K131232

510(k) SUMMARY

MAY 3 1 2013

1. Date: May 29, 2013

2. Submitter: Guangzhou Wondfo Biotech Co., Ltd.
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Guangzhou, P.R. China 510641

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4. Device Name: Wondfo Methadone Urine Test (MTD200)
Wondfo Morphine Urine Test (MOP100)

Classification:

Product Code	CFR #	Panel
DJR	21 CFR, 862.3620 Methadone Test System	Toxicology
DJG	21 CFR, 862.3640 Morphine Test System	Toxicology

5. Predicate Devices:
K050394
Medtox Diagnostics Sure-Screen

6. Intended Use
Wondfo Methadone Urine Test (MTD 200) is an immunochromatographic assay for the qualitative determination of Methadone in human urine at a Cut-Off concentration of 200 ng/mL. The test is available in a Dip Card format and a Cup format. This product is only intended for prescription use and is not intended for point-of-care use. 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.

Wondfo Morphine Urine Test (MOP 100) is an immunochromatographic assay for the qualitative determination of Morphine in human urine at a Cut-Off concentration of 100 ng/mL. The test is available in a Dip Card format and a Cup format. This product is only intended for prescription use and is not intended for point-of-care use.

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.

7. Device Description

Immunochromatographic assays for Methadone and Morphine Urine Tests use a lateral flow, one step system for the qualitative detection of Methadone and Morphine (target analyte) in human urine. Each assay uses a monoclonal antibody-dye conjugate against drugs with gold chloride and fixed drug-protein conjugates and anti-mouse IgG polyclonal antibody in membranes.

8. Substantial Equivalence Information

A summary comparison of features of the Wondfo Methadone Urine Test (MTD 200) and Wondfo Morphine Urine Test (MOP 100) and the predicate device is provided in Table 1 & Table 2.

Table 1: Features Comparison of Wondfo Methadone Urine Test (MTD 200) and the Predicate Devices

Item	Device	Predicate - K050394
Indication(s) for Use	For the qualitative determination of Methadone in human urine. For prescription use.	Same (but the number of drugs detected is different)
Calibrator	Methadone	Same
Methodology	Competitive binding, lateral flow immunochromatographic assays based on the principle of antigen antibody immunochemistry.	Same
Type of Test	Qualitative to indicate positive or negative result	Same
Specimen Type	Human Urine	Same
Cut-Off Values	200 ng/mL	Same
Configurations	Cup, Dip Card	Cup

Table 2: Features Comparison of Wondfo Morphine Urine Test (MOP 100) and the Predicate Devices

Item	Device	Predicate - K050394
Indication(s) for Use	For the qualitative determination of Morphine in human urine. For prescription use.	Same(but the number of drugs detected is different)

Item	Device	Predicate - K050394
Calibrator	Morphine	Same
Methodology	Competitive binding, lateral flow immunochromatographic assays based on the principle of antigen antibody immunochemistry.	Same
Type of Test	Qualitative to indicate positive or negative result	Same
Specimen Type	Human Urine	Same
Cut-Off Values	100 ng/mL	Same
Configurations	Cup, Dip Card	Cup

9. Test Principle

It is a rapid test for the qualitative detection of Methadone and Morphine in urine samples. It is a lateral flow chromatographic immunoassay. When the absorbent end 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 concentration 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 cutoff, 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.

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, +25% cut off, +50% cut off , +75% cut off and +100% cut off. These samples were prepared by spiking drug in negative samples. Each drug concentration was confirmed by GC/MS. All sample aliquots were blinded labeled by the person who prepared the samples and that person did not take part in the sample testing. For each concentration, tests were performed two runs per day for 25 days. The results obtained are summarized in the following table.

Cup Format

MTD 200

Result / MTD 200	-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
LOT W1570901	50-/0+	50-/0+	50-/0+	50-/0+	45+/5-	50+/0-	50+/0-	50+/0-	50+/0-

Result / MTD 200	-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
CU2									
LOT W1570902 CU2	50-/0+	50-/0+	50-/0+	50-/0+	44+/6-	50+/0-	50+/0-	50+/0-	50+/0-
LOT W1570903 CU2	50-/0+	50-/0+	50-/0+	50-/0+	46+/4-	50+/0-	50+/0-	50+/0-	50+/0-

