

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

A. 510(k) Number:

K040445

B. Analyte:

Propoxyphene

C. Type of Test:

Qualitative immunoassay

D. Applicant:

Acon Laboratories, Inc.

E. Proprietary and Established Names:

ACON[®] One Step Propoxyphene Test Device and Test Strip

F. Regulatory Information:

1. Regulation section:
21 CFR § 862.3700
2. Classification:
Class II
3. Product Code:
JXN
4. Panel:
Toxicology (91)

G. Intended Use:

1. Intended use(s):
Refer to Indications for use.
2. Indication(s) for use:
The ACON[®] One Step Propoxyphene Test Device and Test Strip are enzyme immunoassays for the qualitative determination of propoxyphene in human urine. The assay has a cutoff concentration of 300 ng/mL.

The device is for in vitro diagnostic use.
The device is for prescription use.
3. Special condition for use statement(s):
The ACON[®] One Step Propoxyphene Test Device and Test Strip provide only a preliminary analytical test result. A more specific alternative chemical method must be used to obtain a confirmed analytical result. Gas

chromatography/Mass spectrometry is the preferred confirmatory method. Other chemical confirmation methods are available. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are used.

The assay is intended for use in point-of-care settings.

4. Special instrument Requirements:
Not applicable. The device is a visually read single-use device.

H. Device Description:

This submission includes both a single-use dipstick (referred to as a test strip) and a cassette (referred to as a test device). With the dipstick, operators dip the test strip into the urine and the reaction is initiated by movement of the sample through the test strip. With the cassette, operators add several drops of the sample to the sample well. The test reaction is initiated by movement of the sample through the test strip.

I. Substantial Equivalence Information:

1. Predicate device name(s):
Instant-View[®] Propoxyphene (PPX) Urine Test Cassette
2. Predicate K number(s):
K022915
3. Comparison with predicate:

Both devices are for the qualitative determination of the same analyte in the same matrix, and utilize the same cutoff concentration. Both are visually-read single use devices.

Similarities		
Item	Devices (Dipstick and Cassette)	Predicate
Methodology	Same	Lateral flow immunochromatographic
Type of assay	Same	Qualitative
Matrix	Same	Urine
Cutoff	Same	300 ng/mL
Intended user	Same	Professional use
Endpoint	Same	Colored lines
Differences		
Item	Device (Dipstick and Cassette)	Predicate
Read time	5 minutes	4 – 7 minutes

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

The sponsor referenced the following guidance document(s) in their submission:

Premarket Submission and Labeling Recommendations for Drugs of Abuse Screening Tests - Draft Guidance for Industry and FDA Staff, published December 2003

The sponsor indicated deviation from this guidance in regards to interference testing.

K. Test Principle:

The test employs lateral flow immunochromatographic technology.

Drug in the sample and drug-labeled conjugate (containing a chromagen) compete for antibody binding sites in the test area of the test strip. Binding of drug in the sample causes the absence of a line at the test area, i.e., a positive result. When drug is not present in the sample, the drug-labeled conjugate binds at the test line, resulting in formation of a line, i.e., a negative result. The absence or presence of the line is determined visually by the operator.

The test antibody consists of monoclonal mouse antibody against propoxyphene.

The internal process control consists of goat anti-rabbit IgG antibody as the stationary phase and rabbit IgG-colloidal gold conjugate as the mobile phase.

L. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. *Precision/Reproducibility:*

Specimen description: drug free urine spiked with propoxyphene

Number of days: three

Replicates per day: ten

Lots of product used: three

Number of operators: three

Operator: laboratorian

Testing Facility: manufacturer's laboratory

Results of the study are presented below:

Propoxyphene Precision Study Results, Lot 1, Day 1 – Test Strip

Concentration of sample, ng/mL	Number of determinations	Results # Neg/ #Pos
0	30	30/0
150	30	30/0
225	30	24/6
375	30	7/23
450	30	0/30
600	30	0/30

Propoxyphene Precision Study Results, Lot 2, Day 2 – Test Strip

Concentration of sample, ng/mL	Number of determinations	Results # Neg/ #Pos
0	30	30/0
150	30	30/0
225	30	25/5
375	30	8/22
450	30	0/30
600	30	0/30

