DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

December 18, 2014

GUANGZHOU WONDFO BIOTECH CO., LTD.
C/O JOE SHIA
LSI INTERNATIONAL INC.
504 EAST DIAMOND AVE. SUITE F
GAITHERSBURG MD 20878

Re: K142609
Trade/Device Name: CR3 Keyless Split Sample Cup Nortriptyline-Buprenorphine
Regulation Number: 21 CFR 862.3910
Regulation Name: Tricyclic antidepressant drugs test system
Regulatory Class: II
Product Code: LFG, DJG
Dated: October 13, 2014
Received: October 16, 2014

Dear Mr. Joe Shia:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Katherine Serrano -S

For: Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
k142609

Device Name
CR3 Keyless Split Sample Cup Nortriptyline – Buprenorphine

Indications for Use *(Describe)*
CR3 Keyless Split Sample Cup Nortriptyline–Buprenorphine is a rapid test for the qualitative detection of Nortriptyline (a major metabolite of Tricyclic Antidepressants) and Buprenorphine in human urine at a cutoff concentration of 1000ng/mL and 10ng/mL, respectively. The test is the first step in a two-step process. The second step is to send the sample for laboratory testing if preliminary positive results are obtained. The test is intended for over-the-counter and for prescription use.

The test may yield preliminary positive results even when prescription drugs including Tricyclic Antidepressants and Buprenorphine are ingested, at prescribed doses; it is not intended to distinguish between prescription use or abuse of these drugs. There are no uniformly recognized cutoff concentration levels for Nortriptyline and Buprenorphine in urine. 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.

For in vitro diagnostic use only.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) SUMMARY

1. Date: December 10, 2014

2. Submitter: Guangzhou Wondfo Biotech Co., Ltd.
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3. Contact person: Joe Shia
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Email:shiajl@yahoo.com

4. Device Name: CR^3 Keyless Split Sample Cup Nortriptyline – Buprenorphine

Classification: Class II

Product Code	CFR #
LFG	21CFR 862.3910
DJG	21CFR 862.3650

5. Predicate Devices: k132812
UCP Multi-Drug Test Key Cups

6. Intended Use

CR3 Keyless Split Sample Cup Nortriptyline–Buprenorphine is a rapid test for the qualitative detection of Nortriptyline (a major metabolite of Tricyclic Antidepressants) and Buprenorphine in human urine at a cutoff concentration of 1000ng/mL and 10ng/mL, respectively. The test is the first step in a two-step process. The second step is to send the sample for laboratory testing if preliminary positive results are obtained. The test is intended for over-the-counter and for prescription use.

The test may yield preliminary positive results even when prescription drugs including Tricyclic Antidepressants and Buprenorphine are ingested, at prescribed doses; it is not intended to distinguish between prescription use or abuse of these drugs. There are no uniformly recognized cutoff concentration levels for Nortriptyline and Buprenorphine in urine. 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.

For in vitro diagnostic use only.

7. Device Description

The CR3 Keyless Split Sample Cup Nortriptyline–Buprenorphine test uses immunochromatographic assays for nortriptyline and buprenorphine. The test is a lateral flow, one step system for the qualitative detection of nortriptyline and buprenorphine in human urine.

8. Substantial Equivalence Information

Item	Device	Predicate
Indication(s) for use	For the qualitative determination of drugs of abuse in human urine	Same
Methodology	Competitive binding, lateral flow immunochromatographic assays based on the principle of antigen antibody immunochemistry.	Same
Results	Qualitative	Same
Specimen Type	Human urine	Same
Cut Off Values	Nortriptyline: 1000ng/ml Buprenorphine: 10ng/ml	Same for Nortriptyline and Buprenorphine
Configurations	Cup	Cup
Conditions for Use	Over-the-Counter & Prescription Use	Same

9. Test Principle

The CR3 Keyless Split Sample Cup Nortriptyline - Buprenorphine test is a rapid test for the qualitative detection of Nortriptyline and Buprenorphine in urine samples and contains lateral flow chromatographic immunoassays for nortriptyline and buprenorphine. Each assay uses a mouse monoclonal anti-drug antibody-dye conjugate, fixed drug-protein conjugates, and anti-mouse IgG polyclonal antibodies coated on the test membranes. When the absorbent end of the test is immersed into a urine sample, the urine is absorbed into the

device by capillary action and mixes with the antibody-dye conjugate, flowing across the pre-coated membrane. At analyte concentrations below the target cut-off, antibody-dye conjugates bind to the drug-protein conjugate immobilized in the Test Region (T) of the device. This produces a colored test line that indicates a negative result. When analyte concentration is above the cut-off, analyte molecules bind 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. No colored band shows in the test region, indicating a potentially positive result. A band should form in the control region (C) of the device regardless of the presence of drug or metabolite in the sample.