MOP 100

Result / MOR 100	-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
LOT W1670901 CU2	50-/0+	50-/0+	50-/0+	50-/0+	46+/4-	50+/0-	50+/0-	50+/0-	50+/0-
LOT W1670902 CU2	50-/0+	50-/0+	50-/0+	50-/0+	46+/4-	50+/0-	50+/0-	50+/0-	50+/0-
LOT W1670903 CU2	50-/0+	50-/0+	50-/0+	50-/0+	45+/5-	50+/0-	50+/0-	50+/0-	50+/0-

Dip Card Format

MTD 200

Result / MTD 200	-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
LOT W1570901 P	50-/0+	50-/0+	50-/0+	50-/0+	45+/5-	50+/0-	50+/0-	50+/0-	50+/0-
LOT W1570902 P	50-/0+	50-/0+	50-/0+	50-/0+	47+/3-	50+/0-	50+/0-	50+/0-	50+/0-
LOT W1570903 P	50-/0+	50-/0+	50-/0+	50-/0+	46+/4-	50+/0-	50+/0-	50+/0-	50+/0-

MOP 100

Result / MOR 100	-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
LOT W1670901 P	50-/0+	50-/0+	50-/0+	50-/0+	45+/5-	50+/0-	50+/0-	50+/0-	50+/0-
LOT W1670902 P	50-/0+	50-/0+	50-/0+	50-/0+	47+/3-	50+/0-	50+/0-	50+/0-	50+/0-
LOT W1670903 P	50-/0+	50-/0+	50-/0+	50-/0+	49+/1-	50+/0-	50+/0-	50+/0-	50+/0-

b. Linearity

Not applicable, this is a visually read device

c. Stability

Stable at 4-30℃ for 18 months based on the accelerated stability study at 50℃ and real time stability determination at both 4℃ and 30℃.

Cut-off

Total of 150 samples equally distributed at concentrations of -50% Cut-Off; -25% Cut-Off; Cut-Off; +25% Cut-Off; +50% Cut-Off were tested using three different lots of each device by three different operators. Results were all positive at and above +25% Cut-off and all negative at and below -25% Cut-off for both methadone and morphine. The following cut-off values for the test devices have been verified.

Test	Calibrator	Cut-off (ng/mL)
Wondfo Methadone Urine Test (MTD 200)	Methadone	200
Wondfo Morphine Urine Test (MOP 100)	Morphine	100

d. Interference

Potential interfering substances found in human urine of physiological or pathological conditions were added to drug-free urine and target drugs urine with concentration at 25% below and 25% above Cut-Off level respectively. These urine samples were tested using three batches of each device for both Dip Card and Cup formats.

Compounds that showed no interference at a concentration of 100μg/mL are summarized in the following tables. There were no differences observed for both Dip Card and Cup formats.

MTD 200

Acetaminophen	Erythromycin	Oxymetazoline
Acetophenetidin	β-Estradiol	Papaverine
N-Acetylprocainamide	Estrone-3-sulfate	Penicillin-G
Acetylsalicylic acid	Ethyl-p-aminobenzoate	Pentazocine hydrochloride
Aminopyrine	Fenoprofen	Pentobarbital
Amitryptyline	Furosemide	Perphenazine
Amobarbital	Gentisic acid	Phencyclidine
Amoxicillin	Hemoglobin	Phenelzine
Ampicillin	Hydralazine	Phenobarbital
L-Ascorbic acid	Hydrochlorothiazide	Phentermine
DL-Amphetamine sulfate	Hydrocodone	Trans-2-phenylcyclo-propyl amine hydrochloride

Apomorphine	Hydrocortisone	L-Phenylephrine
Aspartame	O-Hydroxyhippuric acid	β-Phenylethylamine
Atropine	p-Hydroxyamphetamine	Phenylpropanolamine
Benzilic acid	p-Hydroxymethamphetamine	Prednisolone
Benzoic acid	3-Hydroxytyramine	Prednisone
Benzoylecgonine	Ibuprofen	Procaine
Benzphetamine	Imipramine	Promazine
Bilirubin	Iproniazid	Promethazine
(±) - Brompheniramine	(±) - Isoproterenol	DL-Propranolol
Caffeine	Isoxsuprine	D-Propoxyphene
Cannabidiol	Ketamine	D-Pseudoephedrine
Cannabinol	Ketoprofen	Quinacrine
Chloralhydrate	Labetalol	Quinidine
Chloramphenicol	Levorphanol	Quinine
Chlorothiazide	Loperamide	Ranitidine
(±) - Chlorpheniramine	Mephentermine	Salicylic acid
Chlorpromazine	Maprotiline	Secobarbital
Chlorquine	Meperidine	Serotonin
Cholesterol	Meprobamate	Sulfamethazine
Clomipramine	Methamphetamine	Sulindac
Clonidine	Methoxyphenamine	Tetracycline
Cocaethylene	(±)-3,4-Methylenedioxy-amphetamine hydrochloride	Tetrahydrocortisone, 3-acetate
Temazepam	(±)-3,4-Methylenedioxy-methamphetamine hydrochloride	Tetrahydrocortisone 3-(β-D-glucuronide)

