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

A. 510(k) Number:

k160793

B. Purpose for Submission:

New Device

C. Measurand:

MDMA (Methylenedioxymethaneamphetamine)

EDDP (2-ethylidene-1,5-dimethyl-3,3- diphenylpyrrolidine)

Nortriptyline

D. Type of Test:

Qualitative Assay

E. Applicant:

W. H. P. M., Inc.

F. Proprietary and Established Names:

First Sign Drug of Abuse MDMA Cup Test
First Sign Drug of Abuse MDMA Dip Card Test
First Sign Drug of Abuse EDDP Cup Test
First Sign Drug of Abuse EDDP Dip Card Test
First Sign Drug of Abuse Nortriptyline Cup Test
First Sign Drug of Abuse Nortriptyline Dip Card Test

G. Regulatory Information:

Product Code	Classification	Regulation Section	Panel
LAF	Class II	862.3610	91-Toxicology
DJR	Class II	862.3620	91-Toxicology
LFG	Class II	862.3910	91-Toxicology

H. Intended Use:

1. Intended use(s):

   See indications for Use below.

2. Indication(s) for use:

   First Sign Drug of Abuse MDMA Cup Test
   First Sign Drug of Abuse MDMA Dip Card Test
   First Sign Drug of Abuse MDMA Tests are immunoassay tests. The test can detect MDMA in human urine. The cut-off value is 500 ng/mL. The tests are available in a Cup format and a Dip Card format.

   The tests provide only preliminary test results. If you want to get a confirmed result, you must use a more specific chemical method. Gas Chromatography/Mass Spectrometry is the preferred confirmatory method. Clinical consideration and professional judgment should be used when you get any drug of abuse test result. It should be used particularly when the preliminary result is positive.
   For in vitro diagnostic use only. The tests are intended for over-the-counter and for prescription use.

   First Sign Drug of Abuse EDDP Cup Test
   First Sign Drug of Abuse EDDP Dip Card Test
   First Sign Drug of Abuse EDDP Tests are immunoassay tests. The test can detect EDDP in human urine. The cut-off value is 300 ng/mL. The tests are available in a Cup format and a Dip Card format.

   The tests provide only preliminary test results. If you want to get a confirmed result, you must use a more specific chemical method. Gas Chromatography/Mass Spectrometry is the preferred confirmatory method. Clinical consideration and professional judgment should be used when you get any drug of abuse test result. It should be used particularly when the preliminary result is positive.
   For in vitro diagnostic use only. The tests are intended for over-the-counter and for prescription use.

   First Sign Drug of Abuse Nortriptyline Cup Test
   First Sign Drug of Abuse Nortriptyline Dip Card Test
   First Sign Drug of Abuse Nortriptyline Tests are immunoassay tests. The test can detect Nortriptyline in human urine. The cut-off value is 1,000 ng/mL. The tests are available in a Cup format and a Dip Card format.

   The tests provide only preliminary test results. If you want to get a confirmed result, you must use a more specific chemical method. Gas Chromatography/Mass Spectrometry is the preferred confirmatory method. Clinical consideration and professional judgment should be used when you get any drug of abuse test result. It should be used particularly

when the preliminary result is positive.
For in vitro diagnostic use only. The tests are intended for over-the-counter and for prescription use.

3. Special conditions for use statement(s):

   For over-the-counter and prescription use

4. Special instrument requirements:

   Not applicable. The devices are visually read and single-use.

I. Device Description:

These devices are immunochromatographic assays for MDMA, EDDP and Nortriptyline Urine Tests use a lateral flow, one step system for the qualitative detection of MDMA, EDDP and Nortriptyline in human urine. Each assay uses a monoclonal antibody-dye conjugate against drugs with gold chloride and fixed drug-protein conjugates and antimouse IgG polyclonal antibody in membranes.

The assays in this submission include a dip card and cup formats. Each assay and format is available separately.

