



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

June 27, 2016

GUANGZHOU WONDFO BIOTECH CO., LTD.  
C/O JOE SHIA  
504 E DIAMOND AVE., SUITE I  
GAITHERSBURG MD 20877

Re: k161214

Trade/Device Name: Wondfo Amphetamine Urine Test AMP 500 (Cup, Dipcard), Wondfo Cocaine Urine Test COC 150(Cup, Dipcard), Wondfo Methamphetamine Urine Test MET 500 (Cup, Dipcard)

Regulation Number: 21 CFR 862.3250

Regulation Name: Cocaine and cocaine metabolite test system

Regulatory Class: II

Product Code: DIO, DKZ, DJC

Dated: April 21, 2016

Received: April 29, 2016

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 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,

  
**Courtney H. Lias -S**

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)  
k161214

### Device Name

Wondfo Amphetamine Urine Test AMP 500 (Cup, DipCard)  
Wondfo Cocaine Urine Test COC 150 (Cup, DipCard)  
Wondfo Methamphetamine Urine Test MET 500 (Cup, DipCard)

### Indications for Use (Describe)

Wondfo Amphetamine Urine Test AMP 500 Cup is an immunochromatographic assay for the qualitative determination of Amphetamine in human urine at a Cut-Off concentration of 500 ng/mL. This test is calibrated to d-Amphetamine (calibrator).

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. This test is intended for over-the-counter (OTC) consumer use as the first step in a two-step process to provide consumers with information concerning the presence or absence of the above stated drugs or their metabolites in a urine sample. Information regarding confirmatory testing- the second step in the process, is provided in the package labeling.

Wondfo Amphetamine Urine Test AMP 500 DipCard is an immunochromatographic assay for the qualitative determination of Amphetamine in human urine at a Cut-Off concentration of 500 ng/mL. This test is calibrated to d-Amphetamine (calibrator).

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. This test is intended for over-the-counter (OTC) consumer use as the first step in a two-step process to provide consumers with information concerning the presence or absence of the above stated drugs or their metabolites in a urine sample. Information regarding confirmatory testing- the second step in the process, is provided in the package labeling.

Wondfo Cocaine Urine Test COC 150 Cup is an immunochromatographic assay for the qualitative determination of Benzoylcegonine in human urine at a Cut-Off concentration of 150 ng/mL. This test is calibrated to Benzoylcegonine (calibrator).

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. This test is intended for over-the-counter (OTC) consumer use as the first step in a two-step process to provide consumers with information concerning the presence or absence of the above stated drugs or their metabolites in a urine sample. Information regarding confirmatory testing- the second step in the process, is provided in the package labeling.

Wondfo Cocaine Urine Test COC 150 DipCard is an immunochromatographic assay for the qualitative determination of Benzoylcegonine in human urine at a Cut-Off concentration of 150 ng/mL. This test is calibrated to Benzoylcegonine (calibrator).

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. This test is intended for over-the-counter (OTC) consumer use as the first step in a two-step process to provide consumers with information concerning the presence or absence of the above stated drugs or their metabolites in a urine sample. Information regarding confirmatory testing- the second step in the process, is provided in the package labeling.

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Wondfo Methamphetamine Urine Test MET 500 Cup is an immunochromatographic assay for the qualitative determination of Methamphetamine in human urine at a Cut-Off concentration of 500 ng/mL. This test is calibrated to d-Methamphetamine (calibrator).

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. This test is intended for over-the-counter (OTC) consumer use as the first step in a two-step process to provide consumers with information concerning the presence or absence of the above stated drugs or their metabolites in a urine sample. Information regarding confirmatory testing- the second step in the process, is provided in the package labeling.

Wondfo Amphetamine Urine Test MET 500 DipCard is an immunochromatographic assay for the qualitative determination of Methamphetamine in human urine at a Cut-Off concentration of 500 ng/mL. This test is calibrated to d-Methamphetamine (calibrator).

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. This test is intended for over-the-counter (OTC) consumer use as the first step in a two-step process to provide consumers with information concerning the presence or absence of the above stated drugs or their metabolites in a urine sample. Information regarding confirmatory testing- the second step in the process, is provided in the package labeling.

