

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

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

k130650

**B. Purpose for Submission:**

New device

**C. Measurand:**

Oxycodone

**D. Type of Test:**

Qualitative immunoassay

**E. Applicant:**

Princeton BioMeditech Corporation

**F. Proprietary and Established Names:**

Status DS<sup>TM</sup> OXY

**G. Regulatory Information:**

Product Code	Classification	Regulation Section	Panel
DJG	Class II	21 CFR § 862.3650, Opiates test system	91-Toxicology

**H. Intended Use:**

1. Intended use(s):

See Indications for use below.

2. Indication(s) for use:

The Status DS<sup>TM</sup> OXY is an immunochromatographic test for the qualitative detection of Oxycodone in human urine. The detection cut-off concentration of Oxycodone is 100ng/ml. The test may be read visually or by using a DXpress Reader. It is intended for clinical laboratory use only.

This assay provides only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrophotometry (GC/MS) are the preferred confirmatory methods. Clinical consideration and professional judgment should be applied to the test result, particularly when preliminary positive results are obtained.

3. Special conditions for use statement(s):  
The assay is for prescription use only.
4. Special instrument requirements:  
The results contained in the 510(k) were read both visually and using DXpress reader instrument.

**I. Device Description:**

The Status DS™ OXY test kit contains complete reagent components and materials to perform all the tests:

- Status DS™ OXY test device containing a membrane strip and a dye pad. The membrane strip is coated with Oxycodone-protein (from a purified bovine protein source) conjugate for the test band and sheep anti-mouse antibody for the control band. The dye pads contain colloidal gold coated with monoclonal anti-Oxycodone antibody.
- Disposable sample dispenser.
- Instructions for use.
- DXpress Reader: The DXpress reader captures an image of an inserted compatible test device and uses a software algorithm to calculate the intensity of the test line. The DXpress reader interprets test result automatically by comparing the intensity of the test line to the preset cutoff value. In addition, the software will use the presence of the control line to determine whether or not the test result is valid.

**J. Substantial Equivalence Information:**

1. Predicate device name(s):  
MedTox Oxycodone
2. Predicate 510(k) number(s):  
k060351
3. Comparison with predicate:

<b>Similarities</b>		
<b>Item</b>	<b>Predicate device MedTox Oxycodone (k060351)</b>	<b>Candidate device Status DS™OXY Oxycodone Assay</b>
Intended Use/ Indications for Use	Qualitative detection of Oxycone in human urine	Same
Cut-off	100 ng/mL	Same
Sample Type	Human urine	Same
Test Principle	Lateral flow Immuno- chromatographic assay	Same

<b>Similarities</b>		
<b>Item</b>	<b>Predicate device MedTox Oxycodone (k060351)</b>	<b>Candidate device Status DS™ OXY Oxycodone Assay</b>
Test procedure	Urine sample is applied into the sample well	Same
Control	Each strip contains procedural control line	Same
Antibody	Mouse monoclonal anti-Oxycodone antibody	Same
Result readout	Visual	Visual and DXpress reader

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

The sponsor did not reference any standards in this submission.

**L. Test Principle:**

The Status DS™ OXY test is an immunochromatographic assay for the rapid, qualitative detection of oxycodone present in human urine above the cutoff concentration of 100ng/mL. The test may be read visually or by using a DXpress™ Reader. The test relies on the competition between the oxycodone conjugates on the test band and the oxycodone that may be present in the urine sample to bind to the antibodies. In the test procedure, a sample of urine is placed in the Sample well of the device and is allowed to migrate upward. If oxycodone is present in the urine sample, it competes with the oxycodone conjugate which is bound to the membrane, for the limited anti-oxycodone antibody which is bound to the dye. If the oxycodone is above the cut off level, the oxycodone will saturate the oxycodone antibody, thus inhibiting the binding of the dye coated with oxycodone antibodies to the conjugate on the membrane. Therefore, an oxycodone positive urine sample will not generate a line in the test window, indicating a preliminary positive result, while an oxycodone negative urine sample (or sample with concentration below the cutoff) will generate a line in the test window, indicating a negative result.

In addition to the test line that may appear in the test window (T), there is also a procedural control line present in the control window (C). The control line should always appear if the test is performed correctly. Polyclonal sheep anti-mouse antibody is immobilized on the control line. The monoclonal antibody-dye conjugates that migrate through this region will be captured and produce a colored line in the control window (Control line). The control line works as a procedural control, confirming that proper sample volume was used and the reagent system at the control line and the conjugate-color indicator worked. If insufficient sample volume is used, there may not be a Control line, indicating the test is invalid.

