K093175

AUG 25 2010

510(k) SUMMARY
AS REQUIRED BY SECTION 807.92(C)

1. Date the summary was prepared: August 18, 2010

2. Submitter's name: Guangzhou Wondfo Biotech Co., Ltd.
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3. Name of the device
Common or usual name: Immunochromatographic test for the qualitative detection of:
Buprenorphine
Oxycodone
Propoxyphene

Trade or Proprietary or model name:

Trade or Proprietary or model name	Model Number
1. Wondfo One Step Buprenorphine Urine Test Strip	W13-S
2. Wondfo One Step Oxycodone Urine Test Strip	W21-S
3. Wondfo One Step Propoxyphene Urine Test Strip	W57-S

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

Product Code	CFR #
DJG	21CFR 862.3650
DJG	21CFR 862.3650
JXN	21CFR 862.3700

4. The legally marketed device to which we are claiming equivalence [807.92(a)(3)]:

1. Acon Laboratories, Inc. Acon BUP One Step Buprenorphene Test Strip, K060466.
2. Acon Laboratories, Inc. Acon OXY One Step Oxycodone Test Strip, K033047
3. Acon Laboratories, Inc. Acon PPX One Step Propoxyphene Test Strip, K040445

5. Description of the device:

Assay Principle: Immunochromatographic assay for drugs of abuse using a lateral flow, one step system for the qualitative detection of specific drugs in human urine. Each assay uses a monoclonal antibody-dye congugate from mouse against drug with gold chloride and fixed drug-protein conjugate and anti-mouse IgG polyclonal antibody in membrane.

6. Intended use of the device:

Wondfo One Step Buprenorphine Urine Test Strip, Wondfo One Step Oxycodone Urine Test Strip, and Wondfo One Step Propoxyphene Urine Test Strip are intended for the qualitative determination of Buprenorphine, Oxycodone, d-Propoxyphene at the specific cut-off concentration in human urine. They are intended for healthcare professionals in a central laboratory setting only and that it is not for use in point-of-care settings.

7. Comparison to the predicate device

A summary comparison of the features of the Wondfo One Step Buprenorphine Urine Test Strip, Wondfo One Step Oxycodone Urine Test Strip, Wondfo One Step Propoxyphene Urine Test Strip and the predicate devices is provided in the Table 1.

Table 1: Features comparison of Wondfo assays and the predicate devices

Similarities		
Item	Device	Predicate
Intended Use	Same	For the qualitative determination of buprenorphine, oxycodone, propoxyphene individual in human urine.
Calibrator	Same	Buprenorphine (buprenorphine) Oxycodone (oxycodone) Propoxyphene (propoxyphene)
Methodology	Same	Competitive binding, lateral flow immunochromatographic assays based on the principle of antigen antibody immunochemistry.
Type Of Test	Same	Immunoassay principles that rely on antigen-antibody interactions to indicate positive or negative result
Specimen Type	Same	Human urine
Cut Off Values	Same	Buprenorphine (buprenorphine):10ng/ml Oxycodone (oxycodone): 100 ng/ml Propoxyphene (propoxyphene): 300 ng/ml
Configurations	Strip	Strip, Device

8. Performance data

8.1 Accuracy

240 (eighty of each drug) clinical urine specimens were analyzed by GC-MS and by each corresponding Wondfo one step drug of abuse test. Each Wondfo test was read by three viewers. Samples were divided by concentration into four categories: less than half the cutoff, near cutoff negative, near cutoff

positive, and high positive.

Sample description: Unaltered clinical urine samples were evaluated. The testing samples include a total of 80 samples (40 negative and 40 positive) for each drug. Originally 25 drug clinical samples of varying concentrations were from Cutoff Value section, 10 negative samples and additional 45 clinical samples were from Shenzhen Drug Addiction Recovery Center. All these samples concentration were confirmed by GC-MS. The concentrations of drug urine samples range from < -50% cutoff, -50%cutoff~cutoff, Cutoff~+50%cutoff, >+50%cutoff.