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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)

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**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

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510(k) SUMMARY

- 1. Date: June 8, 2016
- 2. Submitter: Wondfo Biotech Co., Ltd.  
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Guangzhou, P.R. China 510641
- 3. Contact person: Joe Shia  
LSI International Inc.  
504 East Diamond Ave., Suite I  
Gaithersburg, MD 20877  
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- 4. Device Name: WONDFO Urine Test Amphetamine (Cup, DipCard)  
WONDFO Urine Test Cocaine (Cup, DipCard)  
WONDFO Urine Test Methamphetamine (Cup, DipCard)

Classification: Class II

Product Code	CFR #	Panel
DIO	21 CFR, 862.3250 Cocaine Test System	Toxicology
DKZ	21 CFR, 862.3100 Amphetamine Test System	Toxicology
DJC	21 CFR, 862.3610 Methamphetamine Test System	Toxicology

- 5. Predicate Devices:  
K122809  
Advin Multi-Drug Screen Test

6. Intended Use

WONDFO Urine Test Amphetamine Cup is a rapid test for the qualitative detection of Amphetamine in human urine at a cutoff concentration of 500 ng/mL. This test is calibrated to d-Amphetamine (calibrator).

The tests provide 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. This test is intended for over-the-counter (OTC) consumer use as the first step in a two-step process to provide consumers with information concerning the presence or absence of the above stated drugs or their metabolites in a urine sample. Information regarding confirmatory testing- the second step in the process, is provided in the package labeling.

WONDFO Urine Test Amphetamine DipCard is a rapid test for the qualitative detection of Amphetamine in human urine at a cutoff concentration of 500 ng/mL. This test is calibrated to d-Amphetamine (calibrator).

The tests provide 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. This test is intended for over-the-counter (OTC) consumer use as the first step in a two-step process to provide consumers with information concerning the presence or absence of the above stated drugs or their metabolites in a urine sample. Information regarding confirmatory testing- the second step in the process, is provided in the package labeling.

WONDFO Urine Test Cocaine Cup is a rapid test for the qualitative detection of Benzoyllecgonine in human urine at a cutoff concentration of 150 ng/ml. This test is calibrated to Benzoyllecgonine (calibrator).

The tests provide 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. This test is intended for over-the-counter (OTC) consumer use as the first step in a two-step process to provide consumers with information concerning the presence or absence of the above stated drugs or their metabolites in a urine sample. Information regarding confirmatory testing- the second step in the process, is provided in the package labeling.

WONDFO Urine Test Cocaine DipCard is a rapid test for the qualitative detection of Benzoyllecgonine in human urine at a cutoff concentration of 150 ng/ml. This test is calibrated to Benzoyllecgonine (calibrator).

The tests provide 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. This test is intended for over-the-counter (OTC) consumer use as the first step in a two-step process to provide consumers with information concerning the presence or absence of the above stated drugs or their metabolites in a urine sample. Information regarding confirmatory testing- the second step in the process, is provided in the package labeling.

WONDFO Urine Test Methamphetamine Cup is a rapid test for the qualitative detection of Methamphetamine in human urine at a cutoff concentration of 500 ng/mL. This test is calibrated to d-Methamphetamine (calibrator).

The tests provide 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. This test is intended for over-the-counter (OTC) consumer use as the first step in a two-step process to provide consumers with information concerning the presence or absence of the above stated drugs or their metabolites in a urine sample. Information regarding confirmatory testing- the second step in the process, is provided in the package labeling.

WONDFO Urine Test Methamphetamine DipCard is a rapid test for the qualitative detection of Methamphetamine in human urine at a cutoff concentration of 500 ng/mL. This test is calibrated to d-Methamphetamine (calibrator).

The tests provide 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. This test is intended for over-the-counter (OTC) consumer use as the first step in a two-step process to provide consumers with information concerning the presence or absence of the above stated drugs or their metabolites in a urine sample. Information regarding confirmatory testing- the second step in the process, is provided in the package labeling.