10. Performance Characteristics
    1. Analytical Performance
        a. Precision

        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. For each concentration, tests were performed two runs per day for 25 days. All sample aliquots were masked and randomized. The results obtained are summarized in the following tables:

A. For Nortriptyline (TCA) testing

Result / TCA	-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
W11910601CU5	50-/0+	50-/0+	50-/0+	50-/0+	44+/6-	50+/0-	50+/0-	50+/0-	50+/0-
W11910602CU5	50-/0+	50-/0+	50-/0+	50-/0+	43+/7-	50+/0-	50+/0-	50+/0-	50+/0-
W11910603CU5	50-/0+	50-/0+	50-/0+	50-/0+	43+/7-	50+/0-	50+/0-	50+/0-	50+/0-

B. For Buprenorphine (BUP) testing

Result / BUP	-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
W11910601CU5	50-/0+	50-/0+	50-/0+	50-/0+	42+/8-	50+/0-	50+/0-	50+/0-	50+/0-
W11910602CU5	50-/0+	50-/0+	50-/0+	50-/0+	43+/7-	50+/0-	50+/0-	50+/0-	50+/0-
W11910603CU5	50-/0+	50-/0+	50-/0+	50-/0+	43+/7-	50+/0-	50+/0-	50+/0-	50+/0-

        b. Linearity

Not applicable.

c. Stability

The CR3 Keyless Split Sample Cup Nortriptyline - Buprenorphine is stable at 4-30^{o}C for 18 months as determined by conducting accelerated and real-time stability testing.

Control materials are not provided with the device. The labeling provides information on how to obtain control materials.

d. Cut-off

A total of 125 nortriptyline samples and 125 buprenorphine samples equally distributed at concentrations of -50%, -25%, at the cut-off, +25%, +50% of their respective cut-offs were labeled by a person who prepared them and would not participate in the sample testing. These samples were tested using three different lots by three different operators. Results were all positive at +25% and +50% cut-off and all negative at -25% and -50% cut-off for both nortriptyline and buprenorphine. The following cut-off values for the test devices have been verified.

Test	**Calibrator**	**Cut-off (ng/ml)**
Nortriptyline (TCA）	nortriptyline	1000
Buprenorphine (BUP)	buprenorphine	10

e. Interference

Potential interfering substances found in human urine of physiological or pathological conditions were added to drug-free urine and to urine containing target drugs (nortriptyline or buprenorphine) at 25% below and 25% above the cut-off. These urine samples were tested using three batches of the CR3Keyless Split Sample Cup Nortriptyline - Buprenorphine by three different operators. Compounds that showed no interference at a concentration of 100μg/mL are summarized below:

Nortriptyline

4-Acetamidophenol	Erythromycin	Oxycodone
Acetophenetidin	β-Estradiol	Oxymetazoline
N-Acetylprocainamide	Estrone-3-sulfate	Papaverine
Acetylsalicylic acid	Ethyl-p-aminobenzoate	Penicillin-G

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

Diphenhydramine	Norethindrone	Tryptamine
Doxylamine	D-Norpropoxyphene	DL-Tryptophan
Ecgonine hydrochloride	Noscapine	Tyramine
Ecgonine methylester	Oxalic acid	Uric acid
Ephedrine	Oxazepam	Verapamil
(L) - Epinephrine	Oxolinic acid	Zomepirac

Buprenorphine

4-Acetamidophenol	Erythromycin	Oxycodone
Acetophenetidin	β-Estradiol	Oxymetazoline
N-Acetylprocainamide	Estrone-3-sulfate	Papaverine
Acetylsalicylic acid	Ethyl-p-aminobenzoate	Penicillin-G
Aminopyrine	Fenoprofen	Pentazocine hydrochloride
Amobarbital	Furosemide	Pentobarbital
Amoxicillin	Gentisic acid	Perphenazine
Ampicillin	Hemoglobin	Phencyclidine
L-ascorbic acid	Hydralazine	Phenelzine
DL-Amphetamine sulfate	Hydrochlorothiazide	Phenobarbital
Apomorphine	Hydrocodone	Phentermine
Aspartame	Hydrocortisone	β-Phenylethylamine
Atropine	O-Hydroxyhippuric acid	Trans-2-phenylcyclopropyl amine hydrochloride
Benzilic acid	p-Hydroxyamphetamine	L-Phenylephrine
Benzoic acid	p-Hydroxy- methamphetamine	Phenylpropanolamine
Benzoylecgonine	3-Hydroxytyramine	Prednisolone
Benzphetamine	Ibuprofen	Prednisone
Bilirubin	Iproniazid	Procaine
(±) - Brompheniramine	(±) - Isoproterenol	DL-Propanolol
Caffeine	Isoxsuprine	D-Propoxyphene
Cannabidiol	Ketamine	D-Pseudoephedrine
Cannabinol	Ketoprofen	Quinacrine
Chloralhydrate	Labetalol	Quinidine
Chloramphenicol	Loperamide	Quinine
Chlorothiazide	MDE	Ranitidine
(±) Chlorpheniramine	Meperidine	Salicylic acid
Chlorpromazine	Meprobamate	Secobarbital
Chlorquine	Methadone	Serotonin
Cholesterol	(L)Methamphetamine	Sulfamethazine
Clonidine	Methoxyphenamine	Sulindac

