510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY

I Background Information:

A 510(k) Number

K242428

B Applicant

Guangzhou Decheng Biotechnology Co., Ltd.

C Proprietary and Established Names

Fentanyl (FTY) Test System

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
NGL	Class II	21 CFR 862.3650 - Opiate Test System	TX - Clinical Toxicology

II Submission/Device Overview:

A Purpose for Submission:

New Device

B Measurand:

Fentanyl

C Type of Test:

lateral flow immunochromatographic assay

III Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) for Use:

Dochek® Fentanyl Urine Test Strip is a competitive binding, lateral flow immunochromatographic assay for the qualitative detection of Fentanyl (FTY) in human urine at the cut-off concentration of 1 ng/mL.
It is intended for over-the-counter (OTC) use. For in vitro diagnostic use only.
The test provides only preliminary results. To obtain a confirmed analytical result, a more specific alternative chemical method must be used. GC/MS or LC/MS is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when the preliminary result is positive.

Dochek® Fentanyl Urine Test Card is a competitive binding, lateral flow immunochromatographic assay for the qualitative detection of Fentanyl (FTY) in human urine at the cut-off concentration of 1 ng/mL.
It is intended for over-the-counter (OTC) use. For in vitro diagnostic use only.
The test provides only preliminary results. To obtain a confirmed analytical result, a more specific alternative chemical method must be used. GC/MS or LC/MS is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when the preliminary result is positive.

Dochek® Fentanyl Urine Test Cup is a competitive binding, lateral flow immunochromatographic assay for the qualitative detection of Fentanyl (FTY) in human urine at the cut-off concentration of 1 ng/mL.
It is intended for over-the-counter (OTC) use. For in vitro diagnostic use only.
The test provides only preliminary results. To obtain a confirmed analytical result, a more specific alternative chemical method must be used. GC/MS or LC/MS is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when the preliminary result is positive.

Dochek® Fentanyl Urine Test Strip Plus is a competitive binding, lateral flow immunochromatographic assay for the qualitative detection of Fentanyl (FTY) in human urine at the cut-off concentration of 1 ng/mL.
For in vitro diagnostic use only.
The test provides only preliminary results. To obtain a confirmed analytical result, a more specific alternative chemical method must be used. GC/MS or LC/MS is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when the preliminary result is positive.

Dochek® Fentanyl Urine Test Card Plus is a competitive binding, lateral flow immunochromatographic assay for the qualitative detection of Fentanyl (FTY) in human urine at the cut-off concentration of 1 ng/mL.
For in vitro diagnostic use only.
The test provides only preliminary results. To obtain a confirmed analytical result, a more

specific alternative chemical method must be used. GC/MS or LC/MS is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when the preliminary result is positive.

Dochek® Fentanyl Urine Test Cup Plus is a competitive binding, lateral flow immunochromatographic assay for the qualitative detection of Fentanyl (FTY) in human urine at the cut-off concentration of 1 ng/mL.
For in vitro diagnostic use only.
The test provides only preliminary results. To obtain a confirmed analytical result, a more specific alternative chemical method must be used. GC/MS or LC/MS is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when the preliminary result is positive..

C Special Conditions for Use Statement(s):

OTC - Over The Counter

D Special Instrument Requirements:

Not applicable

IV Device/System Characteristics:

A Device Description:

Dochek® Fentanyl Urine Test Strip, Dochek® Fentanyl Urine Test Strip Plus, Dochek® Fentanyl Urine Test Card, Dochek® Fentanyl Urine Test Card Plus, Dochek® Fentanyl Urine Test Cup and Dochek® Fentanyl Urine Test Cup Plus are immunochromatographic assays that use a lateral flow system for the qualitative detection of fentanyl in human urine.

Test Strip, Test card and Test Cup use identical test strips made with same chemical formulation and manufacturing procedures.

B Principle of Operation:

The Fentanyl (FTY) Test is an immunoassay based on the principle of competitive binding that is used to screen for the presence of Fentanyl in urine. It is a chromatographic absorbent device in which Fentanyl in a sample competitively combined to a limited number of antibody-dye conjugate binding sites.
During testing, the urine specimen migrates upward by capillary action. Fentanyl, if present in the urine specimen below 1 ng/mL, will not saturate the binding sites of antibody-coated particles in the test device. The antibody-coated particles will then be captured by immobilized FTY conjugate and a visible colored line will appear in the test region (T) to indicate a negative result. The colored line will not appear in the test region (T) if the Fentanyl level exceeds 1 ng/mL because it will saturate all the binding sites of anti-FTY antibodies and prevent the development of a distinct colored line, which indicating a positive result.
To serve as a procedure control, a colored line will always appear at the control region (C), if the test has been performed properly.