## 7. Device Description

WONDFO Urine Test devices are immunochromatographic assays for cocaine, amphetamine and Methamphetamine. Each assay test is a lateral flow, one step system for the qualitative detection of Benzoyllecgonine, or D-amphetamine or D-methamphetamine (target analyte) in human urine. The product is a single-use in vitro diagnostic device, which comes in the form of: DipCards, or Cups. It contains a Test Device (in one of the two formats), a package insert and a urine cup. Each test device is sealed with a desiccant in an aluminum pouch.

## 8. Substantial Equivalence Information

A summary comparison of features of the WONDFO Urine Test and the predicate device is provided in Table 1, Table 2 & Table 3.

**Table 1: Features Comparison of WONDFO Cocaine Test and the Predicate Device**

Item	Device	Predicate - K122809
<b>Indication(s) for Use</b>	For the qualitative determination of Benzoyllecgonine in human urine.	Same

<b>Item</b>	<b>Device</b>	<b>Predicate - K122809</b>
<b>Calibrator</b>	Benzoyllecgonine	Same
<b>Methodology</b>	Competitive binding, lateral flow immunochromatographic assays based on the principle of antigen antibody immunochemistry.	Same
<b>Specimen Type</b>	Human Urine	Same
<b>Cut-Off Values</b>	150 ng/mL	Same
<b>Intended Population</b>	For over-the-counter and prescription uses.	Same
<b>Configurations</b>	Cup, Dip Card	Cup, Dip Card, Cassette

**Table 2: Features Comparison of WONFDO Amphetamine Test and the Predicate Device**

<b>Item</b>	<b>Device</b>	<b>Predicate - K122809</b>
<b>Indication(s) for Use</b>	For the qualitative determination of D-amphetamine in human urine.	Same
<b>Calibrator</b>	D-amphetamine	Same
<b>Methodology</b>	Competitive binding, lateral flow immunochromatographic assays based on the principle of antigen antibody immunochemistry.	Same
<b>Specimen Type</b>	Human Urine	Same
<b>Cut-Off Values</b>	500 ng/mL	Same
<b>Intended Population</b>	For over-the-counter and prescription uses.	Same
<b>Configurations</b>	Cup, Dip Card	Cup, Dip Card, Cassette

**Table 3: Features Comparison of WONFDO Methamphetamine Test and the Predicate Device**

<b>Item</b>	<b>Device</b>	<b>Predicate - K122809</b>
<b>Indication(s) for Use</b>	For the qualitative determination of D-methamphetamine in human urine.	Same
<b>Calibrator</b>	D-methamphetamine	Same

Item	Device	Predicate - K122809
<b>Methodology</b>	Competitive binding, lateral flow immunochromatographic assays based on the principle of antigen antibody immunochemistry.	Same
<b>Specimen Type</b>	Human Urine	Same
<b>Cut-Off Values</b>	500 ng/mL	Same
<b>Intended Population</b>	For over-the-counter and prescription uses.	Same
<b>Configurations</b>	Cup, Dip Card	Cup, Dip Card, Cassette

## 9. Test Principle

WONDFO Urine Tests are rapid tests for the qualitative detection of Benzoyllecgonine, or D-amphetamine or D-methamphetamine in urine samples. Each assay test is a lateral flow chromatographic immunoassay. 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 cutoff-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.

## 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. These samples were prepared by spiking drug in negative 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. The results obtained are summarized in the following tables:

#### **Amphetamine (AMP) Dip Card Format**

<b>Drug \ Result</b>	<b>-100% Cut-off</b>	<b>-75% Cut-off</b>	<b>-50% Cut-off</b>	<b>-25% Cut-off</b>	<b>Cut-off</b>	<b>+25% Cut-off</b>	<b>+50% Cut-off</b>	<b>+75% Cut-off</b>	<b>+100% Cut-off</b>
<b>Lot 1</b>	<b>50-/0+</b>	<b>50-/0+</b>	<b>50-/0+</b>	<b>50-/0+</b>	<b>43+/7-</b>	<b>50+/0-</b>	<b>50+/0-</b>	<b>50+/0-</b>	<b>50+/0-</b>

