

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY TEMPLATE**

A. 510(k) Number:

k152495

B. Purpose for Submission:

Addition of an over-the-counter (OTC) claim

C. Measurand:

Propoxyphene

D. Type of Test:

Qualitative immunochromatographic assay

E. Applicant:

Guangzhou Wondfo Biotech Co., Ltd.

F. Proprietary and Established Names:

Wondfo Propoxyphene Urine Test

G. Regulatory Information:

1. Regulation section:

21 CFR §862.3700

2. Classification:

Class II

3. Product code:

JXN

4. Panel:

Toxicology, 91

H. Intended Use:

1. Intended use(s):

See Indications for Use below.

2. Indication(s) for use:

The Wondfo Propoxyphene Urine Test is an immunochromatographic assay for the qualitative determination of d-Propoxyphene in human urine at a cutoff concentration of 300 ng/mL. The test is available in a dip card format and a test cup format. It is intended for prescription use and over the counter use. The test provides only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. GC/MS is the preferred confirmatory method. The test will yield preliminary positive results when the prescription drug d-propoxyphene is ingested, even at or above therapeutic doses. There is no uniformly recognized cutoff concentration for d-Propoxyphene. It is not intended to distinguish between prescription use or abuse of this drug. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive.

3. Special conditions for use statement(s):

For over-the-counter and prescription use.

4. Special instrument requirements:

Not applicable. The device is a visually read single-use device.

I. Device Description:

The Wondfo Propoxyphene Urine Test is a rapid test for the qualitative detection of Propoxyphene in urine samples.

The device has two formats – test cup and dip card. The test cup comprises two items - a urine storage/transport vial and an integrated a urine collection cup with a lateral flow device.

The dip card comprises three items – urine collection cup, urine storage/transport vial, and lateral flow test device.

Both devices are single-use and visually read.

J. Substantial Equivalence Information:

1. Predicate device name(s):

Wondfo Propoxyphene Urine Test

2. Predicate 510(k) number(s):

k121557

3. Comparison with predicate:

Similarities		
Item	Candidate Device k152495 Wondfo Propoxyphene Urine Test	Predicate Device k121557 Wondfo Propoxyphene Urine Test
Indications for Use	For the qualitative determination of Propoxyphene in human urine.	Same
Methodology	Competitive binding, lateral flow immunochromatographic assay.	Same
Specimen Type	Urine	Same
Cut-off value	300 ng/mL	Same
Test format	Test Cup, Dip Card	Same
Assay type	Qualitative	Same

Differences		
Item	Candidate Device k152495 Wondfo Propoxyphene Urine Test	Predicate Device k121557 Wondfo Propoxyphene Urine Test
Special Conditions for Use	OTC and prescription use.	Prescription use.

K. Standard/Guidance Document Referenced (if applicable):

None were referenced.

L. Test Principle:

The assay type is a competitive immunoassay constructed on a lateral flow device. 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.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. *Precision/Reproducibility:*

Performance characteristics are found in the predicate, k121557.

b. *Linearity/assay reportable range:*

Not applicable, the device is intended for qualitative use.

c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*

Control materials:

External control standards are not supplied with this device; however, this device has internal procedural control. A colored line appearing in the control region confirms sufficient sample volume and adequate membrane wicking. Users are instructed that the test is invalid if a line fails to appear in the control region.

d. *Detection limit:*

See k121557.

e. *Analytical specificity:*

See k121557.

f. *Assay cut-off:*

See k121557.

2. Comparison studies:

a. *Method comparison with predicate device:*

See k121557.

b. *Matrix comparison:*

Not applicable. The assay is intended for urine samples.

3. Clinical studies:

a. *Clinical Sensitivity:*

Not applicable.

b. *Clinical specificity:*

Not applicable.

c. Other clinical supportive data (when a. and b. are not applicable):

Consumer / lay person study:

The lay user study was comprised of 280 lay users who were divided into two groups to test the Dipcard format and the Test Cup format (140 each). The testing was conducted at three intended user sites: one hospital and two drug addiction recovery centers in P.R. China. All participants came from diverse educational and occupational backgrounds. Only one of the 280 participants indicated that they had previous experience in drugs of abuse testing.

In the group testing with the Test Cup, there were 77 male and 63 female participants with ages ranging from 21 to 62 years of age. In the group testing with the Dipcard, there were 73 male and 67 female participants with ages ranging from 21 to 64 years of age.

The samples were urine and prepared at the following concentrations; -100%, +/- 75%, +/-50%, +/-25% of the cut-off by spiking Propoxyphene into drug free, pooled urine specimens. The concentrations of the samples were confirmed by gas chromatography/ mass spectrometry. Each urine sample was aliquoted into individual containers, blind-labeled, and randomized. Each participant was provided with the package insert, 1 blind labeled sample, and a Wondfo Propoxyphene Urine Test for a Dip card or Test cup. The test procedure was conducted solely based on the users reading and understanding of the package insert.

After the test, the consumer was required to fill out questionnaire on the ease of

understanding the package insert instructions. A Flesch-Kincaid reading analysis was performed on the package insert and the score revealed a reading grade level of less than 7. All lay users indicated that the device instructions can be easily followed. The results are summarized below:

Comparison between Test Cup and GC/MS

% of Cut-off	Number of samples	Propoxyphene Concentration by GC/MS	Lay Person Results		Correct results
			No. of Positive	No. of Negative	
-100%	20	0	0	20	100%
-75%	20	75	0	20	100%
-50%	20	148	0	20	100%
-25%	20	226	2	18	90%
+25%	20	378	18	2	90%
+50%	20	452	20	0	100%
+75%	20	523	20	0	100%

Comparison between Dip Card and GC/MS

% of Cut-off	Number of samples	Propoxyphene Concentration by GC/MS	Lay Person Results		Correct results
			No. of Positive	No. of Negative	
-100%	20	0	0	20	100%
-75%	20	75	0	20	100%
-50%	20	148	0	20	100%
-25%	20	226	2	18	90%
+25%	20	378	18	2	90%
+50%	20	452	20	0	100%
+75%	20	523	20	0	100%

4. Clinical cut-off:

Not applicable.

5. Expected values/Reference range:

Not applicable.

N. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

O. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.