V Substantial Equivalence Information:

A Predicate Device Name(s):
AllTest Fentanyl Rapid Test (Urine)

B Predicate 510(k) Number(s):
K231698

C Comparison with Predicate(s):

Device & Predicate Device(s):	K242428	K231698
Device Trade Name	Dochek® Fentanyl Urine Test Strip, Dochek® Fentanyl Urine Test Strip Plus, Dochek® Fentanyl Urine Test Card, Dochek® Fentanyl Urine Test Card Plus, Dochek® Fentanyl Urine Test Cup and Dochek® Fentanyl Urine Test Cup Plus	AllTest Fentanyl Rapid Test (Urine)
General Device Characteristic Similarities		
Indications For Use	For the qualitative determination of fentanyl in human urine.	Same
Specimen	Urine	Same
Cutoff	1 ng/mL	Same
Methodology	Competitive binding, lateral flow immunochromatographic assay based on the principle of antigen antibody immunochemistry	Same
Storage	2-30˚C	Same
General Device Characteristic Differences		
Intended Use	Over-The-Counter Use	Prescription Use
Configuration	Strip, card, and cup	Cassette

VI Standards/Guidance Documents Referenced:

Not applicable.

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:

Precision study was performed using drug-free specimens spiked with Fentanyl at different concentrations: 0ng/mL, 0.25ng/mL, 0.5ng/mL, 0.75ng/mL, 1ng/mL, 1.25ng/mL, 1.5ng/mL, 1.75ng/mL, and 2ng/mL. All concentrations were confirmed with LC-MS/MS. The study was performed 3 runs per day and lasted for 10 non-consecutive days by 6 laboratory professionals using three different lots of Dochek® Fentanyl Urine Test Strip, Dochek® Fentanyl Urine Test Card and Dochek® Fentanyl Urine Test Cup at the manufacturer site. 30 determinations were made for each concentration, and a total of 60 results were obtained per concentration per lot.

Dochek® Fentanyl Urine Test Strip

Sample concentration	% of cutoff	Lot 1		Lot 2		Lot 3	
		Positive	Negative	Positive	Negative	Positive	Negative
0ng/mL	Negative	0	60	0	60	0	60
0.25ng/mL	-75%	0	60	0	60	0	60
0.5ng/mL	-50%	0	60	0	60	0	60
0.75ng/mL	-25%	8	52	4	56	4	56
1ng/mL	cutoff	38	22	34	26	34	26
1.25ng/mL	+25%	54	6	58	2	56	4
1.5ng/mL	+50%	60	0	60	0	60	0
1.75ng/mL	+75%	60	0	60	0	60	0
2ng/mL	+100%	60	0	60	0	60	0

Dochek® Fentanyl Urine Test Card

Sample concentration	% of cutoff	Lot 1		Lot 2		Lot 3	
		Positive	Negative	Positive	Negative	Positive	Negative
0ng/mL	Negative	0	60	0	60	0	60
0.25ng/mL	-75%	0	60	0	60	0	60
0.5ng/mL	-50%	0	60	0	60	0	60
0.75ng/mL	-25%	6	54	2	58	4	56

1ng/mL	cutoff	32	28	34	26	34	26
1.25ng/mL	+25%	58	2	58	2	54	6
1.5ng/mL	+50%	60	0	60	0	60	0
1.75ng/mL	+75%	60	0	60	0	60	0
2ng/mL	+100%	60	0	60	0	60	0

Dochek® Fentanyl Urine Test Cup

Sample concentration	% of cutoff	Lot 1		Lot 2		Lot 3	
		Positive	Negative	Positive	Negative	Positive	Negative
0ng/mL	Negative	0	60	0	60	0	60
0.25ng/mL	-75%	0	60	0	60	0	60
0.5ng/mL	-50%	0	60	0	60	0	60
0.75ng/mL	-25%	4	56	2	58	2	58
1ng/mL	cutoff	34	26	34	26	36	24
1.25ng/mL	+25%	56	4	58	2	56	4
1.5ng/mL	+50%	60	0	60	0	60	0
1.75ng/mL	+75%	60	0	60	0	60	0
2ng/mL	+100%	60	0	60	0	60	0

2. Linearity:

Not applicable. This device is intended for qualitative use only.

