ethylmorphine	150000	Not detected
	Morphine3-β-D-glucuronide	150000	Not detected
	Norcodeine	150000	Not detected

Drug/Cutoff	Compound	Minimum concentration required to obtain a positive result (ng/mL)	% Cross-Reactivity
	Oxycodone	150000	Not detected
	Oxymorphone	150000	Not detected
	Procaine hydrochloride	150000	Not detected
	Thebaine	150000	Not detected
	6-Acetylcodeine	150000	Not detected
	Buprenorphine	150000	Not detected
	Dihydrocodeine	150000	Not detected
	Dextromethorphan	150000	Not detected
	Imipramine hydrochloride	150000	Not detected
	Meperidine	150000	Not detected
	(±)-Methadone	150000	Not detected
	Mitragynine(kratom)	150000	Not detected
	Morphine-6-β-D-glucuronide	150000	Not detected
	Naloxone hydrochloride	150000	Not detected
	Naltrexone hydrochloride	150000	Not detected
	Naproxen	150000	Not detected
	Norbuprenorphine	150000	Not detected
	Norbuprenorphine glucuronide	150000	Not detected
	Noroxycodone HCL	150000	Not detected
	Noroxymorphone HCL	150000	Not detected
	(+)-Norpropoxyphene maleate	150000	Not detected
	Oxymorphone-3β-D-glucuronide	150000	Not detected
	Tapentadol HCl	150000	Not detected
	Tramadol	150000	Not detected
FTY1	Acetyl fentanyl	16	6.25%
	Acrylfentanyl	1	100.00%
	ω-1-Hydroxyfentanyl	20,000	0.005%
	Isobutyryl fentanyl	1	100.00%
	Ocfentanil	2.3	43.48%
	Butyryl fentanyl	2	50.00%
	Furanyl fentanyl	1	100.00%
	Valeryl fentanyl	2.5	40.00%
	(±) β-hydroxythiofentanyl	2.5	40.00%
	4-Fluoro-isobutyrylfentanyl	3	33.33%

Drug/Cutoff	Compound	Minimum concentration required to obtain a positive result (ng/mL)	% Cross-Reactivity
	Para-fluorobutyryl fentanyl	4	25.00%
	Para-fluoro fentanyl	2.5	40.00%
	(+)-3-cis-methyl fentanyl	50	2.00%
	Carfentanil	2	50.00%
	Sufentanil	15	6.67%
	Alfentanil	7500	0.01%
	Despropionyl fentanyl (4-ANPP)	2,000	0.05%
	Remifentanil	150000	Not detected
	Norfentanyl	150000	Not detected
	Acetyl norfentanyl	150000	Not detected
	Norcarfentanil	150000	Not detected
	Trazodone	25000	0.004%
NFTY5	Fentanyl	10	50%
	Acetyl fentanyl	150	3.3%
	Acetyl Norfentanyl	200	2.5%
	□ ±)-β-Hydroxythiofentanyl HCl	2500	0.2%
	Acryl Fentanyl	2500	0.2%
	Butyryl Fentanyl	5000	0.1%
	Furanyl Fentanyl	10000	0.05%
	Para-fluoro butyrl Fentanyl (P-FBF)	80000	0.006%
	Para-fluoro Fentanyl	40000	0.013%
	9-HydroxyRisperidone	10000	0.05%
	Alfentanil	20000	0.025%
	Isobutyryl Fentanyl	5000	0.1%
	Remifentanil	15000	0.03%
	Valeryl Fentanyl	20000	0.025%
	Thienyl Fentanyl	50	10%
	(+)-3-cis-methyl fentanyl	50	10%
	4-Fluoro-isobutyryl Fentanyl	30000	Not detected
	Despropionyl fentanyl (4-ANPP)	30000	Not detected
	MT-45 diHCL	150000	Not detected
	Ocfentanil	150000	Not detected
	Risperidone	150000	Not detected