J. Substantial Equivalence Information:

1. Predicate device name(s):
   Co-Innovation Biotech One Step Single/Multi-Drug Test

2. Predicate 510(k) number(s):
   k142800
   k140748

3. Comparison with predicate:

Similarities		
Item	Candidate Device	Predicate (k142800)
Intended Use	For the qualitative determination of MDMA in human urine.	Rapid Single/Multi-drug test Cup and Rapid Single/Multi-drug test Dipcard are lateral flow chromatographic immunoassays designed to qualitatively detect the presence of drugs and drug metabolites in human urine
Calibrator Drug	MDMA	Delta-9-THC-COOH Benzolecgonine

Similarities		
Item	Candidate Device	Predicate (k142800)
		D-Amphetamine D-Methamphetamine Morphine Secobarbital Oxazepam 3,4-Methylenedioxymethamphetamine Methadone Oxycodone Phencyclidine
Methodology	Competitive binding, lateral flow immunochromatographic assays based on the principle of antigen antibody immunochemistry.	Same
Specimen Type	Human Urine	Same
Cut-Off Values	500 ng/mL (MDMA)	Same
Intended Populations	For over-the-counter use and prescription uses	Same

Similarities		
Item	Candidate Device	Predicate (k140748)
Intended Use	For the qualitative determination of EDDP and Nortriptyline in human urine.	One Step Single/Multi-drug Test Cup and One Step Single/Multi-drug Test Dipcard are lateral flow chromatographic immunoassays designed to qualitatively detect the presence of drugs and drug metabolites in human urine
Calibrator Drug	EDDP Nortriptyline	Buprenorphine 2-ethylidene-1, 5-dimethyl-3, 3-diphenylpyrrolidine" Morphine Propoxyphene Nortriptyline
Methodology	Competitive binding, lateral flow immunochromatographic assays based on the principle of antigen antibody	Same

Similarities		
Item	Candidate Device	Predicate (k140748)
	immunochemistry.	
Specimen Type	Human Urine	Same
Cut-Off Values	300 ng/mL (EDDP) 1000 ng/mL (Nortriptyline)	Same
Intended Populations	For over-the-counter use and prescription uses	Same

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

None were referenced

L. Test Principle:

First Sign Drug of Abuse MDMA Test, First Sign Drug of Abuse EDDP Test and First Sign Drug of Abuse Nortriptyline Test are immunochromatographic assays. Each assay test is a lateral flow system for the qualitative detection of MDMA, or EDDP or Nortriptyline in human urine. During testing, a urine specimen migrates upward by capillary action. If target drugs are present in the urine specimen below its cut-off concentration, it will not saturate the binding sites of its specific antibody (monoclonal mouse antibody) coated on the particles. The antibody-coated particles will then be captured by immobilized drug-conjugate and a visible colored line will show up in the test line region. The colored line will not form in the test line region if the target drug level exceeds its cut-off concentration because it will saturate all the binding sites of the antibody coated on the particles. A band should form in the control region of the devices regardless of the presence of drug or metabolite in the sample.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

   a. *Precision/Reproducibility:*
   Precision studies were carried out for samples with concentrations of -100% cut-off, -75% cut-off, -50% cut-off, -25% cut-off, at the cut-off, +25% cut-off, +50% cut-off, +75% cut-off and +100% cut-off. These samples were prepared by spiking drug in negative urine samples. Each drug concentration was confirmed by GC/MS. All sample aliquots were blinded labeled and randomized. For each concentration, tests were performed two runs per day for 25 days.

MDMA Dip Card

MDMA	-100% cut off	-75% cut off	-50% cut off	-25% Cutoff	cut off	+25% cutoff	+50% cutoff	+75% cutoff	+100% cutoff
Lot 1	50-/0+	50-/0+	50-/0+	50-/0+	2-/48+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 2	50-/0+	50-/0+	50-/0+	50-/0+	3-/47+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 3	50-/0+	50-/0+	50-/0+	50-/0+	3-/47+	50+/0-	50+/0-	50+/0-	50+/0-

MDMA Cup

MDMA	-100% cut off	-75% cut off	-50% cut off	-25% Cutoff	cut off	+25% cutoff	+50% cutoff	+75% cutoff	+100% cut off
Lot 4	50-/0+	50-/0+	50-/0+	50-/0+	3-/47+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 5	50-/0+	50-/0+	50-/0+	50-/0+	2-/48+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 6	50-/0+	50-/0+	50-/0+	50-/0+	2-/48+	50+/0-	50+/0-	50+/0-	50+/0-