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

1. Analytical performance:

a. *Precision/Reproducibility:*

The sponsor performed internal precision studies by spiking Oxycodone into drug-free urine samples at various concentrations relative to the cutoff concentration (-100%, -50%, -25%, cut off, +25%, +50%, and +100%). Concentrations were confirmed using GC/MS. The results were obtained using visual reads of 3 operators and 3 DXpress readers. The study was carried using two lots in duplicates over two days.

Precision Study Data - Visual Test:

	Urine Sample Concentration (ng/mL)	% Cutoff	#of Tested Devices	#of Positive	#of Negative	% Agreement
Operator 1	0	0	40	0	40	100
	50	50	40	0	40	100
	75	75	40	0	40	100
	100	100	40	6	34	N/A
	125	125	40	37	3	92.5
	150	150	40	40	0	100
	200	200	40	40	0	100
Operator 2	0	0	40	0	40	100
	50	50	40	0	40	100
	75	75	40	1	39	97.5
	100	100	40	12	28	N/A
	125	125	40	38	2	90
	150	150	40	40	0	100
	200	200	40	40	0	100
Operator 3	0	0	40	0	40	100
	50	50	40	0	40	100
	75	75	40	0	40	100
	100	100	40	9	31	N/A
	125	125	40	37	3	92.5
	150	150	40	40	0	100
	200	200	40	40	0	100
Total	0	0	120	0	120	100
	50	50	120	0	120	100
	75	75	120	1	119	99.2
	100	100	120	27	93	N/A
	125	125	120	112	8	93.3
	150	150	120	120	0	100
	200	200	120	120	0	100

Precision Study Data - Reader Test:

	Urine Sample Concentration (ng/mL)	% Cutoff	#of Tested Devices	#of Positive	#of Negative	% Agreement
Reader 1	0	0	40	0	40	100
	50	50	40	0	40	100
	75	75	40	4	36	90
	100	100	40	30	10	N/A
	125	125	40	40	0	100
	150	150	40	40	0	100
	200	200	40	40	0	100
Reader 2	0	0	40	0	40	100
	50	50	40	0	40	100
	75	75	40	5	35	87.5
	100	100	40	31	9	N/A
	125	125	40	40	0	100
	150	150	40	40	0	100
	200	200	40	40	0	100
Reader 3	0	0	40	0	40	100
	50	50	40	0	40	100
	75	75	40	3	37	92.5
	100	100	40	23	17	N/A
	125	125	40	40	0	100
	150	150	40	40	0	100
	200	200	40	40	0	100
Total	0	0	120	0	120	100
	50	50	120	0	120	100
	75	75	120	12	108	90
	100	100	120	84	36	N/A
	125	125	120	120	0	100
	150	150	120	120	0	100
	200	200	120	120	0	100

The performance of the Status DS™ OXY test device was also evaluated at 3 different sites by 6 operators/intended users (nurse, lead clinical assistant, laboratory supervisor, etc), 2 operators per site. Each urine sample containing concentration of 0, 50%, 75%, 125%, 150%, and 200% of cutoff, was tested on 10 devices (5 per operator) and results obtained both visually and using DXpress reader. The urine samples were prepared by spiking a commercial standard material into drug-free urine and by serially diluting to the concentrations above. After preparation, the concentration of each level is confirmed by GC/MS.

For the visual test, the results of the 0, 50%, 125%, 150% and 200% cutoff concentrations showed 100% agreement with the expected results. The urine samples of 75% cutoff showed 80% agreement. The results for the visual test are summarized in the table below:

Study Data for 3 sites for Visual test:

	Urine Sample Concentration (ng/mL)	% Cutoff	#of Tested Devices	#of Positive	#of Negative	% Agreement
Site 1	0	0	10	0	10	100
	50	50	10	0	10	100
	75	75	10	1	9	90
	125	125	10	10	0	100
	150	150	10	10	0	100
	200	200	10	10	0	100
Site 2	0	0	10	0	10	100
	50	50	10	0	10	100
	75	75	10	4	6	60
	125	125	10	10	0	100
	150	150	10	10	0	100
	200	200	10	10	0	100
Site 3	0	0	10	0	10	100
	50	50	10	0	10	100
	75	75	10	1	9	90
	125	125	10	10	0	100
	150	150	10	10	0	100
	200	200	10	10	0	100
Total	0	0	30	0	30	100
	50	50	30	0	30	100
	75	75	30	6	24	80
	125	125	30	30	0	100
	150	150	30	30	0	100
	200	200	30	30	0	100