Propoxyphene Precision Study Results, Lot 3, Day 3 – Test Strip

Concentration of sample, ng/mL	Number of determinations	Results # Neg/ #Pos
0	30	30/0
150	30	30/0
225	30	26/4
375	30	7/23
450	30	0/30
600	30	0/30

Propoxyphene Precision Study Results, Lot 1, Day 1 – Test Device

Concentration of sample, ng/mL	Number of determinations	Results # Neg/ #Pos
0	30	30/0
150	30	30/0
225	30	26/4
375	30	8/22
450	30	0/30
600	30	0/30

Propoxyphene Precision Study Results, Lot 2, Day 2 – Test Device

Concentration of sample, ng/mL	Number of determinations	Results # Neg/ #Pos
0	30	30/0
150	30	30/0
225	30	26/4
375	30	7/23
450	30	0/30
600	30	0/30

Propoxyphene Precision Study Results, Lot 3, Day 3 – Test Device

Concentration of sample, ng/mL	Number of determinations	Results # Neg/ #Pos
0	30	30/0
150	30	30/0
225	30	27/3
375	30	7/23
450	30	0/30
600	30	0/30

b. *Linearity/assay reportable range:*

Not applicable. The assay is intended for qualitative use.

c. *Traceability (controls, calibrators, or method):*

Control materials are required but are not specifically identified in the labeling. The sponsor's Package Insert directs the user to follow local, state, and federal guidelines for testing QC materials and to process the controls in the same manner as unknown samples

The device has an internal process control which confirms sufficient specimen volume, adequate membrane wicking, and correct procedural technique.

d. *Detection limit:*

Sensitivity of this assay is characterized by validating performance around the claimed cutoff concentration of the assay, including a determination of the lowest concentration of drug that is capable of producing a positive result.

Drug-free urine specimens were spiked with propoxyphene to concentrations of 0, 150, 225, 300, 375, 450, and 600 ng/mL. The spiked samples were then tested with both the test strip and test device, with the following results:

Test Strip

Concentration of sample, ng/mL	% Of cutoff	Number of determinations	Results # Neg/ #Pos
0	0	30	30/0
150	-50%	30	30/0
225	-25%	30	24/6
300	Cutoff	30	17/13
375	+25%	30	7/23
450	+50%	30	0/30
600	+100%	30	0/30

Test Device

Concentration of sample, ng/mL	% Of cutoff	Number of determinations	Results # Neg/ #Pos
0	0	30	30/0
150	-50%	30	30/0
225	-25%	30	26/4
300	Cutoff	30	19/11
375	+25%	30	8/22
450	+50%	30	0/30
600	+100%	30	0/30

e. Analytical specificity:

Cross-reactivity was established by spiking various concentrations of similarly structured drug compounds into drug-free urine. By analyzing various concentration of each compound the sponsor determined the concentration of the drug that produced a response approximately equivalent to the cutoff concentration of the assay. Results of those studies appear in the table below:

Propoxyphene

Drug Compound	Response equivalent to cutoff in ng/mL
D-norpropoxyphene	300

The following compounds were evaluated for potential positive and/or negative interference with the assay. To evaluate for interference the sponsor prepared three urine pools with propoxyphene concentrations of 0, 150, and 450 ng/mL. To aliquots of these pools the sponsor added the potential interferent at a concentration of 100 µg/mL. There were no deviations from the expected results:

Compounds Tested at 100 µg/mL Conc.	ACON PPX One Step Propoxyphene Test Strip			ACON PPX One Step Propoxyphene Test Device		
	0 ng/mL PPX	150 ng/mL PPX	450 ng/mL PPX	0 ng/mL PPX	150 ng/mL PPX	450 ng/mL PPX
4-Acetaminophenol	Negative	Negative	Positive	Negative	Negative	Positive
Acetone	Negative	Negative	Positive	Negative	Negative	Positive
Acetophenetidin	Negative	Negative	Positive	Negative	Negative	Positive
N-Acetylprocainamide	Negative	Negative	Positive	Negative	Negative	Positive
Acetylsalicylic acid	Negative	Negative	Positive	Negative	Negative	Positive
Albumin	Negative	Negative	Positive	Negative	Negative	Positive
Amitriptyline	Negative	Negative	Positive	Negative	Negative	Positive
Amobarbital	Negative	Negative	Positive	Negative	Negative	Positive
Amoxapine	Negative	Negative	Positive	Negative	Negative	Positive
Amoxicillin	Negative	Negative	Positive	Negative	Negative	Positive
Ampicillin	Negative	Negative	Positive	Negative	Negative	Positive
Ascorbic acid	Negative	Negative	Positive	Negative	Negative	Positive
DL-Amphetamine	Negative	Negative	Positive	Negative	Negative	Positive
Apomorphine	Negative	Negative	Positive	Negative	Negative	Positive
Aspartame	Negative	Negative	Positive	Negative	Negative	Positive
Atropine	Negative	Negative	Positive	Negative	Negative	Positive
Benzilic acid	Negative	Negative	Positive	Negative	Negative	Positive
Benzoic acid	Negative	Negative	Positive	Negative	Negative	Positive
Benzoylcegonine	Negative	Negative	Positive	Negative	Negative	Positive
Benzphetamine	Negative	Negative	Positive	Negative	Negative	Positive
Bilirubin	Negative	Negative	Positive	Negative	Negative	Positive
(±) - Brompheniramine	Negative	Negative	Positive	Negative	Negative	Positive
Buspirone	Negative	Negative	Positive	Negative	Negative	Positive
Caffeine	Negative	Negative	Positive	Negative	Negative	Positive
Cannabidiol	Negative	Negative	Positive	Negative	Negative	Positive
Cannabinol	Negative	Negative	Positive	Negative	Negative	Positive
Chloralhydrate	Negative	Negative	Positive	Negative	Negative	Positive
Chloramphenicol	Negative	Negative	Positive	Negative	Negative	Positive
Chlordiazepoxide	Negative	Negative	Positive	Negative	Negative	Positive
Chloroquine	Negative	Negative	Positive	Negative	Negative	Positive
Chlorothiazide	Negative	Negative	Positive	Negative	Negative	Positive

Compounds Tested at 100 µg/mL Conc.	ACON PPX One Step Propoxyphene Test Strip			ACON PPX One Step Propoxyphene Test Device		
	0 ng/mL PPX	150 ng/mL PPX	450 ng/mL PPX	0 ng/mL PPX	150 ng/mL PPX	450 ng/mL PPX
(±) - Chlorpheniramine	Negative	Negative	Positive	Negative	Negative	Positive
Chlorpromazine	Negative	Negative	Positive	Negative	Negative	Positive
Chlorprothixene	Negative	Negative	Positive	Negative	Negative	Positive
Cholesterol	Negative	Negative	Positive	Negative	Negative	Positive
Clomipramine	Negative	Negative	Positive	Negative	Negative	Positive
Clonidine	Negative	Negative	Positive	Negative	Negative	Positive
Cocaine HCl	Negative	Negative	Positive	Negative	Negative	Positive
Cortisone	Negative	Negative	Positive	Negative	Negative	Positive
(-) Cotinine	Negative	Negative	Positive	Negative	Negative	Positive
Creatinine	Negative	Negative	Positive	Negative	Negative	Positive
Cyclobenzaprine	Negative	Negative	Positive	Negative	Negative	Positive
Deoxycorticosterone	Negative	Negative	Positive	Negative	Negative	Positive
(-) Deoxyephedrine	Negative	Negative	Positive	Negative	Negative	Positive
R(-) Deprenyl HCl	Negative	Negative	Positive	Negative	Negative	Positive
Dextromethorphan	Negative	Negative	Positive	Negative	Negative	Positive
Diclofenac	Negative	Negative	Positive	Negative	Negative	Positive
Diflunisal	Negative	Negative	Positive	Negative	Negative	Positive
Digoxin	Negative	Negative	Positive	Negative	Negative	Positive
4-Dimethylaminoantipyrine	Negative	Negative	Positive	Negative	Negative	Positive
Diphenhydramine	Negative	Negative	Positive	Negative	Negative	Positive
Dicylomine	Negative	Negative	Positive	Negative	Negative	Positive
5,5 - Diphenylhydantoin	Negative	Negative	Positive	Negative	Negative	Positive
Doxylamine	Negative	Negative	Positive	Negative	Negative	Positive
Ecgonine HCl	Negative	Negative	Positive	Negative	Negative	Positive
Ecgonine Methyleneester	Negative	Negative	Positive	Negative	Negative	Positive
EDDP	Negative	Negative	Positive	Negative	Negative	Positive
EMDP	Negative	Negative	Positive	Negative	Negative	Positive
Ephedrine	Negative	Negative	Positive	Negative	Negative	Positive
(-) -Ψ-Ephedrine	Negative	Negative	Positive	Negative	Negative	Positive
[1R,2S] (-) Ephedrine	Negative	Negative	Positive	Negative	Negative	Positive
(+/-) Epinephrine	Negative	Negative	Positive	Negative	Negative	Positive
Erythromycin	Negative	Negative	Positive	Negative	Negative	Positive
β-Estradiol	Negative	Negative	Positive	Negative	Negative	Positive
Estrone-3-sulfate	Negative	Negative	Positive	Negative	Negative	Positive
Ethanol	Negative	Negative	Positive	Negative	Negative	Positive
Ethyl-p-aminobenzoate	Negative	Negative	Positive	Negative	Negative	Positive
Fenfluramine	Negative	Negative	Positive	Negative	Negative	Positive
Fenoprofen	Negative	Negative	Positive	Negative	Negative	Positive
Furosemide	Negative	Negative	Positive	Negative	Negative	Positive