Cocaine hydrochloride	Morphine-3-β-D glucuronide	Tetrahydrozoline
Codeine	Morphine Sulfate	Thebaine
Cortisone	Nalidixic acid	Thiamine
(-) Cotinine	Naloxone	Thioridazine
Creatinine	Naltrexone	DL-Tyrosine
Deoxycorticosterone	Naproxen	Tolbutamide
Dextromethorphan	Niacinamide	Triamterene
Diazepam	Nifedipine	Trifluoperazine
Diclofenac	Norcodein	Trimethoprim
Diflunisal	Norethindrone	Trimipramine
Digoxin	D-Norpropoxyphene	Tryptamine
Diphenhydramine	Noscapine	DL-Tryptophan
Ecgonine hydrochloride	DL-Octopamine	Tyramine
Ecgonine methyl ester	Oxalic acid	Uric acid
(-) -Ψ-Ephedrine	Oxazepam	Verapamil
[1R,2S] (-) Ephedrine	Oxolinic acid	Zomepirac
(L) - Epinephrine	Oxycodone	

MOP 100

4-Acetamidophenol	Ecgonine methylester	Oxolinic acid
Acetophenetidin	(-) -Y -Ephedrine	Oxymetazoline
N-Acetylprocainamide	Erythromycin	Papaverine
Acetylsalicylic acid	β-Estradiol	Penicillin-G
Aminopyrine	Estrone-3-sulfate	Pentazocine
Amitryptyline	Ethyl-p-aminobenzoate	Pentobarbital
Amobarbital	Fenoprofen	Perphenazine

Amoxicillin	Furosemide	Phencyclidine
Ampicillin	Gentisic acid	Phenelzine
Ascorbic acid	Hemoglobin	Phenobarbital
D,L-Amphetamine	Hydralazine	Phentermine
Apomorphine	Hydrochlorothiazide	L-Phenylephrine
Aspartame	Hydrocortisone	β-Phenylethylamine
Atropine	O-Hydroxyhippuric acid	Phenylpropanolamine
Benzilic acid	p-Hydroxy methamphetamine	Prednisone
Benzoic acid	3-Hydroxytyramine	D,L-Propanolol
Benzoylecgonine	Ibuprofen	D-Propoxyphene
Benzphetamine	Imipramine	D-Pseudoephedrine
Bilirubin (±)	Iproniazid	Quinidine
Brompheniramine	Isoproterenol	Quinine
Caffeine	Isoxsuprine	Ranitidine
Cannabidiol	Ketamine	Salicylic acid
Chloralhydrate	Ketoprofen	Secobarbital
Chloramphenicol	Labetalol	Serotonin (5-Hydroxytyramine)
Chlordiazepoxide	Loperamide	Sulfamethazine
Chlorothiazide	Maprotiline	Sulindac
(±) Chlorpheniramine	Meperidine	Temazepam
Chlorpromazine	Meprobamate	Tetracycline
Chlorquine	Methadone	Tetrahydrocortisone, 3 Acetate
Cholesterol	Methoxyphenamine	Tetrahydrocortisone3 (β-D glucuronide)

Clomipramine	(+) 3,4-Methylenedioxy-amphetamine	Tetrahydrozoline
Clonidine	(+)3,4-Methylenedioxy-methamphetamine	Thiamine
Cocaine hydrochloride	Nalidixic acid	Thioridazine
Cortisone	Nalorphine	D, L-Tyrosine
(-) Cotinine	Naloxone	Tolbutamide
Creatinine	Naltrexone	Triamterene
Deoxycorticosterone	Naproxen	Trifluoperazine
Dextromethorphan	Niacinamide	Trimethoprim
Diazepam	Nifedipine	Trimipramine
Diclofenac	Norethindrone	Tryptamine
Diflunisal	D-Norpropoxyphene	D, L-Tryptophan
Digoxin	Noscapine	Tyramine
Diphenhydramine	D,L-Octopamine	Uric acid
Doxylamine	Oxalic acid	Verapamil
Ecgonine hydrochloride	Oxazepam	Zomepirac

e.Specificity

To test the specificity, drug metabolites and other components that are likely to interfere in urine samples were tested using three batches of each device for both Dip Card and Cup formats. Compounds that produced positive results are listed below. There were no differences observed for both Dip Card and Cup formats.