<b>Drug \ Result</b>	<b>-100% Cut-off</b>	<b>-75% Cut-off</b>	<b>-50% Cut-off</b>	<b>-25% Cut-off</b>	<b>Cut-off</b>	<b>+25% Cut-off</b>	<b>+50% Cut-off</b>	<b>+75% Cut-off</b>	<b>+100% Cut-off</b>
<b>Lot 2</b>	50-/0+	50-/0+	50-/0+	50-/0+	44+/6-	50+/0-	50+/0-	50+/0-	50+/0-
<b>Lot 3</b>	50-/0+	50-/0+	50-/0+	50-/0+	44+/6-	50+/0-	50+/0-	50+/0-	50+/0-

**Amphetamine (AMP) Cup Format**

<b>Drug \ Result</b>	<b>-100% Cut-off</b>	<b>-75% Cut-off</b>	<b>-50% Cut-off</b>	<b>-25% Cut-off</b>	<b>Cut-off</b>	<b>+25% Cut-off</b>	<b>+50% Cut-off</b>	<b>+75% Cut-off</b>	<b>+100% Cut-off</b>
<b>Lot 1</b>	50-/0+	50-/0+	50-/0+	50-/0+	44+/6-	50+/0-	50+/0-	50+/0-	50+/0-
<b>Lot 2</b>	50-/0+	50-/0+	50-/0+	50-/0+	43+/7-	50+/0-	50+/0-	50+/0-	50+/0-
<b>Lot 3</b>	50-/0+	50-/0+	50-/0+	50-/0+	44+/6-	50+/0-	50+/0-	50+/0-	50+/0-

**Cocaine (COC) Dip Card Format**

<b>Drug \ Result</b>	<b>-100% Cut-off</b>	<b>-75% Cut-off</b>	<b>-50% Cut-off</b>	<b>-25% Cut-off</b>	<b>Cut-off</b>	<b>+25% Cut-off</b>	<b>+50% Cut-off</b>	<b>+75% Cut-off</b>	<b>+100% Cut-off</b>
<b>Lot 1</b>	50-/0+	50-/0+	50-/0+	50-/0+	43+/7-	50+/0-	50+/0-	50+/0-	50+/0-
<b>Lot 2</b>	50-/0+	50-/0+	50-/0+	50-/0+	44+/6-	50+/0-	50+/0-	50+/0-	50+/0-
<b>Lot 3</b>	50-/0+	50-/0+	50-/0+	50-/0+	43+/7-	50+/0-	50+/0-	50+/0-	50+/0-

**COC Cup Format**

<b>Drug \ Result</b>	<b>-100% Cut-off</b>	<b>-75% Cut-off</b>	<b>-50% Cut-off</b>	<b>-25% Cut-off</b>	<b>Cut-off</b>	<b>+25% Cut-off</b>	<b>+50% Cut-off</b>	<b>+75% Cut-off</b>	<b>+100% Cut-off</b>
<b>Lot 1</b>	50-/0+	50-/0+	50-/0+	50-/0+	44+/6-	50+/0-	50+/0-	50+/0-	50+/0-
<b>Lot 2</b>	50-/0+	50-/0+	50-/0+	50-/0+	43+/7-	50+/0-	50+/0-	50+/0-	50+/0-
<b>Lot 3</b>	50-/0+	50-/0+	50-/0+	50-/0+	43+/7-	50+/0-	50+/0-	50+/0-	50+/0-

The Methamphetamine precision data was reported in K122961.

b. Linearity

Not applicable, these are visually read devices.

c. Stability

The devices are stable at 4-30°C (39-86°F) for 24 months based on the accelerated stability study at 50°C. Control materials are not provided with the device. The labeling provides information on how to obtain control materials.

d. Cut-off

A 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 +50% cut-off and all negative at and below -50% cut-off for Amphetamine, Cocaine and Methamphetamine (K122961). The following cut-off values for the test devices have been verified.

Test	Calibrator	Cut-off (ng/mL)
<b>WONFDO Urine Test Amphetamine Cup (DipCard)</b>	D-amphetamine	500
<b>WONFDO Urine Test Cocaine Cup (DipCard)</b>	Benzoylcegonine	150
<b>WONFDO Urine Test Methamphetamine Cup (DipCard)</b>	D-methamphetamine	500

e. 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 levels. 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 are summarized in the following tables. There were no differences observed for different formats.

