DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

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

January 13, 2015

Re: K143535
Trade/Device Name: CR³ Keyless Split Sample Cup Secobarbital-Methadone
Regulation Number: 21 CFR 862.3150
Regulation Name: Barbiturate test system
Regulatory Class: II
Product Code: DIS, DJR
Dated: December 9, 2014
Received: December 15, 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,

Stayce Beck -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)*
k143535

Device Name
CR3 Keyless Split Sample Cup Secobarbital-Methadone

Indications for Use *(Describe)*
CR3 Keyless Split Sample Cup Secobarbital-Methadone is a rapid test for the qualitative detection of Secobarbital and Methadone in human urine at a cutoff concentration of 300ng/mL for each of the drugs.

The test may yield preliminary positive results when prescription drugs Secobarbital and Methadone are ingested, even at or above therapeutic doses. There are no uniformly recognized drug levels for Secobarbital and Methadone 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. Gas Chromatography/Mass Spectrometry 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: January 8, 2015

2. Submitter: Guangzhou Wondfo Biotech Co., Ltd.
No.8 Lizhishan Road, Science City, Luogang District, Guangzhou, P.R. China 510663

3. Contact person: Joe Shia
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4. Device Name: CR^3 Keyless Split Sample Cup Secobarbital-Methadone

Classification: Class II

Product Code	CFR #	Panel
DIS	21 CFR, 862.3150 Barbiturate Test System	Toxicology
DJR	21 CFR, 862.3620 Methadone Test System	Toxicology

5. Predicate Devices: K122904
Wondfo Multi-Drug Urine Test Cup

6. Intended Use:
CR3 Keyless Split Sample Cup Secobarbital-Methadone is a rapid test for the qualitative detection of Secobarbital and Methadone in human urine at a cutoff concentration of 300ng/mL for each of the drugs.

The test may yield preliminary positive results when prescription drugs Secobarbital and Methadone are ingested, even at or above therapeutic doses. There are no uniformly recognized drug levels for Secobarbital and Methadone 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. Gas Chromatography/Mass Spectrometry 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 Secobarbital – Methadone test uses immunochromatographic assays for secobarbital and methadone. The test is a lateral flow system for the qualitative detection of secobarbital and methadone in human urine. 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.

8. Substantial Equivalence Information

Item	Device	Predicate – K122904
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	Secobarbital: 300ng/ml Methadone: 300ng/ml	Same for Secobarbital and Methadone
Configurations	Cup	Cup, Dipcard
Conditions for Use	Over-the-Counter & Prescription Use	Same

9. Test Principle

The CR3 Keyless Split Sample Cup Secobarbital – Methadone test is a rapid test for the qualitative detection of Secobarbital and Methadone in urine samples and contains lateral flow chromatographic immunoassays for secobarbital and methadone. 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 by three operators for 25 days. All sample aliquots were masked and randomized. The results obtained are summarized in the following tables:

A. For Secobarbital (BAR) testing

Result / BAR	-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
W12010501CU5	50-/0+	50-/0+	50-/0+	50-/0+	43+/7-	50+/0-	50+/0-	50+/0-	50+/0-
W12010502CU5	50-/0+	50-/0+	50-/0+	50-/0+	42+/8-	50+/0-	50+/0-	50+/0-	50+/0-
W12010503CU5	50-/0+	50-/0+	50-/0+	50-/0+	42+/8-	50+/0-	50+/0-	50+/0-	50+/0-

B. For Methadone (MTD) testing

Result / MTD	-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
W12010501CU5	50-/0+	50-/0+	50-/0+	50-/0+	43+/7-	50+/0-	50+/0-	50+/0-	50+/0-
W12010502CU5	50-/0+	50-/0+	50-/0+	50-/0+	41+/9-	50+/0-	50+/0-	50+/0-	50+/0-
W12010503CU5	50-/0+	50-/0+	50-/0+	50-/0+	42+/8-	50+/0-	50+/0-	50+/0-	50+/0-

b. Linearity

Not applicable.

c. Stability

The CR3 Keyless Split Sample Cup Secobarbital – Methadone 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 secobarbital samples and 125 methadone samples equally distributed at concentrations of -50%, -25%, at the cut-off, +25%, +50% of their respective cut-offs. 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 secobarbital and methadone. The following cut-off values for the test devices have been verified.