For the DXpress™ reader test, the results of the 0, 50%, 125%, 150%, and 200% cutoff concentrations showed 100% agreement with the expected results. The urine samples of 75% cutoff showed 93% agreement. The results for the reader test are summarized in the table below:

Study Data for 3 sites for Reader test

	Urine Sample Concentration (ng/mL)	% Cutoff	#of Tested Devices	#of Positive	#of Negative	% Agreement
Site 1	0	0	10	0	10	100
	50	50	10	0	10	100
	75	75	10	2	8	80
	125	125	10	10	0	100
	150	150	10	10	0	100
	200	200	10	10	0	100
Site 2	0	0	10	0	10	100
	50	50	10	0	10	100
	75	75	10	0	10	100
	125	125	10	10	0	100
	150	150	10	10	0	100
	200	200	10	10	0	100
Site 3	0	0	10	0	10	100
	50	50	10	0	10	100
	75	75	10	0	10	100
	125	125	10	10	0	100
	150	150	10	10	0	100
	200	200	10	10	0	100
Total	0	0	30	0	30	100
	50	50	30	0	30	100
	75	75	30	2	28	80
	125	125	30	30	0	100
	150	150	30	30	0	100
	200	200	30	30	0	100

b. *Linearity/assay reportable range:*

Not applicable. The assay is intended for qualitative use.

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

External control materials are not supplied with this device, however controls are commercially available and are recommended in the labeling instructions to be tested at regular intervals as good laboratory testing process. The labeling instructions also recommend that a control be tested before using a new lot or a new shipment. Users are further instructed to follow their laboratory's standard Q.C. procedures, federal, state, and local guidelines when determining when to run external controls. (See Test Principle section above regarding procedural controls).

d. *Detection limit:*

See precision studies above (M.1.a.) for information on test performance around the cutoff concentration.

e. *Analytical specificity:*

The cross-reactivity of the Status DS™ OXY test with oxycodone metabolites and related compounds was evaluated by adding these to drug-free urine at various concentrations and testing these samples with test devices from two production lots. The results below are expressed in terms of the lowest concentration of metabolite or compound required to produce a positive result.

Specificity:

<b>Compound</b>	<b>Concentration (ng/mL) that yields a response equivalent to that of oxycodone at the cutoff concentration</b>	<b>Percent Cross-Reactivity (%)</b>
Oxycodone	100	100
6-Acetylcodeine	>100,000	<1
6-Acetylmorphine	>100,000	<1
Amorphone	>100,000	<1
Codeine	1,500	6.7
Dihydrocodeine	3,000	3.3
Dihydromorphine	10,000	1
Ethylmorphine	1,000	10
Heroin	>100,000	<1
Hydrocodone	5,000	2
Hydromorphone	7,500	13.3
Levorphanol	>100,000	<1
Meperidine	>100,000	<1
Morphine	5,000	2
Morphine-3b-d-glucuronide	>100,000	<1
Nalorphine	>100,000	<1
Naloxone	4,000	2.5
Norcodeine	20,000	<1
Oxymorphone	150	67
Procaine	>100,000	<1
Thebaine	>100,000	<1

Endogenous substances:

The potential interference of the following endogenous compounds on the Status DS™ OXY test devices was evaluated by testing spiked urine samples. Each substance was dissolved in urine containing oxycodone at a concentration of 50% of the cutoff and 150% of the cutoff. All samples containing oxycodone at 50% of the cutoff produced negative results and all samples containing oxycodone at 150% of the cutoff produced positive results at the tested concentrations indicating no interference at those concentrations. The potential interferent concentrations tested are shown below:

<b>Compound</b>	<b>Concentration (mg/dL)</b>
Bilirubin	2
Creatinine	20
Glucose	1500
Hemoglobin	25
Protein (BSA)	2000
Sodium Chloride	1500
Sodium Nitrate	100
Acetaldehyde	20
Acetone	60
Albumin	2000
D,L Thyroxin	20
Epinephrine	20
Estriol	10

Exogenous substances (Chemical/Drug Interference):

The following compounds were tested to evaluate the interference of externally ingested compounds on the performance of Status DS™ OXY test device. Each compound was added into urine samples containing oxycodone at 50% cutoff and oxycodone at 150% cutoff urine samples. Potential interferents were added to a concentration of 100µg/mL and then tested in duplicate per sample with the exception of 11-Nor-9-carboxy-Δ9-THC tested at 25µg/mL and Oxazepam glucuronide which were tested at 50µg/mL. All samples with oxycodone at 150% of the cutoff gave positive results and all samples with oxycodone at 50% of the cutoff gave negative results at the tested concentration indicating no interference at those concentrations.