**AMP**

4-Acetamidophenol	L-Ephedrine	Oxycodone
Acetophenetidin	(-) Y Ephedrine	Oxymetazoline
N-Acetylprocainamide	Erythromycin	Papaverine
Acetylsalicylic acid	β-Estradiol	Penicillin-G
Aminopyrine	Estrone-3-sulfate	Pentazocaine
Amitriptyline	Ethyl aminobenzoate	Pentobarbital
Amobarbital	Fenfluramine	Perphenazine
Amoxicillin	Fenoprofen	Phencyclidine
Ampicillin	Furosemide	Phenelzine
Ascorbic acid	Gentisic acid	Phenobarbital
Aspartame	Hemoglobin	Phetoin
Atropine	Hydralazine	L-Phenylephrine
Benzilic acid	Hydrochlorothiazide	Phenylpropanolamine

Benzoic acid	Hydrocodone	Prednisolone
Benzoylcegonine	Hydrocortisone	Prednisone
Bilirubin	O-Hydroxyhippuric acid	Procaine
Brompheniramine	3-Hydroxytyramine	Promazine
Caffeine	Ibuprofen	Promethazine
Cannabidiol	Imipramine	D,L-Propranolol
Cannabinol	(-) Isoproterenol	D-Propoxyphene
Chloralhydrate	Isoxsuprine	Quinidine
Chloramphenicol	Ketamine	Quinine
Chlordiazepoxide	Ketoprofen	Ranitidine
Chlorothiazide	Labetalol	Salicylic acid
(±) Chlorpheniramine	Levorphanol	Secobarbital
Chlorpromazine	Loperamide	Sulfamethazine
Chloroquine	Maprotiline	Sulindac
Cholesterol	Meperidine	Temazepam
Clomipramine	Meprobamate	Tetracycline
Clonidine	Methadone	Tetrahydrocortisone
Cocaine hydrochloride	Methylphenidate	Tetrahydrozoline
Codeine	Morphine-3-Dglucuronide	Δ9-THC-COOH
Cortisone	Nalidixic acid	Thebaine
(-) Cotinine	Naloxone	Thiamine
Creatinine	Naltrexone	Thioridazine
Deoxycorticosterone	Naproxen	D,L-Thyroxine
Dextromethorphan	Niacinamide	Tolbutamide
Diazepam	Nifedipine	Triamterene
Diclofenac	Norcodein	Trifluoperazine
Diflunisal	Norethindrone	Trimethoprim
Digoxin	D-Norpropoxyphene	Trimipramine
Diphenhydramine	Noscapine	Tryptamine
Doxylamine	D,L-Octopamine	D, L-Tyrosine
Ecgonine hydrochloride	Oxalic acid	Uric acid
Ecgonine methylester	Oxazepam	Verapamil
(1R,2S)-(-)-Ephedrine	Oxolinic acid	Zomepirac

### COC

Acetaminophen	Estrone-3-sulfate	Oxymetazoline
Acetophenetidin	Ethyl-p-aminobenzoate	Papaverine
N-Acetylprocainamide	Fenoprofen	Penicillin-G
Acetylsalicylic acid	Furosemide	Pentobarbital

