

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

**A. 510(k) Number:**

k122752

**B. Purpose for Submission:**

New device and addition of new analyte

**C. Measurand:**

Propoxyphene (PPX)

**D. Type of Test:**

Qualitative, immunochromatographic

**E. Applicant:**

Branan Medical Corporation

**F. Proprietary and Established Names:**

QuickTox® Drug Screen Dipcard  
Fastect® II PPX Drug Screen Dipstick  
Fastect® II Drug Screen Dipstick

**G. Regulatory Information:**

<b>Product Code</b>	<b>Classification</b>	<b>Regulation Section</b>	<b>Panel</b>
JXN	II	862.3700 – Propoxyphene test system	91-Toxicology

**H. Intended Use:**

1. Intended use(s):

See indications for use below

2. Indication(s) for use:

The Fastect® II PPX Drug Screen Dipstick Test is a lateral flow immunoassay for the rapid detection of propoxyphene in human urine at or above 300 ng/mL.

The Fastect® II Drug Screen Dipstick and QuickTox® Drug Screen Dipcard are

lateral flow immunoassay for the rapid detection of multiple drugs and drug metabolites in human urine at or above the following cutoff concentration:

THC	11-nor- $\Delta^9$ -Tetrahydrocannabinol-9-carboxylic acid	50 ng/ml
COC	Benzoyllecgonine	300 ng/ml
OPI	Morphine	300 ng/ml
MET	Methamphetamine	500 ng/ml
AMP	Amphetamine	1000 ng/ml
PCP	Phencyclidine	25 ng/ml
BZO	Oxazepam	300 ng/ml
BAR	Secobarbital	300 ng/ml
MTD	Methadone	300 ng/ml
TCA	Nortriptyline	1000 ng/ml
MDMA	3,4-methylenedioxyamphetamine	500 ng/ml
OXY	Oxycodone	100 ng/ml
BUP	Buprenorphine	10 ng/ml
PPX	Propoxyphene	300 ng/ml

These tests provide visual qualitative results and are intended for in vitro diagnostic use only. It is for prescription point-of-care use only and not intended for over-the-counter sale to non-professionals.

These tests provide only a preliminary test result. For a quantitative result or to confirm preliminary positive results obtained by the QuickTox® Drug Screen Dipcard, Fastect® II Drug Screen Dipstick or Fastect® II PPX Drug Screen Dipstick tests, a more specific alternative method such as Gas Chromatography/Mass Spectrometry (GC/MS) must be used. Clinical Consideration and professional judgment should be applied to any drug of abuse test results, particularly when a preliminary positive result is indicated.

3. Special conditions for use statement(s):

These tests are for prescription point-of-care use only and not intended for over-the-counter use.

4. Special instrument requirements:

Not applicable

**I. Device Description:**

The Fastect® II Drug Screen Dipstick with Propoxyphene and QuickTox® Drug Screen Dipcard with Propoxyphene contain multiple drugs and drug metabolites in addition to Propoxyphene. Propoxyphene is added as a new analyte. The Fastect® II PPX Drug Screen Dipstick only contains the propoxyphene analyte. All dipstick and dipcard devices are based on the principle of highly specific immunochemical reactions between antigens and antibodies and all devices utilize a competitive immunoassay procedure in which an immobilized drug conjugate competes with the

drug present in urine for limited antibody binding sites.

The Fastect® II PPX Drug Screen Dipstick, Fastect® II Drug Screen Dipstick and QuickTox® Drug Screen Dipcard devices are standardized to detect Propoxyphene in human urine at a cutoff concentration of 300 ng/ml. These tests can be performed without the use of any additional instruments.

A control band with a different antigen/antibody reaction is added to the immunochromatographic membrane strip and should always appear regardless of the presence of drug or metabolite. The appearance of the control band during testing indicates that the test has completed and the test is valid.