3. Analytical Specificity/Interference:

a. Interference

Clinical urine samples may contain substances that could potentially interfere with the test. The following compounds were added to drug-free urine or drug positive urine containing Fentanyl with the concentration 50% below the cutoff and the concentration 50% above the cutoff, respectively. All potential interfering substances were added at a concentration of 100µg/mL or specified concentrations are summarized in the following tables. The urine specimens were tested with 3 lots of Dochek® Fentanyl Urine Test. None of the substances listed below were shown to interfere.

Opioids compounds

6-Acetyl morphine	Amphetamine	Buprenorphine	Buprenorphine glucuronide
Codeine	Dextromethorphan	Dihydrocodeine	EDDP
EMDP	Fluoxetine	Heroin	Hydrocodone
Hydromorphone	Ketamine,	Levorphanol	Meperidine

Methadone	Morphine	Morphine-3-glucuronide	Naloxone
Naltrexone	Norbuprenorphine	Norcodeine	Norketamine
Normeperidine	Normorphine	Noroxycodone	Oxycodone
Oxymorphone	Pentazocine (Talwin)	Pipamperone	Risperidone
Tapentadol	Thioridazine	Tilidine	Tramadol
Tramadol-O-Desmethyl	Tramadol-N-Desmethyl	Trazodone	

Commonly ingested medications or substances

Acetaminophen	Doxepin (50 ug/mL)	Nortriptyline (25 ug/mL)
Acetone (1000 mg/dL)	Ecgonine methyl ester	Noscapine
Acetophenetidin	Ephedrine	O-Hydroxyhippuric acid
Acetylsalicylic acid	Erythromycin	Octopamine
Albumin (100 mg/dL)	Ethanol (1%)	Oxalic acid (100 mg/dL)
Albuterol	Fenoprofen	Oxazepam
Aminopyrine	Fluphenazine	Oxolinic acid
Amitriptyline (35 ug/mL)	Furosemide	Oxymetazoline
Amobarbital	Galactose (10 mg/dL)	Papaverine
Amoxicillin	Gamma Globulin (500mg/dL)	Penicillin G
Ampicillin	Gentisic acid	Perphenazine
Apomorphine	Glucose (3000 mg/dL)	Phencyclidine
Ascorbic acid	Hemoglobin	Phenelzine
Aspartame	DL-Tyrosine	Prednisone
Atropine	Hydralazine	Propoxyphene (50 ug/mL)
Benzilic acid	Hydrochlorothiazide	Propranolol
Benzoic acid	Hydrocortisone	Pseudoephedrine
Benzoylecgonine	Hydroxytyramine	Quinine
Bilirubin	Ibuprofen	Ranitidine
Boric Acid (1%)	Imipramine (30 ug/mL)	Riboflavin (7.5 mg/dL)
Bupropion (50 ug/mL)	Isoproterenol	Salicylic acid
Caffeine	Isoxsuprine	Secobarbital
Carbamazepine	Ketoprofen	Serotonin (5-Hydroxytyramine)
Chloral hydrate	Labetalol	Sulfamethazine
Chloramphenicol	Lidocaine (50 ug/mL)	Sulindac
Chlorothiazide	Loperamide	Tetrahydrocortisone 3-(β-Dglucuronide)
Chlorpromazine	Maprotiline (50 ug/mL)	Tetrahydrocortisone 3-acetate
Cholesterol	Meprobamate	Tetrahydrozoline
Clomipramine (50 ug/mL)	Methapyrilene (10 ug/mL)	Thiamine
Clonidine	Methaqualone (50 ug/mL)	Triamterene
Cortisone	Methoxyphenamine	Trifluoperazine
Cotinine	Metronidazole (300 ug/mL)	Trimethoprim
Creatinine	N-Acetylprocainamide	Tyramine
Cyclobenzaprine (10 ug/mL)	NaCl (4000 mg/dL)	Urea (2000 mg/dL)
Deoxycorticosterone	Nalidixic acid	Uric acid
Desipramine (50 ug/mL)	Naproxen	Valproic acid (250 ug/mL)
Diclofenac	Niacinamide	Venlafaxine
Diflunisal	Nicotine (10 ug/mL)	Verapamil
Digoxin	Nifedipine	Zomepirac
Diphenhydramine	Norethindrone	β-Estradiol
DL-Tryptophan	Phenobarbital	

Cross-Reactivity

The following table lists the lowest concentration (ng/mL) of compounds that gave a positive result on the Dochek® Fentanyl Urine Test at the tested concentrations shown.