Drug/Cutoff	Compound	Minimum concentration required to obtain a positive result (ng/mL)	% Cross-Reactivity
	Sufentanil	150000	Not detected
	Carfentanil	150000	Not detected
	Labetalol Hydrochloride	150000	Not detected
	Trazodone	150000	Not detected
	U-47700	150000	Not detected
	ω -1-Hydroxyfentanyl	30000	Not detected
	6-Acetyl morphine	150000	Not detected
	(\pm)-Amphetamine	150000	Not detected
	Buprenorphine	150000	Not detected
	Buprenorphine-3 β -D-glucuronide	150000	Not detected
	Codeine	150000	Not detected
	Dextromethorphan	150000	Not detected
	Dihydrocodeine	150000	Not detected
	EDDP	150000	Not detected
	EMDP	150000	Not detected
	Fluoxetine	150000	Not detected
	Heroin	150000	Not detected
	Hydrocodone	150000	Not detected
	Hydromorphone	150000	Not detected
	Ketamine	150000	Not detected
	Levorphanol tartrate	150000	Not detected
	Meperidine	150000	Not detected
	(\pm)-Methadone	150000	Not detected
	Morphine	150000	Not detected
	Morphine-3- β -D-glucuronide	150000	Not detected
	Naloxone hydrochloride	150000	Not detected
	Naltrexone hydrochloride	150000	Not detected
	Norbuprenorphine	150000	Not detected
	Norcodeine	150000	Not detected
	Norketamine	150000	Not detected
	Normeperidine	150000	Not detected
	Normorphine	150000	Not detected
	Noroxycodone	150000	Not detected
	Oxycodone	150000	Not detected
	Oxymorphone	150000	Not detected

Drug/Cutoff	Compound	Minimum concentration required to obtain a positive result (ng/mL)	% Cross-Reactivity
	Pentazocine (Talwin)	150000	Not detected
	Pipamperone	150000	Not detected
	Tapentadol hydrochloride	150000	Not detected
	Thioridazine	150000	Not detected
	Tilidine	150000	Not detected
	Tramadol	150000	Not detected
	O-Desmethyl -cris-Tramadol	150000	Not detected
	N-Desmethyl -cris-Tramadol	150000	Not detected
	Norcarfentanil	150000	Not detected
THC 20	(-)-11-nor-9-carboxy-Delta8-THC	20	100%
	(-)-11-Nor-Δ9-THC- 9-carboxylic acid glucuronide	30	66.7%
	(±)-11-Hydroxy-Δ9-THC	20	100%
	(-)-11-nor-9-carboxy-Δ 9-THC	20	100%
	(-)-Δ9-THC	6000	0.3%
	(-)-Δ8-THC	4000	0.5%
	Cannabinol	8000	0.25%
	Cannabidiol	150000	Not detected
TRA100	n-Desmethyl -cris-Tramadol	400	25%
	o-Desmethyl -cris-Tramadol	1000	10%
	o-Desmethyl Venlafaxine	15000	Not detected
	Venlafaxine HCl	150000	Not detected

Interference

A study to evaluate potential interference from various endogenous and exogenous compounds. by spiking the substances into pooled urine containing target drugs at near-cutoff concentrations (at +50% and -50% of cutoff). Unless otherwise indicated, substances were tested for potential interference at concentrations of 100 µg/mL. The following substances demonstrated no positive. The following substances demonstrated no positive or negative interference on the assays encompassed in this submission.

Acetaminophen	Effexor	Nimodipine
Acetophenetidin	Enalapril Maleate	Nitroglycerin
Acetylsalicylic Acid	Erythromycin	Norethindrone
Acyclovir	Esomeprazole Magnesium	N-Acetylprocainamide