EDDP Dip Card

EDDP	-100% cut off	-75% cut off	-50% cut off	-25% Cutoff	cut off	+25% cutoff	+50% cutoff	+75% cutoff	+100% cut off
Lot 1	50-/0+	50-/0+	50-/0+	50-/0+	3-/47+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 2	50-/0+	50-/0+	50-/0+	50-/0+	2-/48+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 3	50-/0+	50-/0+	50-/0+	50-/0+	2-/48+	50+/0-	50+/0-	50+/0-	50+/0-

EDDP Cup

EDDP	-100% cut off	-75% cut off	-50% cut off	-25% Cutoff	cut off	+25% cutoff	+50% cutoff	+75% cutoff	+100% cut off
Lot 4	50-/0+	50-/0+	50-/0+	50-/0+	2-/48+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 5	50-/0+	50-/0+	50-/0+	50-/0+	2-/48+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 6	50-/0+	50-/0+	50-/0+	50-/0+	3-/47+	50+/0-	50+/0-	50+/0-	50+/0-

Nortriptyline Dip Card

Nortriptyline	-100% cut off	-75% cut off	-50% cut off	-25% Cutoff	cut off	+25% cutoff	+50% cutoff	+75% cutoff	+100 % cut off
Lot 1	50-/0+	50-/0+	50-/0+	50-/0+	3-/47+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 2	50-/0+	50-/0+	50-/0+	50-/0+	2-/48+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 3	50-/0+	50-/0+	50-/0+	50-/0+	2-/48+	50+/0-	50+/0-	50+/0-	50+/0-

Nortriptyline Cup

Nortriptyline	-100% cut off	-75% cut off	-50% cut off	-25% Cutoff	cut off	+25% cutoff	+50% cutoff	+75% cutoff	+100% cut off
Lot 4	50-/0+	50-/0+	50-/0+	50-/0+	2-/48+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 5	50-/0+	50-/0+	50-/0+	50-/0+	3-/47+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 6	50-/0+	50-/0+	50-/0+	50-/0+	3-/47+	50+/0-	50+/0-	50+/0-	50+/0-

b. *Linearity/assay reportable range:*

Not applicable, these devices are intended for qualitative use only.

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

Stability
Real-time and accelerated stability studies were conducted on three lots of each device. The protocols for the stability studies were reviewed and found to be acceptable. The results of these studies indicated that all devices were found to be stable at 4-30℃ (39-86^{o}F) for 24 months based on the accelerated stability study at 50℃ and a shelf life study at 30℃. Control materials are not provided with the device. The labeling provides information on how to obtain control materials.

Transportation Study
A Transportation stability study was conducted on three lots of each device. The protocols for the transportation stability study were reviewed and found to be acceptable. The results of these studies indicated that all devices were found to be stable during transport of the device in temperatures between -20 and 40℃.

d. *Detection limit:*

Not applicable.

e. *Analytical specificity:*
Compounds sharing structural or conformational similarity with the analytes were tested for cross-reactivity with the candidate device. The structurally related compounds that exhibited cross-reactivity with the candidate device were titrated to determine the percent cross-reactivity. The concentration (ng/mL) of cross-reactant that gives a response equivalent to the cutoff, and the percent cross-reactivity are presented in the table below.

MDMA Cross Reactivity

Drugs	**Concentration (ng/ml)**	**Reactivity**
Methylenedioxymethamphetamine (MDMA)	500	100%
3,4-Methylenedioxyamphetamine (MDA)	8000	6.3%
3,4-Methylenedioxyethylamphetamine (MDEA)	1000	50%
Ephedrine	40000	1.3%
d-methamphetamine	Negative at	Not Detected

Drugs	Concentration (ng/ml)	Reactivity
	100000	
d-amphetamine	Negative at 100000	Not Detected
l-amphetamine	Negative at 100000	Not Detected
l-methamphetamine	Negative at 100000	Not Detected