Aminopyrine	Gentisic acid	Perphenazine
Amitriptyline	Hemoglobin	Phencyclidine
Amobarbital	Hydralazine	Phenelzine
Amoxicillin	Hydrochlorothiazide	Phenobarbital
Ampicillin	Hydrocodone	Phentermine
L-Ascorbic acid	Hydrocortisone	L-Phenylephrine
DL-Amphetamine Sulfate	O-Hydroxyhippuric acid	$\beta$ -Phenylethylamine
Apomorphine	p-Hydroxymethamphetamine	Phenylpropanolamine
Aspartame	3-Hydroxytyramine	Prednisolone
Atropine	Ibuprofen	Prednisone
Benzilic acid	Imipramine	Procaine
Benzoic acid	Iproniazid	Promazine
Benzphetamine	( $\pm$ ) - Isoproterenol	Promethazine
( $\pm$ ) -Brompheniramine	Isoxsuprine	DL-Propranolol
Caffeine	Ketamine	D-Propoxyphene
Cannabidiol	Ketoprofen	D-Pseudoephedrine
Cannabinol	Labetalol	Quinidine
Chloralhydrate	Levorphanol	Quinine
Chloramphenicol	Loperamide	Ranitidine
Chlordiazepoxide	Maprotiline	Salicylic acid
Chlorothiazide	Meperidine	Secobarbital
( $\pm$ ) -Chlorpheniramine	Meprobamate	Serotonin
Chlorpromazine	Methadone	Sulfamethazine
Chloroquine	Methoxyphenamine	Sulindac
Cholesterol	( $\pm$ ) -3,4-Methylene dioxymphetamine	Temazepam
Clomipramine	Methylene-dioxymphetamine	Tetracycline
Clonidine	Morphine-3- $\beta$ -D glucuronide	Tetrahydrocortisone 3-( $\beta$ -D glucuronide)
Codeine	Morphine Sulfate	Tetrahydrozoline
Cortisone	Nalidixic acid	Thebaine
(-) Cotinine	Naloxone	Thiamine
Creatinine	Naltrexone	Thioridazine
Deoxycorticosterone	Naproxen	DL-Tyrosine
Dextromethorphan	Niacinamide	Tolbutamide
Diazepam	Nifedipine	Triamterene
Diclofenac	Norcodein	Trifluoperazine
Diflunisal	Norethindrone	Trimethoprim
Digoxin	D-Norpropoxyphene	Trimipramine

Diphenhydramine	Noscapine	Tryptamine
Doxylamine	DL-Octopamine	DL-Tryptophan
Ecgonine methylester	Oxalic acid	Tyramine
(-) - $\Psi$ -Ephedrine	Oxazepam	Uric acid
Erythromycin	Oxolinic acid	Verapamil
$\beta$ -Estradiol	Oxycodone	Zomepirac

**MET:** The MET interference data was reported in K122961.

f. 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 all formats. The obtained lowest detectable concentration was used to calculate the cross-reactivity. There were no differences observed for different formats.

<b>AMP</b> (D- Amphetamine, <b>Cut-off=500 ng/mL</b> )	<b>Result</b> Positive at 500 ng/mL	<b>Reactivity</b> 100%
L - Amphetamine	25000	2%
D,L - Amphetamine	1500	33%
Phentermine	1500	33%
Hydroxyamphetamine	8000	6%
Methylenedioxyamphetamine (MDA)	2500	20%
d-Methamphetamine	Negative at 100000	<1%
l-Methamphetamine	Negative at 100000	<1%
ephedrine	Negative at 100000	<1%
Methylenedioxyethylamphetamine (MDE)	Negative at 100000	<1%
3,4-methylenedioxy-methamphetamine (MDMA)	Negative at 100000	<1%

<b>COC</b> (Benzoylcegonine, <b>Cut-off=150 ng/mL</b> )	<b>Result</b> Positive at 150 ng/mL	<b>Reactivity</b> 100%
Cocaine HCl	Positive at 375 ng/mL	40%
Cocaethylene	Positive at 6250 ng/mL	2.4%
Ecgonine	Positive at 16000 ng/mL	0.9%
Norcocaine	Positive at 50000 ng/mL	0.3%

<b>MET</b> (D- Methamphetamine, <b>Cut-off=500 ng/mL</b> )	<b>Result</b> Positive at 500 ng/mL	<b>Reactivity</b> 100%
(+/-) 3,4-Methylenedioxy-n-ethylamphetamine(MDEA)	Positive at 500 ng/mL	100%
(+/-) 3,4-Methylenedioxyamphetamine (MDA)	Positive at 500 ng/mL	100%
d/l-Methamphetamine	Positive at 500 ng/mL	100%

l-Methamphetamine	Positive at 10,000 ng/mL	5%
l-Amphetamine	Positive at 37,500 ng/mL	1.3%

**MET:** Additional MET interference data was reported in K122961.

g. Effect of Urine Specific Gravity and Urine pH

To investigate the effect of urine specific gravity and urine pH, urine samples with of 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.