Compounds Tested at 100 µg/mL Conc.	ACON PPX One Step Propoxyphene Test Strip			ACON PPX One Step Propoxyphene Test Device		
	0 ng/mL PPX	150 ng/mL PPX	450 ng/mL PPX	0 ng/mL PPX	150 ng/mL PPX	450 ng/mL PPX
Gentisic acid	Negative	Negative	Positive	Negative	Negative	Positive
D-Glucose	Negative	Negative	Positive	Negative	Negative	Positive
Guaiacol Glyceryl Ether	Negative	Negative	Positive	Negative	Negative	Positive
Hemoglobin	Negative	Negative	Positive	Negative	Negative	Positive
Hydralazine	Negative	Negative	Positive	Negative	Negative	Positive
Hydrochlorothiazide	Negative	Negative	Positive	Negative	Negative	Positive
Hydrocodone	Negative	Negative	Positive	Negative	Negative	Positive
Hydrocortisone	Negative	Negative	Positive	Negative	Negative	Positive
O-Hydroxyhippuric acid	Negative	Negative	Positive	Negative	Negative	Positive
p -Hydroxyamphetamine	Negative	Negative	Positive	Negative	Negative	Positive
p-Hydroxymethamphetamine	Negative	Negative	Positive	Negative	Negative	Positive
p-Hydroxynorephedrine	Negative	Negative	Positive	Negative	Negative	Positive
3-Hydroxytyramine	Negative	Negative	Positive	Negative	Negative	Positive
Hydroxyzine	Negative	Negative	Positive	Negative	Negative	Positive
Ibuprofen	Negative	Negative	Positive	Negative	Negative	Positive
Imipramine	Negative	Negative	Positive	Negative	Negative	Positive
Iproniazid	Negative	Negative	Positive	Negative	Negative	Positive
(-) Isoproterenol	Negative	Negative	Positive	Negative	Negative	Positive
Isoxsuprine	Negative	Negative	Positive	Negative	Negative	Positive
Ketoprofen	Negative	Negative	Positive	Negative	Negative	Positive
Labetalol	Negative	Negative	Positive	Negative	Negative	Positive
Lidocaine	Negative	Negative	Positive	Negative	Negative	Positive
Lithium Carbonate	Negative	Negative	Positive	Negative	Negative	Positive
Loperamide	Negative	Negative	Positive	Negative	Negative	Positive
Maprotiline	Negative	Negative	Positive	Negative	Negative	Positive
Meperidine	Negative	Negative	Positive	Negative	Negative	Positive
Mephentamine	Negative	Negative	Positive	Negative	Negative	Positive
Meprobamate	Negative	Negative	Positive	Negative	Negative	Positive
Methamphetamine	Negative	Negative	Positive	Negative	Negative	Positive
L-Methamphetamine	Negative	Negative	Positive	Negative	Negative	Positive
Methaqualone	Negative	Negative	Positive	Negative	Negative	Positive
Methadol	Negative	Negative	Positive	Negative	Negative	Positive
Methoxyphenamine	Negative	Negative	Positive	Negative	Negative	Positive
Methylphenidate	Negative	Negative	Positive	Negative	Negative	Positive
(+/-)3,4-Methylenedioxyamphetamine	Negative	Negative	Positive	Negative	Negative	Positive
Methyprylon	Negative	Negative	Positive	Negative	Negative	Positive
Nalidixic acid	Negative	Negative	Positive	Negative	Negative	Positive
Nalorphine	Negative	Negative	Positive	Negative	Negative	Positive