Number of study sites: one
Type of study site: Our internal facility
Operator description: Our internal staff

The following results are tabulated from comparison studies:

Buprenorphine Method Comparison Study Results

Viewer A:

Wondfo Result	Negative	Less than half the cutoff concentration by GC/MS analysis	Near Cutoff Negative (Between 50% below the cutoff and the cutoff concentration)	Near Cutoff Positive (Between the cutoff and 50% above the cutoff concentration)	High Positive (greater than 50% above the cutoff concentration)
Positive	0	0	1	16	20
Negative	10	10	19	4	0

% agreement among positives is 90% (95% Confidence Interval 74.5% - 100%)

% agreement among negatives is 97.5% (95% Confidence Interval 82.0% - 100%)

Viewer B:

Wondfo Result	Negative	Less than half the cutoff concentration by GC/MS analysis	Near Cutoff Negative (Between 50% below the cutoff and the cutoff concentration)	Near Cutoff Positive (Between the cutoff and 50% above the cutoff concentration)	High Positive (greater than 50% above the cutoff concentration)
Positive	0	0	2	16	20
Negative	10	10	18	4	0

% agreement among positives is 90% (95% Confidence Interval 74.5% - 100%)

% agreement among negatives is 95% (95% Confidence Interval 79.5% - 100%)

Viewer C:

Wondfo Result	Negative	Less than half the cutoff concentration by GC/MS analysis	Near Cutoff Negative (Between 50% below the cutoff and the cutoff concentration)	Near Cutoff Positive (Between the cutoff and 50% above the cutoff concentration)	High Positive (greater than 50% above the cutoff concentration)
Positive	0	0	0	16	20
Negative	10	10	20	4	0

% agreement among positives is 90% (95% Confidence Interval 74.5% - 100%)

% agreement among negatives is 100% (95% Confidence Interval 84.5% - 100%)

Oxycodone Method Comparison Study Results

Viewer A:

Wondfo Result	Negative	Less than half the cutoff concentration by GC/MS analysis	Near Cutoff Negative (Between 50% below the cutoff and the cutoff concentration)	Near Cutoff Positive (Between the cutoff and 50% above the cutoff concentration)	High Positive (greater than 50% above the cutoff concentration)
Positive	0	0	1	15	23
Negative	10	10	19	2	0

% agreement among positives is 95% (95% Confidence Interval 79.5% - 100%)

% agreement among negatives is 97.5% (95% Confidence Interval 82.0% - 100%)

Viewer B:

Wondfo Result	Negative	Less than half the cutoff concentration by GC/MS analysis	Near Cutoff Negative (Between 50% below the cutoff and the cutoff concentration)	Near Cutoff Positive (Between the cutoff and 50% above the cutoff concentration)	High Positive (greater than 50% above the cutoff concentration)
Positive	0	0	2	14	23
Negative	10	10	18	3	0

% agreement among positives is 92.5% (95% Confidence Interval 77.0% - 100%)

% agreement among negatives is 95% (95% Confidence Interval 79.5% - 100%)

Viewer C:

Wondfo Result	Negative	Less than half the cutoff concentration by GC/MS analysis	Near Cutoff Negative (Between 50% below the cutoff and the cutoff concentration)	Near Cutoff Positive (Between the cutoff and 50% above the cutoff concentration)	High Positive (greater than 50% above the cutoff concentration)
Positive	0	0	0	13	23
Negative	10	10	20	4	0

% agreement among positives is 90% (95% Confidence Interval 74.5% - 100%)

% agreement among negatives is 100% (95% Confidence Interval 84.5% - 100%

Propoxyphene Method Comparison Study Results

Viewer A:

Wondfo Result	Negative	Less than half the cutoff concentration by GC/MS analysis	Near Cutoff Negative (Between 50% below the cutoff and the cutoff concentration)	Near Cutoff Positive (Between the cutoff and 50% above the cutoff concentration)	High Positive (greater than 50% above the cutoff concentration)
Positive	0	0	2	17	19
Negative	10	16	12	4	0

% agreement among positives is 90% (95% Confidence Interval 74.5% - 100%)

% agreement among negatives is 95% (95% Confidence Interval 79.5% - 100%)

Viewer B:

Wondfo Result	Negative	Less than half the cutoff concentration by GC/MS analysis	Near Cutoff Negative (Between 50% below the cutoff and the cutoff concentration)	Near Cutoff Positive (Between the cutoff and 50% above the cutoff concentration)	High Positive (greater than 50% above the cutoff concentration)
Positive	0	0	1	18	19
Negative	10	16	13	3	0

