



Food and Drug Administration
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GUANGZHOU WONDFO BIOTECH CO., LTD.
C/O JOE SHIA
BUSINESS DIRECTOR
504 EAST DIAMOND AVE. SUITE F
GAITHERSBURG MD 20877

July 1, 2015

Re: K151478

Trade/Device Name: Wondfo CR3 Keyless Split Sample Cup
Regulation Number: 21 CFR 862.3650
Regulation Name: Opiate test system
Regulatory Class: II
Product Code: DJG, LFG, LCM, DKZ, DIS, JXM, LDJ, DIO, LAF, DJR
Dated: May 26, 2015
Received: June 2, 2015

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

Indications for Use

510(k) Number (if known)
k151478

Device Name
Wondfo CR3 Keyless Split Sample Cup

Indications for Use (Describe)

The Wondfo CR3 Keyless Split Sample Cup is a competitive binding, lateral flow immunochromatographic assay for qualitative and simultaneous detection of Amphetamine, Secobarbital, Oxazepam, Cocaine, Cannabinoids, Methamphetamine, Methylenedioxymethamphetamine, Morphine, Phencyclidine, Oxycodone, Buprenorphine, Methadone and Natriptyline in human urine at the cutoff concentrations of:

Drug(Identifier)	Cut-off level
Amphetamine	1000 ng/mL
Secobarbital	300 ng/mL
Oxazepam	300 ng/mL
Cocaine	300 ng/mL
Cannabinoids	50 ng/mL
Methamphetamine	1000 ng/mL
Methylenedioxymethamphetamine	500 ng/mL
Morphine	300 ng/mL or 2000 ng/mL
Phencyclidine	25 ng/mL
Oxycodone	100 ng/mL
Buprenorphine	10 ng/mL
Methadone	300/ng/mL
Natriptyline	1000ng/mL

Configuration of the Wondfo CR3 Keyless Split Sample Cup can consist of any combination of the above listed drug analytes.

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 or LC/MS is the preferred confirmatory method.

The test will yield preliminary positive results when prescription drugs Buprenorphine, Oxazepam, Oxycodone and Secobarbital are ingested, even at or above therapeutic doses. It is not intended to distinguish between prescription use or abuse of these drugs.

Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive.

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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SUMMARY

1. Date the summary was prepared: June 29, 2015

2. Submitter's name: Guangzhou Wondfo Biotech Co., Ltd.
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3. Name of contact person: Joe Shia
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 Telephone: 240-505-7880
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4. Name of the device

 Common or usual name: Multi-Drug Urine Test Cup
 Trade or proprietary name: Wondfo CR3 Keyless Split Sample Cup

5. Classification: All are Class II medical devices with the following various product codes with Code of Federal

Product Code	Classification	Regulation Section	Panel
DKZ	II	21 CFR § 862.3100, Amphetamine Test System	Toxicology (91)
LDJ	II	21 CFR § 862.3870, Cannabinoids Test System	Toxicology (91)
DIO	II	21 CFR § 862.3250, Cocaine and Cocaine Metabolites Test System	Toxicology (91)
LAF	II	21 CFR § 862.3610, Methamphetamine Test System	Toxicology (91)
DJG	II	21 CFR § 862.3650, Opiate test system	Toxicology (91)
JXM	II	21 CFR § 862.3170, Benzodiazepine Test System	Toxicology (91)
LCM	unclassified	Enzyme Immunoassay Phencyclidine	Toxicology (91)
DIS	II	21 CFR § 862.3150, Barbiturate Test System	Toxicology (91)
DJR	II	21 CFR § 862.3620, Methadone Test System	Toxicology (91)
LFG	II	21 CFR § 862.3910, Tricyclic antidepressant drug Test System	Toxicology (91)

6. Description of the device:

The Wondfo CR3 Keyless Split Sample Cup uses immunochromatographic assays for qualitative and simultaneous detection of Amphetamine, Secobarbital, Oxazepam, Cocaine, Cannabinoids, Methamphetamine, Methylenedioxymethamphetamine, Morphine, Phencyclidine, Oxycodone Buprenorphine, Methadone and Natriptyline in human urine samples. The test is a lateral flow, competitive binding system. 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.

7. Test Principle

The Wondfo CR3 Keyless Split Sample Cup is a rapid test for the qualitative detection of Amphetamine, Secobarbital, Oxazepam, Cocaine, Cannabinoids, Methamphetamine, Methylenedioxymethamphetamine, Morphine, Phencyclidine, Oxycodone Buprenorphine, Methadone and Natriptyline in urine samples and contains lateral flow chromatographic immunoassays for these analytes. 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.