MTD 200

MTD(Methadone) (Methadone, Cut-off=200 ng/mL)	**Minimum Concentration Required to Obtain a Positive Result (ng/mL)**	**% Cross-Reactivity**
Methadone	200	100
Doxylamine	40,000	0.5

MOP 100

MOR(Morphine) (Morphine, Cut-off=100 ng/mL)	**Minimum Concentration Required to Obtain a**	**% Cross-Reactivity**

	Positive Result (ng/mL)	
Morphine	100	100
Codeine	100	100
Ethylmorphine	200	50
Hydrocodone	400	25
Hydromorphine	200	50
Levorphanol	5000	2.0
σ-Monoacetylmorphine	200	50
Morphine 3-β-D-glucuronide	200	50
Norcodeine	500	20
Normorphone	5000	2.0
Oxycodone	1000	10
Oxymorphine	1000	10
Procaine	100000	<1.0
Thebaine	5000	2.0

f. Effect of Urine Specific Gravity and Urine pH

To investigate the effect of urine specific gravity and urine pH, the urine samples, with 1.000~1.035 specific gravity or urine samples with pH 4~9 were spiked with target drugs at 25% below and 25% above Cut-Off level, respectively. These samples were tested using three batches of each device for both Dip Card and Cup 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 both Dip Card and Cup formats.

2. Comparison Studies

The method comparison for the Wondfo Methadone Urine Test (MTD200), Wondfo Morphine Urine Test (MOP100) was performed in-house with three laboratory assistants. Operators ran 80 (40 negative and 40 positive) unaltered clinical samples. The samples were blind labeled and compared to GC/MS results. The results are presented in the table below:

MTD 200:

Cup Format

Wondfo Result		**Drug-free**	**Low Negative by GC/MS (Less than -50%)**	**Near Cut-Off Negative by GC/MS (Between -50% and Cut-Off)**	**Near Cut-Off Positive by GC/MS (Between the Cut-Off and +50%)**	**High Positive by GC/MS (Greater than +50%)**
Viewer A	**Positive**	0	0	2	15	25
	Negative	10	13	15	0	0
Viewer B	**Positive**	0	0	2	15	25

	Negative	10	13	15	0	0
Viewer C	**Positive**	0	0	1	15	25
	Negative	10	13	16	0	0

Dip Card Format

Wondfo Result		**Drug-free**	**Low Negative by GC/MS (Less than -50%)**	**Near Cut-Off Negative by GC/MS (Between -50% and Cut-Off)**	**Near Cut-Off Positive by GC/MS (Between the Cut-Off and +50%)**	**High Positive by GC/MS (Greater than +50%)**
Viewer A	**Positive**	0	0	1	15	25
	Negative	10	13	16	0	0
Viewer B	**Positive**	0	0	2	15	25
	Negative	10	13	15	0	0
Viewer C	**Positive**	0	0	2	15	25
	Negative	10	13	15	0	0

Discordant Results of MTD 200

Viewer	**Sample Number**	**GC/MS Result**	**Cup Format Viewer Result**
Viewer A	MTD2061	186	Positive
Viewer A	MTD2063	192	Positive
Viewer B	MTD2061	186	Positive
Viewer B	MTD2063	192	Positive
Viewer C	MTD2063	192	Positive

Viewer	**Sample Number**	**GC/MS Result**	**Dip Card Format Viewer Results**
Viewer A	MTD2061	186	Positive
Viewer B	MTD2061	186	Positive
Viewer B	MTD2063	192	Positive
Viewer C	MTD2061	186	Positive
Viewer C	MTD2063	192	Positive

MOP 100:

Cup Format

Wondfo Result		Drug-free	Low Negative by GC/MS (Less than -50%)	Near Cut-Off Negative by GC/MS (Between -50% and Cut-Off)	Near Cut-Off Positive by GC/MS (Between the Cut-Off and +50%)	High Positive by GC/MS (Greater than +50%)
Viewer A	Positive	0	0	2	28	12
	Negative	10	16	12	0	0
Viewer B	Positive	0	0	3	28	12
	Negative	10	16	11	0	0
Viewer C	Positive	0	0	2	28	12
	Negative	10	16	12	0	0

Dip Card Format

Wondfo Result		Drug-free	Low Negative by GC/MS (Less than -50%)	Near Cut-Off Negative by GC/MS (Between -50% and Cut-Off)	Near Cut-Off Positive by GC/MS (Between the Cut-Off and +50%)	High Positive by GC/MS (Greater than +50%)
Viewer A	Positive	0	0	3	28	12
	Negative	10	16	11	0	0
Viewer B	Positive	0	0	2	28	12
	Negative	10	16	12	0	0
Viewer C	Positive	0	0	3	28	12
	Negative	10	16	11	0	0

Discordant Results of MOP 100

Viewer	Sample Number	GC/MS Result	Cup Format Viewer Result

Viewer	Sample Number	GC/MS Result	Cup Format Viewer Result
Viewer A	OPI1061	98	Positive
Viewer A	OPI1215	97	Positive
Viewer B	OPI1063	95	Positive
Viewer B	OPI1061	98	Positive
Viewer B	OPI1215	97	Positive
Viewer C	OPI1064	93	Positive
Viewer C	OPI1061	98	Positive

Viewer	Sample Number	GC/MS Result	Dip Card Format Viewer Results
Viewer A	OPI1064	93	Positive
Viewer A	OPI1061	98	Positive
Viewer A	OPI1215	97	Positive
Viewer B	OPI1063	95	Positive
Viewer B	OPI1215	97	Positive
Viewer C	OPI1062	94	Positive
Viewer C	OPI1065	94	Positive
Viewer C	OPI1063	95	Positive

3. Clinical Studies

   Not applicable

11. Conclusion

Based on the test principle and acceptable performance characteristics including precision, cut-off, interference, specificity and method comparison of the devices, it's concluded that Wondfo Methadone Urine Test (MTD 200), and Wondfo Morphine Urine Test (MOP 100) are substantially equivalent to the predicate.

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

May 31, 2013

Guangzhou Wondfo Biotech Co., Ltd.
C/O Mr. Joe Shia
LSI International Inc.
504 East Diamond Ave, Suite F
GAITHERSBURG MD 20878

Re: K131232
Trade/Device Name: Wondfo Methadone Urine Test (MTD 200)
Wondfo Morphine Urine Test (MOP 100)
Regulation Number: 21 CFR 862.3620
Regulation Name: Methadone test system
Regulatory Class: II
Product Code: DJR, DJG
Dated: April 26, 2013
Received: May 06, 2013

Dear Mr. 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 Part 801); 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 regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

Carol E. Benson -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

Indications for Use

510(k) Number (if known): K131232

Device Name: Wondfo Methadone Urine Test (MTD 200)
Wondfo Morphine Urine Test (MOP 100)

Indications for Use:

Wondfo Methadone Urine Test (MTD 200)

Wondfo Methadone Urine Test (MTD 200) is an immunochromatographic assay for the qualitative determination of Methadone in human urine at a Cut-Off concentration of 200 ng/mL. The test is available in a Dip Card format and a Cup format. This product is only intended for prescription use and is not intended for point-of-care use.

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.

Prescription Use __X__ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____ (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Denise Johnson-Iyles-S
2013.05.31 10:04:45 -04'00'

Division Sign-Off
Office of In Vitro Diagnostics and Radiological Health

510(k) k131232

Indications for Use

510(k) Number (if known): K131232

Device Name: Wondfo Methadone Urine Test (MTD 200)
Wondfo Morphine Urine Test (MOP 100)

Indications for Use:

Wondfo Morphine Urine Test (MOP 100)

Wondfo Morphine Urine Test (MOP 100) is an immunochromatographic assay for the qualitative determination of Morphine in human urine at a Cut-Off concentration of 100 ng/mL. The test is available in a Dip Card format and a Cup format. This product is only intended for prescription use and is not intended for point-of-care use.

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.

Prescription Use __X__ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____ (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Denise Johnson-Iyles -S
2013.05.31 10:05:08 -04'00'

Division Sign-Off
Office of In Vitro Diagnostics and Radiological Health

510(k) k131232