Compounds Tested at 100 µg/mL Conc.	ACON PPX One Step Propoxyphene Test Strip			ACON PPX One Step Propoxyphene Test Device		
	0 ng/mL PPX	150 ng/mL PPX	450 ng/mL PPX	0 ng/mL PPX	150 ng/mL PPX	450 ng/mL PPX
Naloxone	Negative	Negative	Positive	Negative	Negative	Positive
Naltrexone	Negative	Negative	Positive	Negative	Negative	Positive
α-Naphthaleneacetic acid	Negative	Negative	Positive	Negative	Negative	Positive
Naproxen	Negative	Negative	Positive	Negative	Negative	Positive
Niacinamide	Negative	Negative	Positive	Negative	Negative	Positive
Nifedipine	Negative	Negative	Positive	Negative	Negative	Positive
NorMOR	Negative	Negative	Positive	Negative	Negative	Positive
Nimesulide	Negative	Negative	Positive	Negative	Negative	Positive
Norethindrone	Negative	Negative	Positive	Negative	Negative	Positive
Noscapine	Negative	Negative	Positive	Negative	Negative	Positive
D,L-Octopamine	Negative	Negative	Positive	Negative	Negative	Positive
Orphenadrine	Negative	Negative	Positive	Negative	Negative	Positive
Oxalic acid	Negative	Negative	Positive	Negative	Negative	Positive
Oxazepam	Negative	Negative	Positive	Negative	Negative	Positive
Oxolinic acid	Negative	Negative	Positive	Negative	Negative	Positive
Oxycodone	Negative	Negative	Positive	Negative	Negative	Positive
Oxymetazoline	Negative	Negative	Positive	Negative	Negative	Positive
OxyMOR	Negative	Negative	Positive	Negative	Negative	Positive
Penicillin-G	Negative	Negative	Positive	Negative	Negative	Positive
Pentazocine	Negative	Negative	Positive	Negative	Negative	Positive
Pentobarbital	Negative	Negative	Positive	Negative	Negative	Positive
Perphenazine	Negative	Negative	Positive	Negative	Negative	Positive
Phencyclidine	Negative	Negative	Positive	Negative	Negative	Positive
Phenelzine	Negative	Negative	Positive	Negative	Negative	Positive
Pheniramine	Negative	Negative	Positive	Negative	Negative	Positive
Phenobarbital	Negative	Negative	Positive	Negative	Negative	Positive
Phenothiazine	Negative	Negative	Positive	Negative	Negative	Positive
Phentermine	Negative	Negative	Positive	Negative	Negative	Positive
L-Phenylephrine	Negative	Negative	Positive	Negative	Negative	Positive
β-Phenylethylamine	Negative	Negative	Positive	Negative	Negative	Positive
Phenylpropanolamine	Negative	Negative	Positive	Negative	Negative	Positive
Prednisolone	Negative	Negative	Positive	Negative	Negative	Positive
Prednisone	Negative	Negative	Positive	Negative	Negative	Positive
Procaine	Negative	Negative	Positive	Negative	Negative	Positive
Promazine	Negative	Negative	Positive	Negative	Negative	Positive
Promethazine	Negative	Negative	Positive	Negative	Negative	Positive
DL-Propranolol	Negative	Negative	Positive	Negative	Negative	Positive
D-Pseudoephedrine	Negative	Negative	Positive	Negative	Negative	Positive
Quinacrine	Negative	Negative	Positive	Negative	Negative	Positive