EDDP Cross Reactivity

Drugs	Concentration (ng/ml)	Reactivity
EDDP (2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine)	300	100%
EMDP (2-Ethyl-5-methyl-3,3-diphenylpyrroline)	Negative at 100000	Not Detected
Disopyramide	Negative at 100000	Not Detected
Methadone	Negative at 100000	Not Detected
LAAM (Levo-alpha-acetylmethadol)	Negative at 100000	Not Detected
Alpha Methadol	Negative at 100000	Not Detected
Doxylamine	Negative at 100000	Not Detected

Nortriptyline Cross Reactivity

Drugs	Concentration (ng/ml)	Reactivity
Nortriptyline	1000	100%
Amitriptyline	1500	67%
Clomipramine	15000	6.7%
Desipramine	1000	100%
Doxepine	2000	50%
Imipramine	600	167%
Nordoxepin	1000	100%
Promazine	24000	4%

Trimipramine	4000	25%
Cyclobenzaprine	1500	67%
Maprotiline	Negative at 100000	Not Detected
Promethazine	Negative at 100000	Not Detected
Norclomipramine	Negative at 100000	Not Detected

Interference Study

Potential interfering substances found in human urine of physiological or pathological conditions were added to drug-free urine and target drugs. These urine samples were tested using three batches of each device for all formats.

Compounds that showed no interference at a concentration of 100µg/mL for different formats (cup, dipcard) are listed below:

MDMA Interference

4-Acetamidophenol	(L) - Epinephrine	Pentobarbital
Acetophenetidin	Erythromycin	Perphenazine
N-Acetylprocainamide	β-Estradiol	Phencyclidine
Acetylsalicylic acid	Estrone-3-sulfate	Phenelzine
Aminopyrine	Ethyl-p-aminobenzoate	Phenobarbital
Amitryptyline	Fenoprofen	Phentermine
Amobarbital	Furosemide	Trans-2-phenylcyclopropylamine hydrochloride
Amoxicillin	Gentisic acid	
Ampicillin	Hemoglobin	
L-Ascorbic acid	Hydralazine	L-Phenylephrine
Apomorphine	Hydrochlorothiazide	β-Phenylethylamine
Aspartame	Hydrocodone	Phenylpropanolamine
Atropine	Hydrocortisone	Prednisolone
Benzilic acid	O-Hydroxyhippuric acid	Prednisone
Benzoic acid	3-Hydroxytyramine	Procaine
Benzoylecgonine	Ibuprofen	Promazine
Bilirubin	Imipramine	Promethazine
(±) - Brompheniramine	Iproniazid	DL-Propranolol
Buspiron	(±) - Isoproterenol	D-Propoxyphene
Caffeine	Isoxsuprine	D-Pseudoephedrine
Cannabidiol	Ketamine	Quinacrine
Cannabinol	Ketoprofen	Quinidine
Chloralhydrate	Labetalol	Quinine
Chloramphenicol	Levorphanol	Ranitidine
	Loperamide	Salicylic acid
	Maprotiline	Secobarbital

Chlordiazepoxide	Meperidine	Serotonin (5-Hydroxytyramine)
Chlorothiazide	Meprobamate	Sulfamethazine
(±) - Chlorpheniramine	Methadone	Sulindac
Chlorpromazine	Morphine-3-β-Dglucuronide	Sustiva
Chloroquine	Morphine sulfate	Temazepam
Cholesterol	Nalidixic acid	Tetracycline
Clomipramine	Naloxone	Tetrahydrocortisone 3-(β-Dglucuronide)
Clonidine	Naltrexone	Tetrahydrozoline
Cocaethylene	Naproxen	Thebaine
Cocaine hydrochloride	Niacinamide	Theophynine
Codeine	Nifedipine	Thiamine
Cortisone	Nimesulidate	Thioridazine
(-) Cotinine	Norcodein	Tolbutamide
Creatinine	Norethindrone	Trazodone
Deoxycorticosterone	D-Norpropoxyphene	Triamterene
Dextromethorphan	Noscapine	DL-Tyrosine
Diclofenac	D,L-Octopamine	Trifluoperazine
Diazepam	Oxalic acid	Trimethoprim
Diflunisal	Oxazepam	Trimipramine
Digoxin	Oxolinic acid	Tryptamine
Dicylomine	Oxycodone	D L-Tryptophan
Diphenhydramine	Oxymetazoline	Tyramine
5,5 - Diphenylhydantoin	Papaverine	Uric acid
Doxylamine	Penicillin-G	Verapamil
Ecgonine hydrochloride	Pentazocinehydrochloride	Zomepirac
Ecgonine methylester		
[1R,2S](-) Ephedrine		

