February 6, 2025

Guangzhou Decheng Biotechnology Co., Ltd.
Jenny Mao
Regulatory Affairs Supervisor
Floor 3/4/5/7, Building A1, No.12, Nanyun 1st Road
Science City, Huangpu District
Guangzhou, Guangdong 510663
China

Re: K242428
Trade/Device 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, Dochek® Fentanyl Urine Test Cup Plus
Regulation Number: 21 CFR 862.3650
Regulation Name: Opiate Test System
Regulatory Class: Class II
Product Code: NGL
Dated: December 20, 2024
Received: December 20, 2024

Dear Jenny Mao:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-

assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Joseph A. Kotarek -S

Digitally signed by Joseph A. Kotarek -S
Date: 2025.02.06 09:05:30 -05'00'

Joseph Kotarek
Branch Chief for Toxicology
Division of Chemistry and Toxicology Devices
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
k242428

Device Name
Dochek® Fentanyl Urine Test Strip Plus, Dochek® Fentanyl Urine Test Card Plus, Dochek® Fentanyl Urine Test Cup Plus

Indications for Use *(Describe)*
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.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
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PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
k242428

Device Name
Dochek® Fentanyl Urine Test Strip, Dochek® Fentanyl Urine Test Card, Dochek® Fentanyl Urine Test Cup

Indications for Use *(Describe)*

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.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

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Section 5- 510(k) SUMMARY

K242428

1. Date: 2025/2/5

2. Submitter:

Guangzhou Decheng Biotechnology Co., Ltd.
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Contact Person: Jenny Mao
Contact Email Address: jenny.mao@dochekbio.com
Telephone: +86-020-82557192

3. Correspondent:

Guangzhou Decheng Biotechnology Co., Ltd.
Address: Floor 3/4/5/7, Building A1, No.12, Nanyun 1st Road, Science City, Huangpu District, Guangzhou, Guangdong, 510663, P.R. China
Contact Person: Jenny Mao
Contact Email Address: jenny.mao@dochekbio.com
Telephone: +86-020-82557192

4. Device Name

Common Name: Fentanyl (FTY) Test System

Proprietary names: 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, Dochek® Fentanyl Urine Test Cup Plus

5. Classification: Class II

Product Code	Regulation Section	Panel
NGL	21 CFR 862.3650, Opiate Test System	Toxicology

6. Predicate Devices:

AllTest Fentanyl Rapid Test (Urine) (k231698)

7. Intended 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.

8. 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.

9. Substantial Equivalence Information:

Item	Device	Predicate (K231698)
Indication for use	Qualitative detection of fentanyl in urine	Same
Intended Use	Professional/HCP Use and Over-The-Counter Use	Prescription Use
Specimen	Urine	Same
Cutoff	1 ng/mL	Same
Results	Qualitative	Same
Methodology	Competitive binding, lateral flow immunochromatographic assay based on the principle of antigen antibody immunochemistry	Same
Configuration	Strip, card and cup	Cassette
Storage	2-30˚C	Same

10. Standard/Guidance Document Reference (if applicable)

Draft Guidance for Industry and FDA Staff: Premarket Submission and Labeling Recommendations for Drugs of Abuse Screening Tests

11. Test Principle

The Fentanyl (FTY) Test System 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.

12. Performance Characteristics

A. Analytical performance

a. 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 using three different lots of Dochek® Fentanyl Urine Test Strip, Dochek® Fentanyl Urine Test Card and Dochek® Fentanyl Urine Test Cup. 30 determinations were made for each concentration, and a total of 60 results were obtained per concentration per lot (each result was read in duplicate by two different operators).

Dochek® Fentanyl Urine Test Strip

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

Dochek® Fentanyl Urine Test Card

Approximate concentration of sample	% of cutoff	Number of determinations per lot	Lot 1		Lot 2		Lot 3	
			Positive	Negative	Positive	Negative	Positive	Negative
0ng/mL	Negative	60	0	60	0	60	0	60
0.25ng/mL	-75% cutoff	60	0	60	0	60	0	60
0.5ng/mL	-50% cutoff	60	0	60	0	60	0	60
0.75ng/mL	-25% cutoff	60	6	54	2	58	4	56
1ng/mL	cutoff	60	32	28	34	26	34	26
1.25ng/mL	+25% cutoff	60	58	2	58	2	54	6
1.5ng/mL	+50% cutoff	60	60	0	60	0	60	0
1.75ng/mL	+75% cutoff	60	60	0	60	0	60	0
2ng/mL	+100% cutoff	60	60	0	60	0	60	0

Dochek® Fentanyl Urine Test Cup

Approximate concentration of sample	% of cutoff	Number of determinations per lot	Lot 1		Lot 2		Lot 3	
			Positive	Negative	Positive	Negative	Positive	Negative
0ng/mL	Negative	60	0	60	0	60	0	60
0.25ng/mL	-75% cutoff	60	0	60	0	60	0	60
0.5ng/mL	-50% cutoff	60	0	60	0	60	0	60
0.75ng/mL	-25% cutoff	60	4	56	2	58	2	58
1ng/mL	cutoff	60	34	26	34	26	36	24

1.25ng/mL	+25% cutoff	60	56	4	58	2	56	4
1.5ng/mL	+50% cutoff	60	60	0	60	0	60	0
1.75ng/mL	+75% cutoff	60	60	0	60	0	60	0
2ng/mL	+100% cutoff	60	60	0	60	0	60	0

b. Linearity/assay reportable range:

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

c. Stability:

The device is stable at 2-30℃ for 24 months based on real time stability study.

d. Analytical specificity/Interference:

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

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

e. 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	Buprenorphineglucuronide
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	

B. Method comparison study

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.