Compound	Lowest Concentration (ng/mL)	% Cross-Reactivity
Acetyl fentanyl	1.0	100
Acetyl norfentanyl	10,000	0.01
Acrylfentanyl	1.5	66.7
Butyryl fentanyl	2.5	40
Carfentanil	50	2
(±)-3-cis-methylfentanyl	50	2
4-Fluoro-isobutyrylfentanyl	5	20
Furanyl fentanyl	2.8	35.7
ω-1-Hydroxyfentanyl	20,000	0.005
(±) β-hydroxythiofentanyl	1.5	66.7
Isobutyryl fentanyl	1.0	100
Ocfentanil	1.8	55.6
Para-fluorobutyrylfentanyl (p-FBF)	4	25
Para-fluoro fentanyl	3	33.3
Sufentanil	20	5
Valeryl fentanyl	5	20
Alfentanil	5,000	0.02
Despropionyl fentanyl (4-ANPP)	20,000	0.005
Remifentanil	10,000	0.01
Norcarfentanil	10,000	0.01
Norfentanyl	10,000	0.01

Effect of Urine Specific Gravity and Urine pH

To investigate the effect of urine specific gravity and urine pH, urine samples, with 1.000, 1.005, 1.010, 1.0154, 1.02, 1.025, 1.030, and 1.035 specific gravity or urine samples with pH 4, 5, 6, 7, 8, and 9 were spiked with Fentanyl targets at 50% below and 50% above Cut-Off levels. These samples were tested using three lots of device. Results were all positive for samples at and above +50% Cut- Offs and all negative for samples at and below -50% Cut-Offs.

4. Assay Reportable Range:

   Not applicable.

5. Traceability, Stability, Expected Values (Controls, Calibrators, or Methods):

6. Detection Limit:

Not applicable.

7. Assay Cut-Off:

Not applicable.

B Comparison Studies:

1. Method Comparison with Predicate Device:

80 clinical urine specimens were analyzed by LC/MS and by 3 lots of the corresponding Dochek® Fentanyl Urine Test Strip, Dochek® Fentanyl Urine Test Card and Dochek® Fentanyl Urine Test Cup. Samples were divided by concentration into five categories: drug free, less than half the cutoff, near cutoff negative, near cutoff positive, and high positive. The study was conducted by 3 laboratory professionals at the manufacturer site. Results were as follows.

Dochek® Fentanyl Urine Test Strip

		Negative	Low Negative by LC/MS (Less than -50%)	Near Cutoff Negative by LC/MS (Between -50% and cutoff)	Near Cutoff Positive by LC/MS (Between cutoff and +50%)	High Positive by LC/MS (Greater than +50%)
Viewer 1	Positive	0	0	1	26	13
	Negative	10	14	15	1	0
Viewer 2	Positive	0	0	1	26	13
	Negative	10	14	15	1	0
Viewer 3	Positive	0	0	1	26	13
	Negative	10	14	15	1	0

Analysis of Discordant Results (Strip)

Operator	Sample ID	Test Result	LC/MS Result (ng/mL)
Viewer 1	F046-6	Positive	0.945
	F062-5	Negative	1.012
Viewer 2	F045-3	Positive	0.894
	F062-6	Negative	1.012
	F060-3	Positive	0.920

Viewer 3	F088-1	Negative	1.077

Dochek® Fentanyl Urine Test Card

		Negative	Low Negative by LC/MS (Less than -50%)	Near Cutoff Negative by LC/MS (Between -50% and cutoff)	Near Cutoff Positive by LC/MS (Between cutoff and +50%)	High Positive by LC/MS (Greater than +50%)
Viewer 1	Positive	0	0	1	26	13
	Negative	10	14	15	1	0
Viewer 2	Positive	0	0	1	26	13
	Negative	10	14	15	1	0
Viewer 3	Positive	0	0	1	26	13
	Negative	10	14	15	1	0

Analysis of Discordant Results (Card)

Operator	Sample ID	Test Result	LC/MS Result (ng/mL)
Viewer 1	F043-6	Positive	0.885
	F062-2	Negative	1.012
Viewer 2	F055-6	Positive	0.894
	F083-4	Negative	1.020
Viewer 3	F046-2	Positive	0.945
	F062-1	Negative	1.012