Test	Calibrator	Cut-off (ng/ml)
Secobarbital (BAR）	Secobarbital	300
Methadone (MTD)	Methadone	300

e. Interference

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

Secobarbital

Acetaminophen	Erythromycin	O-Hydroxyhippuric acid
Acetophenetidin	β-Estradiol	D,L-Octopamine
Acetylsalicylic acid	Estrone-3-sulfate	Oxalic acid
Aminopyrine	Ethyl-p-aminobenzoate	Oxazepam
Amitryptyline	Fenoprofen	Oxolinic acid
Amoxicillin	Furosemide	Oxycodone
DL-Amphetamine sulfate	Gentisic acid	Oxymetazoline
Ampicillin	Hemoglobin	Papaverine
Apomorphine	Hydralazine	Penicillin-G
Ascorbic acid	Hydrochlorothiazide	Pentazocaine
Aspartame	Hydrocodone	Perphenazine
Atropine	Hydrocortisone	Phencyclidine
Benzilic acid	p-Hydroxyamphetamine	Phenelzine
Benzoic acid	p-Hydroxymethamphetamine	β-Phenylethlamine
Benzoylecgonine	3-Hydroxytyramine	Phenylpropanolamine
Bilirubin	Ibuprofen	Prednisolone
Brompheniramine	Imipramine	Prednisone
Caffeine	(-) Isoproterenol	Procaine

Cannabidiol	Isoxsuprine	Promazine
Cannabinol	Ketamine	Promethazine
Chloralhydrate	Ketoprofen	D,L-Propanolol
Chloramphenicol	Labetalol	D-Propoxyphene
Chlorothiazide	Levorphanol	Quinidine
(±) Chlorpheniramine	Loperamide	Quinine
Chlorpromazine	L-Phenylephrine	Ranitidine
Chlorquine	Maprotiline	Salicylic acid
Cholesterol	Meperidine	Serotonin
Clomipramine	Meprobamate	Sulfamethazine
Clonidine	Morphine-3-β-D glucuronide	Sulindac
Cocaine hydrochloride	Methadone	Temazepam
Codeine	Methamphetamine	Tetracycline
Cortisone	±) - 3,4-Methylenedioxy- amphetamine hydrochloride	Tetrahydrozoline
(-) Cotinine	(±)-3,4-Methylenedioxy-methamphetamine hydrochloride	Thebaine
Creatinine	Morphine Sulfate	Thiamine
Deoxycorticosterone	N-Acetylprocainamide	Thioridazine
Dextromethorphan	Nalidixic acid	Triamterene
Diazepam	Naloxone	Trifluoperazine
Diclofenac	Naltrexone	Trimethoprim
Diflunisal	Naproxen	Trimipramine
Digoxin	Niacinamide	Tryptamine
Diphenhydramine	Nifedipine	D, L-Tyrosine
Doxylamine	Norcodein	Uric acid
Ecgonine hydrochloride	Norethindrone	Verapamil
Ecgonine methylester	D-Norpropoxyphene	Zomepirac
(IR,2S)(-)Ephedrine	Noscapine	

Methadone

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

Ascorbic acid
Aspartame
Atropine
Benzilic acid
Benzoic acid
Benzoylecgonine
Bilirubin
Brompheniramine
Caffeine
Cannabidiol
Cannabinol
Chloralhydrate
Chloramphenicol
Chlorothiazide
(±) - Chlorpheniramine
Chlorpromazine
Chlorquine
Cholesterol
Clomipramine
Clonidine

Cocaine hydrochloride

Codeine

(-) Cotinine

Cortisone

Creatinine
Deoxycorticosterone
Dextromethorphan
Diazepam
Diclofenac
Diflunisal
Digoxin
Diphenhydramine
D-Norpropoxyphene
D-Propoxyphene
D,L-Tyrosine
DL-Octopamine

Hydralazine
Hydrochlorothiazide
Hydrocodone
Hydrocortisone
p-Hydroxyamphetamine
p-Hydroxymethamphetamine
3-Hydroxytyramine
Ibuprofen
Imipramine
(-) Isoproterenol
Isoxsuprine
Ketamine
Ketoprofen
Labetalol
Levorphanol
Loperamide
L-Phenylephrine
Maprotiline
Meperidine
Meprobamate

Methamphetamine

Methoxyphenamine

(±) - 3,4-Methylenedioxy-amphetamine hydrochloride
(±)-3,4-Methylenedioxy-methamphetamine hydrochloride
Morphine Sulfate
Morphine-3-β-D glucuronide
N-Acetylprocainamide
Nalidixic acid
Naloxone
Naltrexone
Naproxen
Niacinamide
Nifedipine
Norcodein
Norethindrone
Noscapine

Phenelzine
Phenobarbital
Phentermine
β-Phenylethylamine
Phenylpropanolamine
Prednisolone
Prednisone
Procaine
Promazine
Promethazine
Quinidine
Quinine
Ranitidine
Salicylic acid
Secobarbital
Serotonin
Sulfamethazine
Sulindac
Temazepam
Tetracycline

Tetrahydrocortisone, 3-acetate

Tetrahydrocortisone 3-(β-D-glucuronide)
Tetrahydrozoline

Thebaine

Thiamine
Thioridazine
Triamterene
Trifluoperazine
Trimethoprim
Trimipramine
Tryptamine
DL-Tryptophan
Tyramine
Uric acid
Verapamil
Zomepirac

DL-Propranolol	O-Hydroxyhippuric acid
Ecgonine hydrochloride	Oxalic acid

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 (Secobarbital or Methadone), its drug metabolites and the related compounds were studied. These samples were tested using three batches of the CR3Keyless Split Sample Cup Secobarbital –Methadone 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.