The compounds tested for potential interference included the following:

(-) Ephedrine	dl-Tryptophan	Normeperidine
(-) Isoproterenol	dl-Tyrosine	Norpropoxyphene
(-) Norpseudoephedrine	D-Methamphetamine	Nortriptyline
(+) Ephedrine	Domperidone	Noscapine
(±) Ephedrine	Dopamine	Nylidin
(-)ψ Ephedrine	Doxepin	Ofloxacin
Δ 8-THC	Doxylamine	o-hydroxyhippuric acid

Δ 9-THC	Ecgonine	Olanzapine
11-Nor-9-carboxy-delta 8-THC	Ecgonine methyl ester	Omeprazole
11-Nor-9-carboxy-delta 9-THC	EDDP	Orphenadrine
1-hydroxy alprazolam	Efavirenz (Sustiva)	Oxalic acid
1-hydroxy triazolam	EMDP	Oxazepam
3-hydroxytyramine	Equilin	Oxazepam glucuronide
7-amino-clonazepam	Erythromycin	Oxolinic acid
7-amino-flunitrazepam	Estradiol	Oxymetazoline
Acecinide	Estrone	p-Aminobenzoic acid
Acetamidophenol	Ethanol	Pantoprazole
Acetaminophen	Ethyl-p-aminobenzoate	Papaverine HCl
Acetophenetidine	Fenfluramine	Penicillin-G
Acetylsalicylic acid	Fenoprofen	Pentazocine
Allobarbital	Fentanyl	Pentobarbital
Alprazolam	Flunitrazepam	Perphenazine
Aminoglutethimide	Fluoxetine	Phenacetin
Aminopyrine	Flurazepam	Phencyclidine
Amitriptyline	Furosemide	Phenelzine
Amobarbital	Fuvoxamine	Phenethylamine
Amoxapien	Gentisic acid	Pheniramine
Amoxicillin	Glutethimide	Phenobarbital
Ampicillin	Guaiacol Glyceryl ether	Phenothiazine
Aprobarbital	Guafenesin	Phentermine
Aspartame	Haloperidol	Phenylephrine
Atenolol	Hexobarbital	2-Phenylethylamine
Atropine	Hippuric acid	Phenylpropanolamine
Barbital	Hydralazine	Phenytoin
Barbituric acid	Hydrochlorothiazide	Piroxicam
Benxocaine	Hydrocortison	Prazosin
Benzilic acid	Hydroxybupropion	Prednisolone
Benzoic acid	Hydroxyzine	Prednisone
Benzoyllecgonine	Ibuprofen	Procainamide
Benzphetamine	Imapramine	Procaine
Brompheniramine	I-methamphetamine	Promazine
Buprenorphine	Iproniazid	Promethazine
Bupropion	Isoxsuprine	Propiomazine
Butabarbital	Ketamine	Propoxyphene
Butalbital	Ketoprofen	Propranolol
Caffeine	Ketorolac Tromethamine	Protriptyline
Cannabidol	l-11-hydroxy-delta 9-THC	Pyrilamine
Cannabinol	l-Amphetamine	Quetiapine

Captopril	l-Ascorbic acid	Quinine
Carbamazepine	Lebetalol	R(+)-Methcathinone
Carbamazepine-10,11 epoxide	Leverphanol	Ranitidine
Carisoprodol	Lidocaine	Riboflavin
Chloralhydrate	Lithium carbonate	S(-)-Methcathinone
Chloramphenicol	l-norpseudoephedrine	Salicylic acid
Chlordiaxepoxide	Lorazepam	Scopolamine
Chlorothiazide	Lormetazepam	Secobarbital
Chlorpheniramine	Loxapine Succinate	Serotonine
Chlorpromazine	l-Phenylephrine	Sertraline
Chlorprothixene	LSD	Sildenafil
Chlorquine	L- $\alpha$ -Acetylmethadol (LAAM)	Sulfamethazine
Cholesterol	Maprotiline	Sulinac
Cimetidine	MDA	Temazepam
Clobazam	MDE (MDEA)	Tetracycline
Clomipramine	MDMA	Tetrahydrocortisone
Clonazepam	Melanin	Tetrahydrozoline
Clonidine	Meperidine	Theophylline
Clorazepate	Mepivacaine	Thiamine
Clozapine	Mesoridazine	Thiopental
Cocaine	Methadone	Thioridazine
Codeine	Methaqualone	d-Thyroxine
Cortisone	Methoxyphenylamine	Tolbutamide
Cotinine	Metoprolol	Tramadol
Creatinine	Midazolam	Trazodone
Cyclobenzaprine	Mirtazapine	Triamterene
D-Amphetamine	Morniflumate	Triazolam
Deoxycorticosterone	Morphine	Trifluoperazine
Desalkylflurazepam	N-Acetylprocainamide (NAPA)	Trimethoprim
Desipramine	Nalidixic acid	Trimipramine
Desmethylflunitrazepam	Naltrexone	Tryptamine
Dexamethasone	Naproxen	Tryptophan
Dextromethorphan	Niacinamide	Tyramine
Diazepam	Nicotine	Uric acid
Diclofanac	Nifedipine	Valproic acid
Diethylpropion	Nitrazepam	Venlafaxine
Diflunisal	Nitrofurantoin	Verapamil
Digoxin	Norclomipramine	Zidovudine (AZT)
Dimenhydrinate	Nordiazepam	Zolpidem
Diphenhydramine	Norethindrone	Zomepirac
dl-Octopamine	dl-Tryptophan	Normeperidine
dl-Propranolol		