Dochek® Fentanyl Urine Test Cup

		Negative	Low Negative by LC/MS (Less than -50%)	Near Cutoff Negative by LC/MS (Between -50% and cutoff)	Near Cutoff Positive by LC/MS (Between cutoff and +50%)	High Positive by LC/MS (Greater than +50%)
Viewer 1	Positive	0	0	1	26	13
	Negative	10	14	15	1	0
Viewer 2	Positive	0	0	1	26	13
	Negative	10	14	15	1	0
Viewer 3	Positive	0	0	1	26	13
	Negative	10	14	15	1	0

Analysis of Discordant Results (Cup)

Operator	Sample ID	Test Result	LC/MS Result (ng/mL)

Viewer 1	F055-8	Positive	0.894
	F049-8	Negative	1.044
Viewer 2	F046-4	Positive	0.945
	F049-9	Negative	1.044
Viewer 3	F060-9	Positive	0.920
	F062-4	Negative	1.012

2. Matrix Comparison:

Not applicable.

C Clinical Studies:

1. Clinical Sensitivity:

Not applicable.

2. Clinical Specificity:

Not applicable.

3. Other Clinical Supportive Data (When 1. and 2. Are Not Applicable):

Lay User Study

A lay user study was performed at three intended user sites with 980 lay persons. They had diverse educational and professional backgrounds and ranged in age from 20 to 65 years. Urine samples were prepared at the following concentrations: 0ng/mL, 0.25 ng/mL 0.5ng/mL, 0.75ng/mL, 1.25ng/mL, 1.5ng/mL, 1.75ng/mL cutoff by spiking target drug fentanyl into drug free urine specimens. The concentrations of samples were confirmed by LC/MS. Each sample was aliquoted into individual containers, blind-labeled and randomized. Each participant was provided with the English package insert, 1 blind labeled sample, and a device. Results were as follows:

Lay user study date of Dochek® Fentanyl Urine Test Strip:

Sample concentration	% of cutoff	Number of samples	Layer user Results		Agreement (%)
			Positive	Negative	
0ng/mL	Negative	40	0	40	100%
0.25ng/mL	-75%cutoff	40	0	40	100%
0.5ng/mL	-50%cutoff	40	0	40	100%
0.75ng/mL	-25%cutoff	40	2	38	95%

1.25ng/mL	+25%cutoff	40	38	2	95%
1.5ng/mL	+50%cutoff	40	40	0	100%
1.75ng/mL	+75%cutoff	40	40	0	100%

Lay user study date of Dochek® Fentanyl Urine Test Card (Cassette method):

Sample concentration	% of cutoff	Number of samples	Layer user Results		Agreement (%)
			Positive	Negative	
0ng/mL	Negative	30	0	30	100%
0.25ng/mL	-75%cutoff	30	0	30	100%
0.5ng/mL	-50%cutoff	30	0	30	100%
0.75ng/mL	-25%cutoff	30	1	29	96.7%
1.25ng/mL	+25%cutoff	30	28	2	93.3%
1.5ng/mL	+50%cutoff	30	30	0	100%
1.75ng/mL	+75%cutoff	30	30	0	100%

Lay user study date of Dochek® Fentanyl Urine Test Card (Dip card method):

Sample concentration	% of cutoff	Number of samples	Layer user Results		Agreement (%)
			Positive	Negative	
0ng/mL	Negative	30	0	30	100%
0.25ng/mL	-75%cutoff	30	0	30	100%
0.5ng/mL	-50%cutoff	30	0	30	100%
0.75ng/mL	-25%cutoff	30	2	28	93.3%
1.25ng/mL	+25%cutoff	30	29	1	96.7%
1.5ng/mL	+50%cutoff	30	30	0	100%
1.75ng/mL	+75%cutoff	30	30	0	100%

Lay user study date of Dochek® Fentanyl Urine Test Cup:

Sample concentration	% of cutoff	Number of samples	Layer user Results		Agreement (%)
			Positive	Negative	
0ng/mL	Negative	40	0	40	100%
0.25ng/mL	-75%cutoff	40	0	40	100%

0.5ng/mL	-50%cutoff	40	0	40	100%
0.75ng/mL	-25%cutoff	40	3	37	92.5%
1.25ng/mL	+25%cutoff	40	37	3	92.5%
1.5ng/mL	+50%cutoff	40	40	0	100%
1.75ng/mL	+75%cutoff	40	40	0	100%

D Clinical Cut-Off:

Not applicable

E Expected Values/Reference Range

Not applicable

VIII Proposed Labeling:

The labeling supports the finding of substantial equivalence for this device.

IX Conclusion:

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