Cocaethylene	(±)-3,4-Methylenedioxyamphetamine hydrochloride	Tetracycline
Cocaine hydrochloride	(+)3,4-Methylenedioxymethamphetamine hydrochloride	Tetrahydrocortisone, 3-acetate
Codeine	Morphine-3-β-Dglucuronide	Tetrahydrocortisone 3-(β-D-glucuronide)
Cortisone	Morphine sulfate	Tetrahydrozoline
(-) Cotinine	Nalidixic acid	Thiamine
Creatinine	Naloxone	Thioridazine
Deoxycorticosterone	Naltrexone	DL-Tyrosine
Dextromethorphan	Naproxen	Tolbutamide
Diclofenac	Niacinamide	Triamterene
Diflunisal	Nifedipine	Trifluoperazine
Digoxin	Norcodeine	Trimethoprim
Diphenhydramine	Norethindrone	Tryptamine
Doxylamine	D-Norpropoxyphene	DL-Tryptophan
Ecgonine hydrochloride	Noscapine	Tyramine
Ecgonine methylester	Oxalic acid	Uric acid
Ephedrine	Oxazepam	Verapamil
(L) - Epinephrine	Oxolinic acid	Zomepirac

f. Specificity

To test the specificity, drug metabolites and other components that are likely to be present in urine samples were tested. The target drug (Nortriptyline or Buprenorphine), its drug metabolites and the related compounds were studied. These samples were tested using three batches of the CR3Keyless Split Sample Cup Nortriptyline–Buprenorphine by three different operators. The drug metabolites and other components were tested at different concentrations. The obtained lowest detectable concentration was used to calculate the cross-reactivity. Results are shown in the following tables.

TCA (Nortriptyline**, Cut-off=1000 ng/mL)**	**Result**	**% Cross-Reactivity**
Nortriptyline	Positive at 1000 ng/mL	100%
Nordoxepine	Positive at 1,000 ng/mL	100%
Trimipramiine	Positive at 3,000 ng/mL	33%
Amitriptyline	Positive at 1,500 ng/mL	67%
Promazine	Positive at 1,500 ng/mL	67%
Desipramine	Positive at 200 ng/mL	500%
Imipramine	Positive at 400 ng/mL	250%
Clomipramine	Positive at 12,500 ng/mL	8%

Doxepine	Positive at 2,000 ng/mL	50%
Maprotiline	Positive at 2,000 ng/mL	50%
Promethazine	Positive at 25,000 ng/mL	4%

BUP (Buprenorphine**, Cut-off=10 ng/mL)**	**Result**	**% Cross-Reactivity**
Buprenorphine	Positive at 10 ng/mL	100%
Buprenorphine -3-D-Glucuronide	Positive at 15 ng/mL	67%
Norbuprenorphine	Positive at 20 ng/mL	50%
Norbuprenorphine -3-D-Glucuronide	Positive at 200 ng/mL	5%
Morphine	>100,000	<0.1%
Oxymorphone	>100,000	<0.1%
Hydromorphone	>100,000	<0.1%

g. Effect of Specific Gravity and pH

Twelve urine samples of normal, high, and low specific gravity ranges (1.000 to 1.035) were collected and spiked with either Nortriptyline or Buprenorphine at 25% below and 25% above the corresponding cut-off level. These samples were tested using three batches of the CR3Keyless Split Sample Cup Nortriptyline–Buprenorphine by three different operators.

The pH of an aliquot negative urine pool was adjusted to pH ranges of 4.00 to 9.00 in 1 pH unit increments and spiked with Nortriptyline or Buprenorphine at 25% below and 25% above the corresponding cut-off levels. These samples were tested using three batches of the CR3Keyless Split Sample Cup Nortriptyline–Buprenorphine by three different operators.

The device performance was found not affected by varying specific gravity and pH.