Compounds Tested at 100 µg/mL Conc.	ACON PPX One Step Propoxyphene Test Strip			ACON PPX One Step Propoxyphene Test Device		
	0 ng/mL PPX	150 ng/mL PPX	450 ng/mL PPX	0 ng/mL PPX	150 ng/mL PPX	450 ng/mL PPX
Quinidine	Negative	Negative	Positive	Negative	Negative	Positive
Quinine	Negative	Negative	Positive	Negative	Negative	Positive
Ranitidine	Negative	Negative	Positive	Negative	Negative	Positive
Riboflavin	Negative	Negative	Positive	Negative	Negative	Positive
Salicylic acid	Negative	Negative	Positive	Negative	Negative	Positive
Secobarbital	Negative	Negative	Positive	Negative	Negative	Positive
Serotonin (5-Hydroxytyramine)	Negative	Negative	Positive	Negative	Negative	Positive
Sodium Chloride	Negative	Negative	Positive	Negative	Negative	Positive
Sulfamethazine	Negative	Negative	Positive	Negative	Negative	Positive
Sulindac	Negative	Negative	Positive	Negative	Negative	Positive
Sustiva	Negative	Negative	Positive	Negative	Negative	Positive
Tetracycline	Negative	Negative	Positive	Negative	Negative	Positive
Tetrahydrocortexolone	Negative	Negative	Positive	Negative	Negative	Positive
Tetrahydrocortisone, 3-acetate	Negative	Negative	Positive	Negative	Negative	Positive
Tetrahydrocortisone 3- (β-D-glucuronide)	Negative	Negative	Positive	Negative	Negative	Positive
Tetrahydrozoline	Negative	Negative	Positive	Negative	Negative	Positive
Theophylline	Negative	Negative	Positive	Negative	Negative	Positive
Thiamine	Negative	Negative	Positive	Negative	Negative	Positive
Thioridazine	Negative	Negative	Positive	Negative	Negative	Positive
L-Thyroxine	Negative	Negative	Positive	Negative	Negative	Positive
Tolbutamide	Negative	Negative	Positive	Negative	Negative	Positive
Trans-2- phenylcyclopropylamine	Negative	Negative	Positive	Negative	Negative	Positive
Trazodone	Negative	Negative	Positive	Negative	Negative	Positive
Trimethobenzamide	Negative	Negative	Positive	Negative	Negative	Positive
Triamterene	Negative	Negative	Positive	Negative	Negative	Positive
Trifluoperazine	Negative	Negative	Positive	Negative	Negative	Positive
Trimethoprim	Negative	Negative	Positive	Negative	Negative	Positive
Trimipramine	Negative	Negative	Positive	Negative	Negative	Positive
Tryptamine	Negative	Negative	Positive	Negative	Negative	Positive
DL-Tryptophan	Negative	Negative	Positive	Negative	Negative	Positive
Tyramine	Negative	Negative	Positive	Negative	Negative	Positive
DL-Tyrosine	Negative	Negative	Positive	Negative	Negative	Positive
Uric acid	Negative	Negative	Positive	Negative	Negative	Positive
Verapamil	Negative	Negative	Positive	Negative	Negative	Positive
Zomepirac	Negative	Negative	Positive	Negative	Negative	Positive

There is the possibility that other substances and/or factors not listed above may interfere with the test and cause false results, e.g., technical or procedural errors.

To test for potential positive/and or negative interference from varying pH conditions, the sponsor prepared four sample pools with propoxyphene concentrations of 0, 150, 450, and 600 ng/mL. Aliquots of these samples were then adjusted to a pH of 5 to 9 with HCl or NaOH. Results are reported below:

Effect of Urinary pH - Test Strip

pH	0 ng/mL Propoxyphene	150 ng/mL Propoxyphene	450 ng/mL Propoxyphene	600 ng/mL Propoxyphene
5	-	-	+	+
5	-	-	+	+
6	-	-	+	+
6	-	-	+	+
7	-	-	+	+
7	-	-	+	+
8	-	-	+	+
8	-	-	+	+
9	-	-	+	+
9	-	-	+	+

Effect of Urinary pH - Test Device

pH	0 ng/mL Propoxyphene	150 ng/mL Propoxyphene	450 ng/mL Propoxyphene	600 ng/mL Propoxyphene
5	-	-	+	+
5	-	-	+	+
6	-	-	+	+
6	-	-	+	+
7	-	-	+	+
7	-	-	+	+
8	-	-	+	+
8	-	-	+	+
9	-	-	+	+
9	-	-	+	+

To test for potential positive/and or negative interference from varying specific gravity, the sponsor selected fifteen drug-free samples with a specific gravity from 1.007 to 1.029. Each sample was then split into three aliquots and spiked to propoxyphene concentrations of 0, 150, and 450 ng/mL. Results are shown below:

Effects of Urinary Specific Gravity - Test Strip

SG	n	0 ng/mL	150 ng/mL	450 ng/mL
1.007	2	-	-	+
1.012	2	-	-	+
1.013	2	-	-	+
1.014	2	-	-	+
1.014	2	-	-	+
1.017	2	-	-	+
1.019	2	-	-	+
1.021	2	-	-	+
1.022	2	-	-	+
1.024	2	-	-	+
1.025	2	-	-	+
1.026	2	-	-	+
1.027	2	-	-	+
1.028	2	-	-	+
1.029	2	-	-	+

Effects of Urinary Specific Gravity - Test Device

1.007	2	-	-	+
1.012	2	-	-	+
1.013	2	-	-	+
1.014	2	-	-	+
1.014	2	-	-	+
1.017	2	-	-	+
1.019	2	-	-	+
1.021	2	-	-	+
1.022	2	-	-	+
1.024	2	-	-	+
1.025	2	-	-	+
1.026	2	-	-	+
1.027	2	-	-	+
1.028	2	-	-	+
1.029	2	-	-	+

The sponsor did not evaluate the effects of albumin on the assay.

f. Assay cut-off:

The Substance Abuse and Mental Health Services Administration (SAMHSA) has not recommended a cutoff concentration for propoxyphene.

Characterization of how the device performs analytically around the claimed cutoff concentration appears in the precision section, above.

2. Comparison studies:

a. Method comparison with predicate device:

A total of 352 samples (177 negative and 175 positive) were evaluated by the candidate device and by GC/MS and/or the predicate device.

Sample description: Unaltered clinical urine samples were evaluated. Fifty-one additional diluted samples were also included in the study. The samples were prepared by diluting clinical samples with high drug concentrations with drug-free urine. This was done in order to obtain samples near the cutoff concentration of the assay, because the sponsor was not able to obtain unaltered samples near the cutoff.

Sample selection: A portion of the negative samples were chosen for the study based on whether they screened positive or negative by the predicate device. Another portion of the negative samples having drug concentrations that were below the cutoff concentration of the assay were analyzed by GC-MS. All of the positive samples with concentrations above the cutoff were evaluated by GC-MS.

The study included an adequate number of samples that contained drugs near to the cutoff concentration of the assay. Approximately 10% of the study samples are evenly distributed between plus and minus 50% of the claimed cutoff concentration.

Number of study sites: one

Type of study site(s): Manufacturer's facility

Operator description: Manufacturer's laboratory staff

Candidate Device Results vs. Predicate Device Results – Test Strip

	Positive by Predicate Device	Negative by Predicate Device
Positive by Candidate Device	157	0
Negative by Candidate Device	0	157

% Agreement among positives is 100%

% Agreement among negatives is 100%

Candidate Device Results vs. Predicate Device Results – Test Device

	Positive by Predicate Device	Negative by Predicate Device
Positive by Candidate Device	157	0
Negative by Candidate Device	0	157

% Agreement among positives is 100%

% Agreement among negatives is 100%

Candidate Device Results vs. stratified GC/MS Values – Test Strip

Candidate Device Results	Negative by the predicate device or 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	2	7	158
Negative	157	18	10	0

GC/MS values used to categorize samples in this table are based on the sum of the concentrations of propoxyphene and norpropoxyphene found in the sample.

% Agreement among positives is 94%

% Agreement among negatives is 99%

Candidate Device Results vs. stratified GC/MS Values – Test Device

Candidate Device Results	Negative by the predicate device or 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	2	7	158
Negative	157	18	10	0

GC/MS values used to categorize samples in this table are based on the sum of the concentrations of propoxyphene and norpropoxyphene found in the sample.

- % Agreement among positives is 94%
- % Agreement among negatives is 99%

b. Matrix comparison:

Not applicable. The assay is intended for only one sample matrix.

3. Clinical studies:

a. Clinical sensitivity:

Not applicable. Clinical studies are not typically submitted for this device type.

b. Clinical specificity:

Not applicable. Clinical studies are not typically submitted for this device type.

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

4. Clinical cut-off:

Not applicable.

5. Expected values/Reference range:

Propoxyphene or its metabolites should not be present in the urine of persons who have not ingested propoxyphene.

M. Conclusion:

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