2. Comparison Studies

The method comparison studies for the WONDFO Urine Test (Amphetamine, Cocaine and Methamphetamine) 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. The results are presented in the tables below:

**AMP**

Dip Card format		Negative	Low Negative by GC/MS (less than -50%)	Near Cutoff Negative by GC/MS (Between -50% and cut-off)	Near Cutoff Positive by GC/MS (Between the cut-off and +50%)	High Positive by GC/MS (greater than +50%)
Viewer A	Positive	0	0	2	30	10
	Negative	10	17	11	0	0
Viewer B	Positive	0	0	2	30	10
	Negative	10	17	11	0	0
Viewer C	Positive	0	0	1	30	10
	Negative	10	17	12	0	0

**Discordant Results of AMP Dip Card**

Viewer	Sample Number	GC/MS Result	Dipcard Format Viewer Results
Viewer A	AMP5062	480	Positive
Viewer A	AMP5065	481	Positive
Viewer B	AMP5062	480	Positive
Viewer C	AMP5062	480	Positive

<b>Viewer</b>	<b>Sample Number</b>	<b>GC/MS Result</b>	<b>Dipcard Format Viewer Results</b>
<b>Viewer B</b>	AMP5218	365	Positive

**AMP**

Cup format		Negative	Low Negative by GC/MS (less than -50%)	Near Cutoff Negative by GC/MS (Between -50% and cut-off)	Near Cutoff Positive by GC/MS (Between the cut-off and +50%)	High Positive by GC/MS (greater than +50%)
Viewer A	Positive	0	0	2	30	10
	Negative	10	17	11	0	0
Viewer B	Positive	0	0	1	30	10
	Negative	10	17	12	0	0
Viewer C	Positive	0	0	2	30	10
	Negative	10	17	11	0	0

**Discordant Results of AMP Cup**

<b>Viewer</b>	<b>Sample Number</b>	<b>GC/MS Result</b>	<b>Cup Format Viewer Results</b>
<b>Viewer A</b>	AMP5062	480	Positive
<b>Viewer A</b>	AMP5065	481	Positive
<b>Viewer B</b>	AMP5062	480	Positive
<b>Viewer C</b>	AMP5062	480	Positive
<b>Viewer C</b>	AMP5065	481	Positive

COC

Dip Card format		Negative	Low Negative by GC/MS (less than -50%)	Near Cutoff Negative by GC/MS (Between -50% and cut-off)	Near Cutoff Positive by GC/MS (Between the cut-off and +50%)	High Positive by GC/MS (greater than +50%)
Viewer A	Positive	0	0	2	30	10
	Negative	10	18	10	0	0
Viewer B	Positive	0	0	2	30	10
	Negative	10	18	10	0	0
Viewer C	Positive	0	0	1	29	11
	Negative	10	18	11	0	0

**Discordant Results of COC DipCard**

Viewer	Sample Number	GC/MS Result	DipCard Format Viewer Results
<b>Viewer A</b>	COC1215	145	Positive
<b>Viewer A</b>	COC1217	146	Positive
<b>Viewer B</b>	COC1215	145	Positive
<b>Viewer B</b>	COC1217	146	Positive
<b>Viewer C</b>	COC1217	146	Positive

**COC**

Cup format		Negative	Low Negative by GC/MS (less than -50%)	Near Cutoff Negative by GC/MS (Between -50% and cut-off)	Near Cutoff Positive by GC/MS (Between the cut-off and +50%)	High Positive by GC/MS (greater than +50%)
Viewer A	Positive	0	0	2	30	10
	Negative	10	18	10	0	0
Viewer B	Positive	0	0	1	30	10
	Negative	10	18	11	0	0
Viewer C	Positive	0	0	2	30	10
	Negative	10	18	10	0	0

**Discordant Results of COC Cup**

Viewer	Sample Number	GC/MS Result	Cup Format Viewer Results
Viewer A	COC1215	145	Positive
Viewer B	COC1215	145	Positive
Viewer C	COC1215	145	Positive
Viewer C	COC1217	146	Positive
Viewer A	COC1217	146	Negative

The Methamphetamine method comparison data was reported in K122961.

#### Lay-user study

A lay user study was performed at three intended user sites with 280 lay persons testing the amphetamine devices, 280 lay persons testing the cocaine devices and 280 lay persons testing the Methamphetamine devices. 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. The results are summarized below.