In addition, the performance of the assay was evaluated under varying pH levels of: 3.0, 4.0, 4.5, 5.0, 6.0, 6.5, 7.0, 8.0 and 9 at  $\pm 50\%$  of the cut-off concentration and showed no effect on results with exception of pH 3.0 at which the device should not be used. This limitation is stated in the labeling. Further, variations in specific gravity of 1.002, 1.01, 1.015, 1.020, 1.025, 1.030, 1.035 and 1.04 had no effect on results. The package insert includes the complete list of all structurally related and unrelated compounds and metabolites tested.

*f. Assay cut-off:*

Analytical performance of the device around the claimed cut-off is described in precision section (1 a.) above.

2. Comparison studies:

*a. Method comparison with predicate device:*

A total of ninety-seven (97) clinical urine samples were evaluated by comparing the Status DS™ OXY test results to GC/MS. The Status DS™ OXY test results were read visually and with the DXpress™ reader. Samples were masked to the operators. Further, the visual test and the DXpress reader test were performed by two different operators, respectively, who were unaware of each other's results. There was 100% agreement between the reader test results and the visual test results. The summarized test results are shown in the table below.

Comparison of Status DS™ OXY test with GC/MS values:

Status DX™ OXY test results (Visual and DXpress Reader)	GC/MS values					
	Negative			Positive		
	Negative (Oxycodone free)	Less than half the Cut-Off	Near Cut-off (between 50% below the cut-off)	Near Cut-off (between 50% above the cut-off)	High Positive (> 150% cut-off)	Percent Agreement with GC/MS for Oxycodone (based on cross reactivity profile)
Positive	0	0	2	4	36	97.6%
Negative	45	5	4	1	0	96.4%

GC/MS Summary of Discordant Results:

Cut-off value (ng/mL) for Oxycodone	Status DS™OXY (POS/NEG)	Drug/Metabolite GC/MS value (ng/mL) based on cross reactivity profile	
		Oxycodone	Oxymorphone
100	POS	26	71
	POS	32	92
	NEG	18	129

b. *Matrix comparison:*

Not applicable. The test is only for urine specimens.

3. Clinical studies:

a. *Clinical Sensitivity:*

Not applicable. Not reviewed for this device type.

b. *Clinical specificity:*

Not applicable.

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

4. Clinical cut-off:

Not applicable

5. Expected values/Reference range:

Not applicable.

**N. Instrument Name:**

DXpress reader

This reader was previously cleared as part of a test system under k050955 and the sponsor has referenced information provided as part of that submission.

Information pertaining to this instrument used with the Status DS Oxycodone test was also reviewed and a summary is included below.

**O. System Descriptions:**

1. Modes of Operation:

Stat

2. Software:

FDA has reviewed applicant's Hazard Analysis and software development processes for this line of product types:

Yes  X  or No \_\_\_\_\_

3. Specimen Identification:

Barcode sample identification function.

4. Specimen Sampling and Handling:  
Manual
5. Calibration:  
Lot specific calibration information for each quantitative test is loaded into the DXpress™ Reader.
6. Quality Control:  
Controls should be tested:
  - For new lots or shipments.
  - As otherwise required by the laboratory's standard quality control procedures.
  - As otherwise required by federal, state and local guidelines.

**P. Other Supportive Instrument Performance Characteristics Data Not Covered In The "Performance Characteristics" Section above: N/A**

**Q. Proposed Labeling:**

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

**R. Conclusion:**

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