Afrin	β-Estradiol	O-Hydroxyhippuric Acid
Albumin (100mg/dL)	1% ethanol	Olanzapine
Aminophylline	Fenofibrate	Omeprazole
Aminopyrine	Fenoprofen	Oxalic Acid
Amiodarone Hydrochloride	Fentanyl Citrate	Oxolinic Acid
Amlodipine Mesylate	Fluoxetine Hydrochloride	Oxymetazoline
Amoxicillin	Fluvoxamine	Ondansetran
Ampicillin	Furosemide	Paliperidone
Apomorphine	Gabapentin	Pantoprazole
Aripiprazole	Gentisic Acid	Papaverine
Aspartame	Glibenclamide	Paroxetine Hydrochloride
Atomoxetine	Gliclazide	Penfluridol
Atorvastatin Calcium	Glipizide	PenicillinV Potassium
Atropine	Glucose	Penicillin-G
Benzilic Acid	Haloperidol	Phenelzine
Benzoic Acid	Hemoglobin	Pioglitazone Hydrochloride
Bilirubin	Hydrochlorothiazide	Piracetam
Bupropion	Hydrocortisone	Pravastatin Sodium
Captopril	3-Hydroxytyramine	Prednisone
Carbamazepine	Isosorbide Dinitrate	Propylthiouracil
Cefradine	Isoxsuprine	Quetiapine Fumarate
Cephalexin	Ibuprofen	Quinine
Chloral Hydrate	Ketoconazole	Ranitidine
Chloramphenicol	Ketoprofen	Rifampicin
Chlorothiazide	Ketamine	Risperidone
Cholesterol	Kratom powder	Salicylic Acid
Ciprofloxacin Hydrochloride	Labetalol	Serotonin
Citalopram	Lamotrigine	Sertraline Hydrochloride
Clarithromycin	Levofloxacin Hydrochloride	Sildenafil Citrate
Clonidine	Levonorgestrel	Simvastatin
Clopidogrel Hydrogen Sulphate	Levothyroxine Sodium	Sodium Valproate
Clozapine	Lidocaine Hydrochloride	Spironolactone
Conjugated Estrogens	Lisinopril	Sulfamethazine
Cortisone	Lithium Carbonate	Sulindac
Creatinine	Liverite	Tetracycline
(-) Cotinine	Loperamide	Tetrahydrocortisone 3 - acetate
chlorpheniramine	Loratadine	Tetrahydrocortisone 3-(β-D glucuronide)
D,L-Octopamine	Magnesium	Tetrahydrozoline

D,L-Propranolol	Meperidine	Thiamine
D,L-Tyrosine	Meprobamate	Thioridazine
Deoxycorticosterone	Metoprolol Tartrate	Topiramate
Dextromethorphan	Mifepristone	Tramadol Hydrochloride
Diclofenac	Mirtazapine	Trazodone Hydrochloride
Diflunisal	Montelukast Sodium	Triamterene
Digoxin	Mosapride Citrate	Trifluoperazine
Diphenhydramine	Minocycline	Trimethoprim
Dirithromycin	Nalidixic Acid	Uric Acid
Domperidone	Naproxen	Valproate
D-Pseudoephedrine	Niacinamide	Verapamil
Duloxetine	Nifedipine	Vitamin B2
Dicyclomine	Nikethamide	Vitamin C
Chloroquine	Ecgonine Methyl Ester	Promethazine

Urine Density & Urine pH

Interference by pH and specific gravity were also evaluated using pooled urine specimens containing target drugs at near-cutoff concentrations (at +50% and -50% of cutoff). The results demonstrated that pH levels of 4 to 9 and specific gravity levels of 1.000 to 1.035 do not affect the results of the assays.

4. Assay Reportable Range:

Not applicable.

5. Traceability, Stability, Expected Values (Controls, Calibrators, or Methods):

The assay is traceable to a commercial standard from Cerilliant Corp.

6. Detection Limit:

Not applicable.

7. Assay Cut-Off:

Analytical performance of the device around the claimed cutoff is described in the precision section VII.A1. above.

B Comparison Studies:

1. Method Comparison with Predicate Device:

In this submission, the method comparison study for 6-Monoacetylmorphine (6-MAM10), Fentanyl (FTY1), Cannabinoids (THC20), Tramadol (TRA100) and Norfentanyl (NFTY5), was

performed by three operators with 80 unaltered urine samples. These samples were blind labeled and compared to LC/MS or GC/MS results. The results are shown in the table below. Method comparison studies demonstrating device accuracy when measuring previously cleared analytes can be found in K182701.

Drug	Operator	Results	Drug-free by LC/MS	Low Neg by LC/MS (less than - 50%)	Near Cutoff Neg by LC/MS (Between - 50% and the Cutoff)	Near Cutoff Pos by LC/MS (Between the cutoff and +50%)	High Pos by LC/MS (greater than +50%)
6-MAM 10	A	Positive	0	0	3	21	18
		Negative	13	14	10	1	0
	B	Positive	0	0	2	21	18
		Negative	13	14	11	1	0
	C	Positive	0	0	1	21	18
		Negative	13	14	12	1	0
FTY 1	A	Positive	0	0	2	21	18
		Negative	12	16	10	1	0
	B	Positive	0	0	1	20	18
		Negative	12	16	11	2	0
	C	Positive	0	0	2	21	18
		Negative	12	16	10	1	0
NFTY 5	A	Positive	0	0	3	23	16
		Negative	10	16	11	1	0
	B	Positive	0	0	2	22	16
		Negative	10	16	12	2	0
	C	Positive	0	0	2	22	16
		Negative	10	16	12	2	0
THC 20	A	Positive	0	0	2	28	10
		Negative	9	15	14	2	0
	B	Positive	0	0	2	29	10
		Negative	9	15	14	1	0
	C	Positive	0	0	2	28	10
		Negative	9	15	14	2	0
TRA 100	A	Positive	0	0	2	27	12
		Negative	10	18	10	1	0
	B	Positive	0	0	1	27	12
		Negative	10	18	11	1	0
	C	Positive	0	0	1	27	12
		Negative	10	18	11	1	0