EDDP Interference

Acetaminophen	Ecgonine hydrochloride	O-Hydroxyhippuric acid
Acetophenetidin	Ecgonine methylester	Oxalic acid
Acetylsalicylic acid	(IR,2S)(-)Ephedrine	Oxazepam
Amobarbital	Erythromycin	Oxolinic acid
Aminopyrine	β-Estradiol	Oxycodone
Amitryptyline	Estrone-3-sulfate	Oxymetazoline
Amoxicillin	Ethyl-p-aminobenzoate	Papaverine
DL-Amphetamine sulfate	Fenoprofen	Penicillin-G
	Furosemide	Pentazocine
Ampicillin	Gentisic acid	Pentobarbital
Apomorphine	Hemoglobin	Perphenazine
Ascorbic acid	Hydralazine	Phencyclidine

Aspartame	Hydrochlorothiazide	Phenelzine
Atropine	Hydrocodone	Phenobarbital
Benzilic acid	Hydrocortisone	Phentermine
Benzoic acid	p-Hydroxyamphetamine	β-Phenylethylamine
Benzoylecgonine	p-Hydroxymethamphetamine	Phenylpropanolamine
Bilirubin	3-Hydroxytyramine	Prednisolone
Brompheniramine	Ibuprofen	Prednisone
Caffeine	Imipramine	Procaine
Cannabidiol	(-) Isoproterenol	Promazine
Cannabinol	Isoxsuprine	Promethazine
Chloralhydrate	Ketamine	Quinidine
Chloramphenicol	Ketoprofen	Quinine
Chlorothiazide	Labetalol	Ranitidine
(±) - Chlorpheniramine	Levorphanol	Salicylic acid
Chlorpromazine	Loperamide	Secobarbital
Chloroquine	L-Phenylephrine	Serotonin
Cholesterol	Maprotiline	Sulfamethazine
Clomipramine	Meperidine	Sulindac
Clonidine	Meprobamate	Temazepam
Cocaine hydrochloride	Methamphetamine	Tetracycline
Codeine	Methoxyphenamine	Tetrahydrocortisone 3- (β-D-glucuronide)
(-) Cotinine	(±) - 3,4-Methylenedioxy-amphetamine hydrochloride	Tetrahydrozoline
Cortisone	(±)-3,4-Methylenedioxy-methamphetamine hydrochloride	Thebaine
Creatinine	Morphine Sulfate	Thiamine
Deoxycorticosterone	Morphine-3-β-D glucuronide	Thioridazine
Dextromethorphan	N-Acetylprocainamide	Triamterene
Diazepam	Nalidixic acid	Trifluoperazine
Diclofenac	Naloxone	Trimethoprim
Diflunisal	Naltrexone	Trimipramine
Digoxin	Naproxen	Tryptamine
Diphenhydramine	Niacinamide	DL-Tryptophan
D-Norpropoxyphene	Nifedipine	Tyramine
D-Propoxyphene	Norcodein	Uric acid
D,L-Tyrosine	Norethindrone	Verapamil
DL-Octopamine	Noscapine	Zomepirac
DL-Propranolol		

Nortriptyline Interference

4-Acetamidophenol	Erythromycin	Oxycodone
Acetophenetidin	β-Estradiol	Oxymetazoline
N-	Estrone-3-sulfate	Papaverine