#### Comparison between GC/MS and Lay Person Results AMP Cup

% of Cutoff	Number of samples	d-Amphetamine 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	126.3	0	20	100
-50% Cutoff	20	248.6	0	20	100
-25% Cutoff	20	377.1	1	19	95.0
+25% Cutoff	20	625.8	18	2	90.0
+50% Cutoff	20	753.2	20	0	100
+75% Cutoff	20	874.3	20	0	100

#### Comparison between GC/MS and Lay Person Results AMP Dip Card

% of Cutoff	Number of samples	d-Amphetamine Concentration by GC/MS (ng/mL)	Lay person results		The percentage of correct results
			No. of	No. of	

			Positive	Negative	(%)
<b>-100% Cutoff</b>	20	0	0	20	100
<b>-75% Cutoff</b>	20	126.3	0	20	100
<b>-50% Cutoff</b>	20	248.6	0	20	100
<b>-25% Cutoff</b>	20	377.1	2	18	90.0
<b>+25% Cutoff</b>	20	625.8	18	2	90.0
<b>+50% Cutoff</b>	20	753.2	20	0	100
<b>+75% Cutoff</b>	20	874.3	20	0	100

**Comparison between GC/MS and Lay Person Results COC Cup**

% of Cutoff	Number of samples	Benzoyllecgonine Concentration by GC/MS (ng/mL)	Lay person results		The percentage of correct results (%)
			No. of Positive	No. of Negative	
<b>-100% Cutoff</b>	20	0	0	20	100
<b>-75% Cutoff</b>	20	38.1	0	20	100
<b>-50% Cutoff</b>	20	75.6	0	20	100
<b>-25% Cutoff</b>	20	113.4	2	18	90.0
<b>+25% Cutoff</b>	20	186.7	18	2	90.0
<b>+50% Cutoff</b>	20	226.3	20	0	100
<b>+75% Cutoff</b>	20	259.8	20	0	100

**Comparison between GC/MS and Lay Person Results COC Dip Card**

% of Cutoff	Number of samples	Benzoyllecgonine Concentration by GC/MS (ng/mL)	Lay person results		The percentage of correct results (%)
			No. of Positive	No. of Negative	
<b>-100% Cutoff</b>	20	0	0	20	100
<b>-75% Cutoff</b>	20	38.1	0	20	100
<b>-50% Cutoff</b>	20	75.6	0	20	100
<b>-25% Cutoff</b>	20	113.4	2	18	90.0
<b>+25% Cutoff</b>	20	186.7	18	2	90.0
<b>+50% Cutoff</b>	20	226.3	20	0	100
<b>+75% Cutoff</b>	20	259.8	20	0	100

**Comparison between GC/MS and Lay Person Results MET Cup**

% of Cutoff	Number of samples	Methamphetamine Concentration by GC/MS (ng/mL)	Lay person results		The percentage of correct results (%)
			No. of Positive	No. of Negative	

<b>-100% Cutoff</b>	20	0	0	20	100
<b>-75% Cutoff</b>	20	124.8	0	20	100
<b>-50% Cutoff</b>	20	251.3	0	20	100
<b>-25% Cutoff</b>	20	377.6	2	18	90.0
<b>+25% Cutoff</b>	20	625.9	18	2	90.0
<b>+50% Cutoff</b>	20	748.3	20	0	100
<b>+75% Cutoff</b>	20	878.1	20	0	100

**Comparison between GC/MS and Lay Person Results MET Dip Card**

% of Cutoff	Number of samples	Methamphetamine Concentration by GC/MS (ng/mL)	Lay person results		The percentage of correct results (%)
			No. of Positive	No. of Negative	
<b>-100% Cutoff</b>	20	0	0	20	100
<b>-75% Cutoff</b>	20	124.8	0	20	100
<b>-50% Cutoff</b>	20	251.3	0	20	100
<b>-25% Cutoff</b>	20	377.6	2	18	90.0
<b>+25% Cutoff</b>	20	625.9	18	2	90.0
<b>+50% Cutoff</b>	20	748.3	20	0	100
<b>+75% Cutoff</b>	20	878.1	20	0	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 each package insert and the scores revealed a reading Grade Level of 7.

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 the WONDFO Urine Test devices are substantially equivalent to the predicate.