8. Intended use of the device:

The Wondfo CR3 Keyless Split Sample Cup is a competitive binding, lateral flow immunochromatographic assay for qualitative and simultaneous detection of Amphetamine, Secobarbital, Oxazepam, Cocaine, Cannabinoids, Methamphetamine, Methylenedioxymethamphetamine, Morphine, Phencyclidine, Oxycodone, Buprenorphine, Methadone and Natriptyline in human urine at the cutoff concentrations of:

Drug(Identifier)	Cut-off level
Amphetamine(AMP)	1000 ng/mL
Secobarbital (BAR)	300 ng/mL
Oxazepam (BZO)	300 ng/mL
Cocaine (COC)	300 ng/mL
Cannabinoids (THC)	50 ng/mL
Methamphetamine (MET)	1000 ng/mL
Methylenedioxymethamphetamine (MDMA)	500 ng/mL
Morphine (MOP)	300 or 2000 ng/mL
Phencyclidine (PCP)	25 ng/mL
Oxycodone (OXY)	100 ng/mL
Buprenorphine (BUP)	10 ng/mL
Methadone (MTD)	300 ng/mL
Natriptyline (TCA)	1000 ng/mL

Configuration of the Wondfo CR3 Keyless Split Sample Cup can consist of any combination of the

above listed drug analytes.

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 or LC/MS is the preferred confirmatory method.

The test will yield preliminary positive results when prescription drugs Buprenorphine, Oxazepam, Oxycodone and Secobarbital are ingested, even at or above therapeutic doses. It is not intended to distinguish between prescription use or abuse of these drugs.

Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive.

9. Comparison to the predicate device

The Wondfo CR3 Keyless Split Sample Cup is a modified product format derived from the previously FDA-cleared Wondfo CR3 Keyless dual drug of abuse tests. A summary comparison of features of the Wondfo CR3 Keyless Split Sample Cup and the predicate devices is provided in the following Table.

Item	New Devices	Predicate devices (k141532, k140089, k142044, k142609, k143535, k150179, k150602)
Indication(s) for use	For the qualitative determination of Amphetamine (AMP), Secobarbital (BAR), Oxazepam (BZO), Cocaine (COC), Cannabinoids (THC), Methamphetamine (MET), Methylenedioxymethamphetamine (MDMA), Morphine (MOP), Phencyclidine (PCP), Oxycodone(OXY), Buprenorphine (BUP), Methadone (MTD) and Natriptyline (TCA) in human urine.	Same
Methodology	Competitive binding, lateral flow immunochromatographic assays based on the principle of antigen antibody immunochemistry.	Same
Type Of Test	Immunoassay principles that rely on antigen- antibody interactions to indicate positive or negative result	Same
Results	Qualitative	Same

Specimen Type	Human urine	Same
Cut Off Values	Amphetamine (AMP): 1,000 ng/ml, Secobarbital(BAR): 300 ng/ml, Oxazepam (BZO):300 ng/ml, Cocaine(COC): 300 ng/ml, Cannabinoids (THC):50 ng/ml, Methamphetamine (MET): 1,000 ng/ml, Methylenedioxymethamphetamine (MDMA): 500 ng/ml, Morphine (MOP): 300 ng/ml or 2000ng/ml, Phencyclidine (PCP): 25 ng/ml, Oxycodone(OXY) : 100 ng/ml, Buprenorphine (BUP): 10 ng/ml, Methadone (MTD): 300 ng/ml, Natriptyline (TCA): 1000 ng/mL	Same
Configurations	Cup, can detect from 2 to 13 drugs	Cup, each test can only detect up to 2 drugs
Intended Use	OTC Use & Prescription Use	Same

10. Performance Characteristics

The test strips of the candidate device are the same as those cleared with the predicate devices. Drug cutoffs of the candidate device are also identical to the predicate devices. Analytical performance was established for each device in the submissions as stated below. In addition, verification studies were conducted in support of the modification to have a multi-drug test cup (that detects 2 to 13 drugs at the same time), including interference studies and a lay-user study.

Drug(Identifier)	510(K) #
Amphetamine(AMP)	k141532
Secobarbital (BAR)	k143535
Oxazepam (BZO)	k140089
Cocaine (COC)	k141532
Cannabinoids (THC)	k150179
Methamphetamine (MET)	k150602
Methylenedioxymethamphetamine (MDMA)	k142044
Morphine (MOP)	k150602
Morphine 2000 (OPI)	k140089
Phencyclidine (PCP)	k142044
Oxycodone (OXY)	k150179
Buprenorphine (BUP)	k142609
Methadone (MTD)	k143535

Notriptyline (TCA)	k142609
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11. Conclusion

Based on the test principle and acceptable performance characteristics, it's concluded that the Wondfo CR3 Keyless Split Sample Cup is substantially equivalent to the predicates.