2. Comparison Studies

The method comparison for the CR^3 Keyless Split Sample Cup Nortriptyline–Buprenorphine was performed in-house with three laboratory assistants. Operators ran 80 (40 negative and 40 positive) unaltered clinical samples. The samples were masked

and randomized. The obtained test results are compared to GC/MS results. The results are presented in the table below:

Nortriptyline

Group / Operators		Negative	Low Negative by GC/MS (less than -50%)	Near Cutoff Negative by GC/MS (Between -50% and cutoff)	Near Cutoff Positive by GC/MS (Between the cutoff and +50%)	High Positive by GC/MS (greater than +50%)
Viewer A	Positive	0	0	3	9	28
	Negative	10	19	8	3	0
Viewer B	Positive	0	0	4	9	28
	Negative	10	19	7	3	0
Viewer C	Positive	0	0	3	8	28
	Negative	10	19	8	4	0

Discordant table:

Viewer	Sample number	GC/MS result	Viewer result
Viewer A	TCAC1061	919	positive
Viewer A	TCAC1062	964	positive
Viewer A	TCAC1063	944	positive
Viewer A	TCAC1064	1082	negative
Viewer A	TCAC1065	1012	negative
Viewer A	TCA 1218	1245	negative
Viewer B	TCAC1034	754	positive
Viewer B	TCAC1061	919	positive
Viewer B	TCAC1062	964	positive
Viewer B	TCAC1063	944	positive
Viewer B	TCAC1064	1082	negative
Viewer B	TCAC1065	1012	negative
Viewer B	TCAC1093	1237	negative
Viewer C	TCAC1061	919	positive
Viewer C	TCAC1062	964	positive
Viewer C	TCAC1063	944	positive
Viewer C	TCAC1064	1082	negative
Viewer C	TCAC1065	1012	negative
Viewer C	TCAC1093	1237	negative
Viewer C	TCA 1218	1245	negative

Buprenorphine

Group / Operators		Negative	Low Negative by GC/MS (less than -50%)	Near Cutoff Negative by GC/MS (Between -50% and cutoff)	Near Cutoff Positive by GC/MS (Between the cutoff and +50%)	High Positive by GC/MS (greater than +50%)
Viewer A	Positive	0	0	3	13	23
	Negative	10	11	16	4	0
Viewer B	Positive	0	0	4	13	23
	Negative	10	11	15	4	0
Viewer C	Positive	0	0	5	14	23
	Negative	10	11	14	3	0

Discordant table:

Viewer	Sample number	GC/MS result	viewer results
Viewer A	BUPC1063	9	positive
Viewer A	BUPC1064	9	positive
Viewer A	BUP1217	9	positive
Viewer A	BUPC1061	11	negative
Viewer A	BUPC1062	10	negative
Viewer A	BUPC1093	12	negative
Viewer A	BUP1224	11	negative
Viewer B	BUPC1063	9	positive
Viewer B	BUPC1064	9	positive
Viewer B	BUP1216	8	positive
Viewer B	BUP1217	9	positive
Viewer B	BUPC1061	11	negative
Viewer B	BUPC1062	10	negative
Viewer B	BUPC1091	12	negative
Viewer B	BUP1224	11	negative
Viewer C	BUPC1033	8	positive
Viewer C	BUPC1065	9	positive
Viewer C	BUP1213	9	positive
Viewer C	BUP1216	8	positive
Viewer C	BUP1217	9	positive
Viewer C	BUPC1061	11	negative
Viewer C	BUPC1091	12	negative
Viewer C	BUP1224	11	negative

Lay-user study

A lay user study was performed at three intended user sites with 260 lay persons, of which, 20 tested for drug-free samples, 120 for nortriptyline samples, 120 for buprenorphine 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; -100%, +/-75%, +/-50%, +/-25% of the cut-off by spiking drug(s) into drug free-pooled urine specimens. The concentrations of the samples were confirmed by GC/MS. Each sample was aliquoted into individual containers, blind-labeled and randomized. Each participant was provided with the package insert, 1 blind labeled sample and a device. The results are summarized below:

Cup format		Number of samples	OTC user		%Agreement With GC/MS
Drug	Concentration		Negative	Positive	
Drug -free	-100%	20	20	0	100%
Nortriptyline	-75%	20	20	0	100%
	-50%	20	20	0	100%
	-25%	20	17	3	85%
	+25%	20	3	17	85%
	+50%	20	0	20	100%
	+75%	20	0	20	100%
Buprenorphine	-75%	20	20	0	100%
	-50%	20	20	0	100%
	-25%	20	18	2	90%
	+25%	20	3	17	85%
	+50%	20	0	20	100%
	+75%	20	0	20	100%

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 the package insert and the score revealed a reading grade level of less than 7.

3. Clinical Studies

   Not applicable

11. Conclusion

Based on the test principle and performance characteristics of the device, it's concluded that CR[3] Keyless Split Sample Cup Nortriptyline –Buprenorphine is substantially equivalent to the predicate.