BAR (Secobarbital**, Cut-off=300 ng/mL)**	**Result**	**% Cross-Reactivity**
Secobarbital	Positive at 300 ng/mL	100%
Amobarbital	Positive at 300 ng/mL	100%
Alphenol	Positive at 150 ng/mL	200%
Aprobarbital	Positive at 200 ng/mL	150%
Butabarbital	Positive at 75 ng/mL	400%
Butathal	Positive at 100 ng/mL	300%
Butalbital	Positive at 2,500 ng/mL	12%
Cyclopentobarbital	Positive at 600 ng/mL	50%
Pentobarbital	Positive at 300 ng/mL	100%
Phenobarbital	Positive at 100 ng/mL	300%

MTD (Methadone**, Cut-off=300 ng/mL)**	**Result**	**% Cross-Reactivity**
Methadone	Positive at 300 ng/mL	100%
Doxylamine	Positive at 50,000 ng/mL	0.6%

g. Effect of Specific Gravity and Urine pH

Twelve urine samples of normal, high, and low specific gravity ranges (1.000 to 1.035) were collected and spiked with either Secobarbital or Methadone at 25% below and 25% above the corresponding cut-off level. These samples were tested using three batches of the CR3 Keyless Split Sample Cup Secobarbital-Methadone 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 Secobarbital or Methadone at 25% below and 25% above the

corresponding cut-off levels. These samples were tested using three batches of the CR3 Keyless Split Sample Cup Secobarbital-Methadone 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 Secobarbital-Methadone 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 were compared to GC/MS results. The results are presented in the table below:

Secobarbital

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	4	15	20
	Negative	10	13	13	5	0
Viewer B	Positive	0	0	3	17	20
	Negative	10	13	14	3	0
Viewer C	Positive	0	0	3	17	20
	Negative	10	13	14	3	0

Discordant table:

Viewer	Sample number	GC/MS result	Viewer result
Viewer A	BARC3061	281	positive
Viewer A	BARC3062	275	positive
Viewer A	BARC3063	302	negative
Viewer A	BARC3065	314	negative
Viewer A	BAR 3212	278	positive
Viewer A	BAR 3214	293	positive
Viewer A	BAR 3218	305	negative
Viewer A	BAR 3223	317	negative
Viewer A	BAR 3229	309	negative
Viewer B	BARC3061	281	positive
Viewer B	BARC3063	302	negative
Viewer B	BARC3064	297	positive
Viewer B	BARC3065	314	negative

Viewer B	BAR 3214	293	positive
Viewer B	BAR 3227	314	negative
Viewer C	BARC3062	275	positive
Viewer C	BARC3063	302	negative
Viewer C	BARC3064	297	positive
Viewer C	BAR 3214	293	positive
Viewer C	BAR 3218	305	negative
Viewer C	BAR 3227	314	negative

Methadone

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	17	20
	Negative	10	12	15	3	0
Viewer B	Positive	0	0	5	16	20
	Negative	10	12	13	4	0
Viewer C	Positive	0	0	4	17	20
	Negative	10	12	14	3	0

Discordant table:

Viewer	Sample number	GC/MS result	viewer results
Viewer A	MTDC3063	304	negative
Viewer A	MTDC3065	291	positive
Viewer A	MTD 3211	284	positive
Viewer A	MTD 3214	299	positive
Viewer A	MTD 3220	306	negative
Viewer A	MTD 3226	301	negative
Viewer B	MTDC3061	297	positive
Viewer B	MTDC3062	313	negative
Viewer B	MTDC3063	304	negative
Viewer B	MTDC3064	286	positive
Viewer B	MTDC3065	291	positive
Viewer B	MTD 3211	284	positive
Viewer B	MTD 3214	299	positive
Viewer B	MTD 3224	311	negative
Viewer B	MTD 3226	301	negative
Viewer C	MTDC3061	297	positive

Viewer C	MTDC3062	313	negative
Viewer C	MTDC3065	291	positive
Viewer C	MTD 3214	299	positive
Viewer C	MTD 3216	278	positive
Viewer C	MTD 3220	306	negative
Viewer C	MTD 3224	311	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 secobarbital samples, 120 for methadone 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 drugs 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%
Secobarbital	-75%	20	20	0	100%
	-50%	20	20	0	100%
	-25%	20	17	3	85%
	+25%	20	4	16	80%
	+50%	20	0	20	100%
	+75%	20	0	20	100%
Methadone	-75%	20	20	0	100%
	-50%	20	20	0	100%
	-25%	20	16	4	80%
	+25%	20	4	16	80%
	+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 Secobarbital – Methadone is substantially equivalent to the predicate.