**J. Substantial Equivalence Information:**

1. Predicate device name(s):

ACON MULTI-CLIN Drug Screen Test Device

2. Predicate K number(s):

k041685

3. Comparison with predicate:

Similarities		
Feature	Candidate Devices (QuickTox® Drug Screen Dipcard, Fastect® II PPX Drug Screen Dipstick and Fastect® II Drug Screen Dipstick)	Predicate Device (ACON® multi-CLIN™ Drug Screen Test Device k041685)
Intended Use	Screening Device	Same
Matrix	Human Urine	Same
Test Principle	Competitive immunoassay	Same
Analytes	Propoxyphene	Same
Cut-Off	300 ng/ml	Same
Sample Volume	10 ml	Same
Target User Population	For professional point of care	Same
Shelf Life	24 Months	Same
Testing Method	Lateral Flow Immunoassay	Same
Antibody/Antigen	Mouse monoclonal antibody PPX antigen	Same

Differences		
Feature	Candidate Devices (QuickTox® Drug Screen Dipcard and Fastect® II Drug Screen Dipstick)	Predicate Device (ACON® multi-CLIN™ Drug Screen Test Device k041685)
Test Strip	Single Drug/Multi-Drug	Multi-Drug
Product Design	Dip method	Dip method and drop method
Storage	Sealed pouch at 15-30°C	Sealed pouch at 2-30°C
Reading Time	5-30 minutes	5-8 hours
Internal Procedural Controls	Negative control line	Positive and negative control lines

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

None were referenced

**L. Test Principle:**

The Fastect® II PPX Drug Screen Dipstick, Fastect® II Drug Screen Dipstick with Propoxyphene and QuickTox® Drug Screen Dipcard with Propoxyphene are based on the principle of highly specific immunochemical reactions between antigens and antibodies. All dipstick and dipcard devices utilize a competitive immunoassay procedure in which an immobilized drug conjugate competes with the drug present in urine for limited antibody binding sites.

**M. Performance Characteristics (if/when applicable):**

1. Analytical performance:

*a. Precision/Reproducibility:*

Precision studies were performed over ten days at three point-of-care sites using drug-free normal urine spiked with drug standards to the following concentrations: cutoff, ±25%, ±50%, ±75% and ±100% of the cutoff. A total of 30 samples were tested at cutoff, ±25%, ±50%, ±75% and +100% cutoff levels, respectively. A total of 60 samples were tested at negative (zero) level. Sample concentrations were confirmed by GC/MS. The intended users performed the testing by following the instructions for use.

PPX measured by QuickTox® Drug Screen Dipcard

Conc.	Site 1		Site 2		Site 3		Combined	
	Neg	Pos	Neg	Pos	Neg	Pos	Neg	Pos
Negative	20	0	20	0	20	0	60	0
-75%	10	0	10	0	10	0	30	0
-50%	10	0	10	0	9	1	29	1
-25%	9	1	8	2	9	1	26	4
Cutoff	4	6	3	7	7	3	14	16
+25%	2	8	0	10	3	7	5	25
+50%	0	10	0	10	0	10	0	30
+75%	0	10	0	10	0	10	0	30
+100%	0	10	0	10	0	10	0	30

PPX measured by Fastect® II Drug Screen Dipsticks

Conc.	Site 1		Site 2		Site 3		Combined	
	Neg	Pos	Neg	Pos	Neg	Pos	Neg	Pos
Negative	20	0	20	0	20	0	60	0
-75%	10	0	10	0	10	0	30	0
-50%	10	0	10	0	10	0	30	0
-25%	9	1	8	2	8	2	25	5
Cutoff	6	4	1	9	7	3	14	16
+25%	2	8	1	9	2	8	5	25
+50%	0	10	0	10	0	10	0	30
+75%	0	10	0	10	0	10	0	30
+100%	0	10	0	10	0	10	0	30

b. *Linearity/assay reportable range:*

Not applicable, the devices are intended for qualitative use.

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

A control band with a different antigen/antibody reaction is added to the immunochromatographic membrane strip and should always appear regardless of the presence of the drug or its metabolites. The appearance of the control band during testing indicates that the test has completed and the test is valid.

Device Stability:

Accelerated studies have been conducted for one lot of Fastect® II Drug Screen Dipsticks and two lots of QuickTox® Drug Screen Dipcard kits. The manufacturer claims that when stored at room temperature (15 - 30 °C), the product is stable for 24 months. Real time studies have been conducted to support a shelf life of 24 months at room temperature. Stability protocols and acceptance criteria were reviewed and considered acceptable.

Sample Storage and Stability:

Urine specimens may be refrigerated at 2-8°C for up to two days.

d. *Detection limit:*

Not applicable, this is a qualitative assay.

e. *Analytical specificity:*

Analytical specificity was established by spiking structurally related compounds into negative human urine. The lowest amount of compounds required to produce a positive response in Fastect® II Drug Screen Dipsticks and QuickTox® Drug Screen Dipcard and their corresponding % cross reactivity are displayed below.