% agreement among positives is 92.5% (95% Confidence Interval 77.0% - 100%)

% agreement among negatives is 97.5% (95% Confidence Interval 82.0% - 100%)

Viewer C:

Wondfo Result	Negative	Less than half the cutoff concentration by GC/MS analysis	Near Cutoff Negative (Between 50% below the cutoff and the cutoff concentration)	Near Cutoff Positive (Between the cutoff and 50% above the cutoff concentration)	High Positive (greater than 50% above the cutoff concentration)
Positive	0	0	0	16	19
Negative	10	16	14	5	0

% agreement among positives is 87.5% (95% Confidence Interval 72.0% - 100%)

% agreement among negatives is 100% (95% Confidence Interval 84.5% - 100%)

8.2 Performance Characteristics and Other Information

The performance characteristics of the Wondfo One Step Buprenorphine Urine Test Strip, Wondfo One Step Oxycodone Urine Test Strip, and Wondfo One Step Propoxyphene Urine Test Strip were verified by cutoff value, specificity and cross-reactivity, interfering substances, effect of specified gravity of urine, effect of urine pH, precision, stability study. Study results indicate that these test devices are robust and can be stable during the shelf life time when used according to the package inserts.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center – WO66-0609
Silver Spring, MD 20993-0002

Guangzhou Wondfo Biotech Co., Ltd.
c/o Mr. Howard Mann
1 Congressional Drive, Apt. C
Greenville, DE 19807

AUG 25 2010

Re: k093175
Trade/Device Name: Wondfo One Step Bruprenorphine Urine Test
Regulation Number: 21 CFR §862.3650
Regulation Name: Opiate Test System
Regulatory Class: Class II
Product Code: DJG, JXN
Dated: August 20, 2010
Received: August 24, 2010

Dear Mr. Mann:

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.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. 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) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney C. Harper, Ph.D.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE FORM

K093175

510(k) Number (if known): K093175

Device Name: Wondfo One Step Buprenorphine Urine Test Strip

Indication For Use: The Wondfo One Step Buprenorphine Urine Test Strip is intended for the qualitative determination of buprenorphine in human urine at the cut-off concentration of 10 ng/ml.

The assay is in strip format. The device is intended for healthcare professionals in a central laboratory setting only and is not for use in point-of-care settings. For in vitro diagnostic use.

This assay provides only a preliminary result. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly in evaluating a preliminary positive result. To obtain a confirmed analytical result, a more specific alternate chemical method is needed. Gas chromatography/mass spectrometry (GC/MS) or Liquid chromatography/mass spectrometry (LC/MS) are the preferred confirmatory methods.

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

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Doug Rhenkemi

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

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INDICATIONS FOR USE FORM

510(k) Number (if known): K093175

Device Name: Wondfo One Step Oxycodone Urine Test Strip

Indication For Use: The Wondfo One Step Oxycodone Urine Test Strip is intended for the qualitative determination of oxycodone in human urine at the cut-off concentration of 100 ng/ml.

The assay is in strip format. The device is intended for healthcare professionals in a central laboratory setting only and is not for use in point-of-care settings. For in vitro diagnostic use.

This assay provides only a preliminary result. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly in evaluating a preliminary positive result. To obtain a confirmed analytical result, a more specific alternate chemical method is needed. Gas chromatography/mass spectrometry (GC/MS) or Liquid chromatography/mass spectrometry (LC/MS) are the preferred confirmatory methods.

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

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

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Office of In Vitro Diagnostic Device
Evaluation and Safety

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INDICATIONS FOR USE FORM

K093175

510(k) Number (if known): K093175

Device Name: Wondfo One Step Propoxyphene Urine Test Strip

Indication For Use: The Wondfo One Step Propoxyphene Urine Test Strip is intended for the qualitative determination of propoxyphene in human urine at the cut-off concentration of 300 ng/ml.

The assay is in strip format. The device is intended for healthcare professionals in a central laboratory setting only and is not for use in point-of-care settings. For in vitro diagnostic use.

This assay provides only a preliminary result. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly in evaluating a preliminary positive result. To obtain a confirmed analytical result, a more specific alternate chemical method is needed. Gas chromatography/mass spectrometry (GC/MS) or Liquid chromatography/mass spectrometry (LC/MS) are the preferred confirmatory methods.

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

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