Acetylprocainamide	Ethyl-p-aminobenzoate	Penicillin-G
Acetylsalicylic acid		Pentazocine hydrochloride
Aminopyrine	Fenoprofen	Pentobarbital
Amobarbital	Furosemide	Perphenazine
Amoxicillin	Gentisic acid	Phencyclidine
Ampicillin	Hemoglobin	Phenelzine
L-ascorbic acid	Hydralazine	Phenobarbital
DL-Amphetamine	Hydrochlorothiazide	Phentermine
Hydrochlorothiazide	Hydrocodone	β-Phenylethylamine
Phenobarbital	Hydrocortisone	Trans-2-
sulfate	O-Hydroxyhippuric acid	phenylcyclopropylamine
Apomorphine	p-Hydroxyamphetamine	hydrochloride
Aspartame		L-Phenylephrine
Atropine	p-Hydroxy-	Phenylpropanolamine
Benzilic acid	methamphetamine	Prednisolone
Benzoic acid	3-Hydroxytyramine	Prednisone
Benzoylecgonine	Ibuprofen	Procaine
Benzphetamine	Iproniazid	DL-Propranolol
Bilirubin	(±) - Isoproterenol	D-Propoxyphene
(±) -	Isoxsuprine	D-Pseudoephedrine
Brompheniramine	Ketamine	Quinacrine
Caffeine	Ketoprofen	Quinidine
Cannabidiol	Labetalol	Quinine
Cannabinol	Loperamide	Ranitidine
Chloralhydrate	MDE	Salicylic acid
Chloramphenicol	Meperidine	Secobarbital
Chlorothiazide	Meprobamate	Serotonin
(±)	Methadone	Sulfamethazine
Chlorpheniramine	(L)Methamphetamine	Sulindac
Chlorpromazine	Methoxyphenamine	Tetracycline
Chloroquine	(±)-3,4-	Tetrahydrocortisone 3-(β-D-
Cholesterol	Methylenedioxyamphetami	glucuronide)
Clonidine	ne	Tetrahydrozoline
Cocaethylene	hydrochloride	Thiamine
Cocaine	Morphine-3-β-	Thioridazine
hydrochloride	Dglucuronide Morphine	DL-Tyrosine
Codeine	sulfate	Tolbutamide
Cortisone	Nalidixic acid	Triamterene
(-) Cotinine	Naloxone	Trifluoperazine
Creatinine	Naltrexone	Trimethoprim
Deoxycorticosterone	Naproxen	Tryptamine
Dextromethorphan	Niacinamide	DL-Tryptophan
Diclofenac	Nifedipine	Tyramine
Diflunisal	Norcodeine	Verapamil
Digoxin	Norethindrone	Zomepirac
Diphenhydramine	D-Norpropoxyphene	

Doxylamine Ecgonine hydrochloride Ecgonine methylester Ephedrine (L) - Epinephrine	Noscapine Oxalic acid Oxazepam Oxolinic acid	

Effect of Urine Specific Gravity and Urine pH

To investigate the effect of urine specific gravity and urine pH, urine samples with 1.000 to 1.035 specific gravity or urine samples with pH 4 to 9 were spiked with target drugs at 25% below and 25% above cut-off levels. These samples were tested using three batches of each device for all formats. Results were all positive for samples at and above +25% cut-off and all negative for samples at and below -25% Cut-Off. There were no differences observed for different formats.

f. Assay cut-off:

Characterization of how the device performs analytically around the claimed cutoff concentration is described in the precision section, M.1.a. above.

2. Comparison studies:

a. Method comparison with predicate device:

The method comparison studies for the First Sign Drug of Abuse tests (MDMA, EDDP and Nortriptyline) were performed in-house with three different laboratory assistants for each format of the device. Operators ran 80 (40 negative and 40 positive) unaltered clinical samples for each drug. The samples were blind labeled and compared to GC/MS results.

MDMA Dip Card

Test		Drug-free	Low Negative (<50% the cutoff conc)	Near Cutoff Negative (Between <50% below up to the cutoff conc)	Near Cutoff Positive (Between the cutoff and 50% above cutoff conc)	High Positive (>50% above the cutoff conc)
Operator A	Positive	0	0	0	13	26
	Negative	10	10	20	1†	0
Operator B	Positive	0	0	1*	14	26
	Negative	10	10	19	0	0
Operator C	Positive	0	0	1*	13	26
	Negative	10	10	19	1†	0

% agreement among positives is 98.3%
% agreement among negatives is 98.3%
* Samples contained MDMA at 474 and 468 ng/mL
† Samples contained MDMA at 544 and 561 ng/mL