Summary of Discordant Results:

Drug	Operator	Sample Number	LC/MS Results (ng/mL)	Device Results
6-MAM 10	Operator A	SU25050045	7.867	Positive
	Operator A	SU25050057	8.193	Positive
	Operator A	SU25050075	9.192	Positive
	Operator A	SU25050029	10.863	Negative
	Operator B	SU25050057	8.193	Positive
	Operator B	SU25050075	9.192	Positive
	Operator B	SU25050074	10.359	Negative
	Operator C	SU25050075	9.192	Positive
	Operator C	SU25050074	10.359	Negative
FTY 1	Operator A	SU25050271	0.848	Positive
	Operator A	SU25050284	0.965	Positive
	Operator A	SU25050249	1.136	Negative
	Operator B	SU25050284	0.965	Positive
	Operator B	SU25050249	1.136	Negative
	Operator B	SU25050270	1.184	Negative
	Operator C	SU25050271	0.848	Positive
	Operator C	SU25050284	0.965	Positive
	Operator C	SU25050270	1.184	Negative
NFTY 5	Operator A	SU25060042	4.315	Positive
	Operator A	SU25060030	4.765	Positive
	Operator A	SU25060011	4.879	Positive
	Operator A	SU25060065	5.341	Negative
	Operator B	SU25060030	4.765	Positive
	Operator B	SU25060011	4.879	Positive
	Operator B	SU25060075	5.526	Negative
	Operator B	SU25060073	5.699	Negative
	Operator C	SU25060042	4.315	Positive
	Operator C	SU25060011	4.879	Positive
	Operator C	SU25060065	5.341	Negative
	Operator C	SU25060073	5.699	Negative
THC 20	Operator A	SU25050194	18.614	Positive
	Operator A	SU25050181	19.363	Positive
	Operator A	SU25050167	20.499	Negative
	Operator A	SU25050220	20.645	Negative
	Operator B	SU25050194	18.614	Positive
	Operator B	SU25050181	19.363	Positive
	Operator B	SU25050167	20.499	Negative
	Operator C	SU25050185	18.422	Positive
	Operator C	SU25050181	19.363	Positive
	Operator C	SU25050220	20.645	Negative
	Operator C	SU25050230	21.541	Negative

Drug	Operator	Sample Number	LC/MS Results (ng/mL)	Device Results
TRA 100	Operator A	SU25050130	98.136	Positive
	Operator A	SU25050098	98.772	Positive
	Operator A	SU25050120	102.471	Negative
	Operator B	SU25050130	98.136	Positive
	Operator B	SU25050144	108.094	Negative
	Operator C	SU25050098	98.772	Positive
	Operator C	SU25050120	102.471	Negative

2. Matrix Comparison:

Not applicable.

C Clinical Studies:

1. Clinical Sensitivity:

Not applicable.

2. Clinical Specificity:

Not applicable.

3. Other Clinical Supportive Data (When 1. and 2. Are Not Applicable):

A lay user study was performed involving a total of 140 participants from 3 sites. 76 males and 64 females tested SAFElife™ T-Cup Multi-Drug Urine Test Cup Configuration 1 (including 6-MAM10, AMP1000, BAR300, BUP10, BZO300, COC300, FTY1, MDMA500, mAMP1000, OPI2000, MTD300, NFTY5, OXY100, THC20, TRA100). 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 18 and over, with diverse educational backgrounds. Urine samples were prepared at the following concentrations: -100%, +/-75%, +/-50%, +/-25% of the cutoff by spiking drug(s) into drug free-pooled urine specimens. Results from the lay user testing are provided in the below table:

Drug/ Cutoff	Result	Concentration						
		-100% cutoff	-75% cutoff	-50% cutoff	-25% cutoff	+25% cutoff	+50% cutoff	+75% cutoff
6-MAM10	Negative	20	20	20	18	1	0	0
	Positive	0	0	0	2	19	20	20
	Total	20	20	20	20	20	20	20
	Agreement (%)	100%	100%	100%	90%	95%	100%	100%

Drug/ Cutoff	Result	Concentration						
		-100% cutoff	-75% cutoff	-50% cutoff	-25% cutoff	+25% cutoff	+50% cutoff	+75% cutoff
AMP1000	Negative	20	20	20	19	1	0	0
	Positive	0	0	0	1	19	20	20
	Total	20	20	20	20	20	20	20
	Agreement (%)	100%	100%	100%	95%	95%	100%	100%
BAR300	Negative	20	20	20	19	2	0	0
	Positive	0	0	0	1	18	20	20
	Total	20	20	20	20	20	20	20
	Agreement (%)	100%	100%	100%	95%	90%	100%	100%
BUP10	Negative	20	20	20	18	2	0	0
	Positive	0	0	0	2	18	20	20
	Total	20	20	20	20	20	20	20
	Agreement (%)	100%	100%	100%	90%	90%	100%	100%
BZO300	Negative	20	20	20	19	2	0	0
	Positive	0	0	0	1	18	20	20
	Total	20	20	20	20	20	20	20
	Agreement (%)	100%	100%	100%	95%	90%	100%	100%
COC300	Negative	20	20	20	18	1	0	0
	Positive	0	0	0	2	19	20	20
	Total	20	20	20	20	20	20	20
	Agreement (%)	100%	100%	100%	90%	95%	100%	100%
FTY1	Negative	20	20	20	18	1	0	0
	Positive	0	0	0	2	19	20	20
	Total	20	20	20	20	20	20	20
	Agreement (%)	100%	100%	100%	90%	95%	100%	100%
mAMP 1000	Negative	20	20	20	19	1	0	0
	Positive	0	0	0	1	19	20	20
	Total	20	20	20	20	20	20	20
	Agreement (%)	100%	100%	100%	95%	95%	100%	100%
MDMA500	Negative	20	20	20	18	1	0	0
	Positive	0	0	0	2	19	20	20
	Total	20	20	20	20	20	20	20
	Agreement (%)	100%	100%	100%	90%	95%	100%	100%
MTD300	Negative	20	20	20	19	1	0	0
	Positive	0	0	0	1	19	20	20
	Total	20	20	20	20	20	20	20
	Agreement (%)	100%	100%	100%	95%	95%	100%	100%
NFTY5	Negative	20	20	20	18	2	0	0
	Positive	0	0	0	2	18	20	20
	Total	20	20	20	20	20	20	20

Drug/ Cutoff	Result	Concentration						
		-100% cutoff	-75% cutoff	-50% cutoff	-25% cutoff	+25% cutoff	+50% cutoff	+75% cutoff
	Agreement (%)	100%	100%	100%	90%	90%	100%	100%
OPI2000	Negative	20	20	20	19	1	0	0
	Positive	0	0	0	1	19	20	20
	Total	20	20	20	20	20	20	20
	Agreement (%)	100%	100%	100%	95%	95%	100%	100%
OXY100	Negative	20	20	20	18	1	0	0
	Positive	0	0	0	2	19	20	20
	Total	20	20	20	20	20	20	20
	Agreement (%)	100%	100%	100%	90%	95%	100%	100%
THC20	Negative	20	20	20	19	2	0	0
	Positive	0	0	0	1	18	20	20
	Total	20	20	20	20	20	20	20
	Agreement (%)	100%	100%	100%	95%	90%	100%	100%
TRA100	Negative	20	20	20	18	1	0	0
	Positive	0	0	0	2	19	20	20
	Total	20	20	20	20	20	20	20
	Agreement (%)	100%	100%	100%	90%	95%	100%	100%

Lay users were also given surveys on the ease of understanding the package insert. All participants indicated that the device instruction is easy to understand and follow. A Flesch-Kincaid reading analysis was performed on each package insert and the scores revealed a reading Grade Level of 7.

D Clinical Cut-Off:

Not applicable.

E Expected Values/Reference Range:

Not applicable.

VIII Proposed Labeling:

The labeling supports the finding of substantial equivalence for this device.

IX Conclusion:

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