Compound	Concentration	% cross reactivity
Propoxyphene	300 ng/mL	100%
Norpropoxyphene	500 ng/mL	60%

Potential interference from structurally unrelated and endogenous compounds was tested by spiking the potentially interfering compound into  $\pm 50\%$  of cutoff urine controls at a concentration of 100,000 ng/mL. No negative or positive interference was observed for the following compounds except furosemide in this study.

Acetaminophen (4-Acetamidophenol; APAP; N-Acetyl-p-aminophenol), Acetone, Acetylsalicylic acid (Aspirin), Albumin, Amoxapine, Amoxicillin, Ampicillin, l-Ascorbic Acid (Vitamin C), Aspartame, Atropine, Benzocaine (Ethyl p-Aminobenzoate), Bilirubin, d-Brompheniramine, Caffeine, Chloroquine, d,l-Chlorpheniramine, Chlorpromazine, l-Cotinine, Creatine, Creatinine, Cyclobenzaprine, Desipramine, Dextromethorphan, 4-Dimethylaminoantipyrine, Diphenhydramine, Dopamine (3-Hydroxytyramine), Doxylamine, l-Ephedrine, d,l-Ephedrine, l-Epinephrine, Erythromycin, Ethanol, 2-Ethylidene-1,5-Dimethyl-1-3,3-Diphenylpyrrolidone, Furosemide\*, Gentisic acid, Glucose, Guaiacol, Glyceryl Ether, Hemoglobin, Hippuric acid, Hydrochlorothizide, Hydrocodone, Hydromorphone, Ibuprofen, Lidocaine, Methaqualone, Methoxyphenamine, Methylphenidate, Methadone, Nalidixic acid, Naloxone, d-Naproxen, Niacinamide, Norethindrone, Oxalic acid, Oxolinic acid, Papaverine, Penicillin-G (Benzylpenicillin), Pentazocine, Perphenazine, Pheniramine, Phenothiazine (Thiodiphenylamine), Phenylephrine,  $\beta$ -Phenylethylamine, Procaine, Promethazine, Quinidine, Ranitidine, Riboflavin, Salicylic acid, Serotonin, Sodium Chloride, Sulfamethazine, Sulindac, Thiamine, Trimethobenzamide, Thioridazine, Trifluoperazine, Trimipramine Maleate, Tryptamine, d,l-Tryptophan, Tyramine, d,l-Tyrosine, Uric Acid, Verapamil, Zomepirac.

Possible false negative result for PPX may be observed for Furosemide at  $\geq 60,000$  ng/mL

The effects of pH and specific gravity of the specimen on the performance of QuickTox® Drug Screen Dipcard and Fastect® II Drug Screen Dipstick test kits at  $\pm 50\%$  of the cutoff levels were also tested. The results demonstrated no interference to results with pH range of 4.5-8.5 and specific gravity range of 1.005 to 1.030.

*f. Assay cut-off:*

Characterization of how the device performs analytically around the claimed cutoff concentration appears in the precision section, M.1.a, above.

2. Comparison studies:

*a. Method comparison with predicate device:*

A total of 84 urine specimens were evaluated with the QuickTox® Drug Screen Dipcard and Fastect® II Drug Screen Dipsticks devices. Of these 84 urine specimens, 42 were negative urine samples with 5 of them between cut-off and -50% cut-off levels. 42 were positive urine samples with 7 of them between cut-off and +50% cut-off levels. Both the QuickTox® Drug Screen Dipcard and Fastect® II Drug Screen Dipstick devices were compared against the values obtained through GC/MS analysis. The results are presented in the table below:

Candidate Device	Candidate Device Results	Clinical Urine Cut-off (CO) Concentrations			
		-100% to <-50%	$\geq -50\%$ to < CO	$\geq$ CO to <+50%	$\geq +50\%$
QuickTox® Drug Screen Dipcard	Positive	0	2	5	35
	Negative	37	3	2	0
Fastect® II Drug Screen Dipsticks	Positive	0	2	7	35
	Negative	37	3	0	0

*b. Matrix comparison:*

Not applicable.

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):*

The sponsor performed an optimal read time evaluation by testing 5 levels of urine controls in 20 replicates per level using both dip stick and dip card devices. The test results supported a reading time of 5 to 60 minutes. The sponsor chose a more conservative reading time of 5 to 30 minutes in their product inserts.

4. Clinical cut-off:

Not applicable.

5. Expected values/Reference range:

Not applicable.

**N. Proposed Labeling:**

The labeling is sufficient and does satisfy the requirements of 21 CFR Part 809.10.

**O. Conclusion:**

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