MDMA Cup

Test		Drug-free	Low Negative (<50% the cutoff conc)	Near Cutoff Negative (Between <50% below up to the cutoff conc)	Near Cutoff Positive (Between the cutoff and 50% above cutoff conc)	High Positive (>50% above the cutoff conc)
Operator A	Positive	0	0	1*	14	26
	Negative	10	10	10	0	0
Operator B	Positive	0	0	0	13	26
	Negative	10	10	20	1†	0
Operator C	Positive	0	0	1*	14	26
	Negative	10	10	19	0	0

% agreement among positives is 99.2%
% agreement among negatives is 98.3%
* Samples contained MDMA at 470 and 477 ng/mL
† Samples contained MDMA at 517 ng/mL

EDDP Dip Card

Test		Drug-free	Low Negative (<50% the cutoff conc)	Near Cutoff Negative (Between <50% below up to the cutoff conc)	Near Cutoff Positive (Between the cutoff and 50% above cutoff conc)	High Positive (>50% above the cutoff conc)
Operator A	Positive	0	0	1*	13	26
	Negative	10	10	19	1†	0
Operator B	Positive	0	0	1*	14	26
	Negative	10	10	19	0	0
Operator C	Positive	0	0	1*	13	26
	Negative	10	10	19	1†	0

% agreement among positives is 98.3%
% agreement among negatives is 97.5%
* Samples contained EDDP at 260, 269, and 276 ng/mL
† Samples contained EDDP at 340 and 344 ng/mL

EDDP Cup

Test		Drug-free	Low Negative (<50% the cutoff conc)	Near Cutoff Negative (Between <50% below up to the cutoff conc)	Near Cutoff Positive (Between the cutoff and 50% above cutoff conc)	High Positive (>50% above the cutoff conc)
Operator A	Positive	0	0	1*	13	26
	Negative	10	10	19	1†	0
Operator B	Positive	0	0	0	13	26
	Negative	10	10	20	1†	0

Operator C	Positive	0	0	1*	13	26
	Negative	10	10	19	1†	0

% agreement among positives is 97.5%
% agreement among negatives is 98.3%
* Samples contained EDDP at 266 and 269 ng/mL
† Samples contained EDDP at 340, 342, and 344 ng/mL

Nortriptyline Dip Card

Test		Drug-free	Low Negative (<50% the cutoff conc)	Near Cutoff Negative (Between <50% below up to the cutoff conc)	Near Cutoff Positive (Between the cutoff and 50% above cutoff conc)	High Positive (>50% above the cutoff conc)
Operator A	Positive	0	0	1*	14	26
	Negative	10	10	19	0	0
Operator B	Positive	0	0	1*	13	26
	Negative	10	10	19	1†	0
Operator C	Positive	0	0	1*	13	26
	Negative	10	10	19	1†	0

% agreement among positives is 98.3%
% agreement among negatives is 97.5%
* Samples contained Nortriptyline at 851, 863, and 879 ng/mL
† Samples contained Nortriptyline at 1069 and 1125 ng/mL

Nortriptyline Cup

Test		Drug-free	Low Negative (<50% the cutoff conc)	Near Cutoff Negative (Between <50% below up to the cutoff conc)	Near Cutoff Positive (Between the cutoff and 50% above cutoff conc)	High Positive (>50% above the cutoff conc)
Operator A	Positive	0	0	1*	13	26
	Negative	10	10	19	1†	0
Operator B	Positive	0	0	1*	14	26
	Negative	10	10	19	0	0

Operator C	Positive	0	0	0	13	26
	Negative	10	10	20	1†	0

% agreement among positives is 98.3%
% agreement among negatives is 98.3%
* Samples contained Nortriptyline at 851 and 870 ng/mL
† Samples contained Nortriptyline at 1084 and 1135 ng/mL

b. Matrix comparison:

N/A

3. Clinical studies:

a. Clinical Sensitivity:

N/A

b. Clinical specificity:

N/A

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

Lay User Study
A lay user study was performed at three intended user sites with 280 lay persons testing the MDMA devices, 280 lay persons testing the EDDP devices and 280 lay persons testing the Nortriptyline devices. A total of 140 females and 140 males tested the MDMA samples, 141 females and 139 males tested EDDP samples, and 141 females and 139 males tested the Nortriptyline samples. They had diverse educational and professional backgrounds and ranged in age from 21 to > 50 years. Urine samples were prepared at the following concentrations; negative, +/-75%, +/-50%, +/-25% of the cutoff by spiking drugs into drug free-pooled urine specimens. The concentrations of the samples were confirmed by GC/MS. Each sample was aliquoted into individual containers and blind-labeled. Each participant was provided with the package insert, 1 blind labeled sample and a device.

Lay-users were also given surveys on the ease of understanding the package insert instructions. All lay users indicated that the device instructions can be easily followed. A Flesch-Kincaid reading analysis was performed on each package insert and the scores revealed a reading Grade Level of 7.

MDMA Dip Card

% of Cutoff	Number of samples	MDMA Concentration by GC/MS (ng/mL)	Lay person results		The percentage of correct results (%)
			No. of Positive	No. of Negative	
-100%Cutoff	20	0	0	20	100
-75%Cutoff	20	115	0	20	100
-50% Cutoff	20	237	0	20	100
-25% Cutoff	20	358	0	20	100
+25% Cutoff	20	598	19	1	95
+50% Cutoff	20	755	20	0	100
+75% Cutoff	20	912	20	0	100

MDMA Cup

% of Cutoff	Number of samples	MDMA Concentration by GC/MS (ng/mL)	Lay person results		The percentage of correct results (%)
			No. of Positive	No. of Negative	
-100%Cutoff	20	0	0	20	100
-75%Cutoff	20	115	0	20	100
-50% Cutoff	20	237	0	20	100
-25% Cutoff	20	358	1	19	95
+25% Cutoff	20	598	20	0	100
+50% Cutoff	20	755	20	0	100
+75% Cutoff	20	912	20	0	100

EDDP Dip Card

% of Cutoff	Number of samples	EDDP Concentration by GC/MS (ng/mL)	Lay person results		The percentage of correct results (%)
			No. of Positive	No. of Negative	
-100%Cutoff	20	0	0	20	100
-75%Cutoff	20	81	0	20	100
-50% Cutoff	20	157	0	20	100
-25% Cutoff	20	235	2	18	90
+25% Cutoff	20	410	20	0	100
+50% Cutoff	20	485	20	0	100
+75% Cutoff	20	566	20	0	100

EDDP Cup

% of Cutoff	Number of samples	EDDP Concentration by GC/MS (ng/mL)	Lay person results		The percentage of correct results (%)
			No. of Positive	No. of Negative	
-100%Cutoff	20	0	0	20	100
-75%Cutoff	20	81	0	20	100
-50% Cutoff	20	157	0	20	100
-25% Cutoff	20	235	1	19	95
+25% Cutoff	20	410	20	0	100
+50% Cutoff	20	485	20	0	100
+75% Cutoff	20	566	20	0	100

Nortriptyline Dip Card

% of Cutoff	Number of samples	Nortriptyline Concentration by GC/MS (ng/mL)	Lay person results		The percentage of correct results (%)
			No. of Positive	No. of Negative	
-100%Cutoff	20	0	0	20	100
-75%Cutoff	20	261	0	20	100
-50% Cutoff	20	495	0	20	100
-25% Cutoff	20	720	1	19	95
+25% Cutoff	20	1180	20	0	100
+50% Cutoff	20	1485	20	0	100
+75% Cutoff	20	1687	20	0	100

Nortriptyline Cup

% of Cutoff	Number of samples	Nortriptyline Concentration by GC/MS (ng/mL)	Lay person results		The percentage of correct results (%)
			No. of Positive	No. of Negative	
-100%Cutoff	20	0	0	20	100
-75%Cutoff	20	261	0	20	100
-50% Cutoff	20	495	0	20	100
-25% Cutoff	20	720	1	19	95
+25% Cutoff	20	1180	19	1	95
+50% Cutoff	20	1485	20	0	100
+75% Cutoff	20	1687	20	0	100

4. Clinical cut-off**:**

   N/A

5. Expected values/Reference range:

   N/A

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.