Comparison data of Dochek® Fentanyl Urine Test Strip

Dochek® Fentanyl Urine Test Strip		LC/MS					Agreement Rate
		Neg. (drug free)	Neg. (<-50% cutoff)	Near cutoff neg. (-50% cutoff to cutoff)	Near cutoff pos. (cutoff to +50% cutoff)	Pos. (>+50% cutoff)	
Lot 1, operator 1	Positive	0	0	1	26	13	97.5% (87.1%-99.6%)
	Negative	10	14	15	1	0	97.5% (87.1%-99.6%)
Lot 2, operator 2	Positive	0	0	1	26	13	97.5% (87.1%-99.6%)
	Negative	10	14	15	1	0	97.5% (87.1%-99.6%)
Lot 3, operator 3	Positive	0	0	1	26	13	97.5% (87.1%-99.6%)
	Negative	10	14	15	1	0	97.5% (87.1%-99.6%)

Analysis of Discordant Results (Strip)

Dochek® Fentanyl Urine Test Strip		LC/MS Analysis	
Lot No. and Operator	Test Result	Concentration range	Fentanyl Concentration (ng/mL)
Lot 1, operator 1	Positive	Near cutoff neg. (-50% cutoff to cutoff)	0.945
	Negative	Near cutoff pos. (cutoff to +50% cutoff)	1.012
Lot 2, operator 2	Positive	Near cutoff neg. (-50% cutoff to cutoff)	0.894
	Negative	Near cutoff pos. (cutoff to +50% cutoff)	1.012
Lot 3, operator 3	Positive	Near cutoff neg. (-50% cutoff to cutoff)	0.920
	Negative	Near cutoff pos. (cutoff to +50% cutoff)	1.077

Comparison data of Dochek® Fentanyl Urine Test Card

Dochek® Fentanyl Urine Test Card		LC/MS					Agreement Rate
		Neg. (drug free)	Neg. (<-50% cutoff)	Near cutoff neg. (-50% cutoff to cutoff)	Near cutoff pos. (cutoff to +50% cutoff)	Pos. (>+50% cutoff)	
Lot 1, operator 1	Positive	0	0	1	26	13	97.5% (87.1%-99.6%)
	Negative	10	14	15	1	0	97.5% (87.1%-99.6%)
Lot 2, operator 2	Positive	0	0	1	26	13	97.5% (87.1%-99.6%)
	Negative	10	14	15	1	0	97.5% (87.1%-99.6%)
Lot 3, operator 3	Positive	0	0	1	26	13	97.5% (87.1%-99.6%)
	Negative	10	14	15	1	0	97.5% (87.1%-99.6%)

Analysis of Discordant Results (Card)

Dochek® Fentanyl Urine Test Card		LC/MS Analysis	
Lot No. and Operator	Test Result	Concentration range	Fentanyl Concentration (ng/mL)
Lot 1, operator 1	Positive	Near cutoff neg. (-50% cutoff to cutoff)	0.885
	Negative	Near cutoff pos. (cutoff to +50% cutoff)	1.012
Lot 2, operator 2	Positive	Near cutoff neg. (-50% cutoff to cutoff)	0.894
	Negative	Near cutoff pos. (cutoff to +50% cutoff)	1.020
Lot 3, operator 3	Positive	Near cutoff neg. (-50% cutoff to cutoff)	0.945
	Negative	Near cutoff pos. (cutoff to +50% cutoff)	1.012

Comparison data of Dochek® Fentanyl Urine Test Cup

Dochek® Fentanyl Urine Test Cup		LC/MS					Agreement Rate
		Neg. (drug free)	Neg. (<-50% cutoff)	Near cutoff neg. (-50% cutoff to cutoff)	Near cutoff pos. (cutoff to +50% cutoff)	Pos. (>+50% cutoff)	
Lot 1, operator 1	Positive	0	0	1	26	13	97.5% (87.1%-99.6%)
	Negative	10	14	15	1	0	97.5% (87.1%-99.6%)
Lot 2, operator 2	Positive	0	0	1	26	13	97.5% (87.1%-99.6%)
	Negative	10	14	15	1	0	97.5% (87.1%-99.6%)
Lot 3, operator 3	Positive	0	0	1	26	13	97.5% (87.1%-99.6%)
	Negative	10	14	15	1	0	97.5% (87.1%-99.6%)

Analysis of Discordant Results (Cup)

Dochek® Fentanyl Urine Test Cup		LC/MS Analysis	
Lot No. and Operator	Test Result	Concentration range	Fentanyl Concentration (ng/mL)
Lot 1, operator 1	Positive	Near cutoff neg. (-50% cutoff to cutoff)	0.894
	Negative	Near cutoff pos. (cutoff to +50% cutoff)	1.044
Lot 2, operator 2	Positive	Near cutoff neg. (-50% cutoff to cutoff)	0.945
	Negative	Near cutoff pos. (cutoff to +50% cutoff)	1.044
Lot 3, operator 3	Positive	Near cutoff neg. (-50% cutoff to cutoff)	0.920
	Negative	Near cutoff pos. (cutoff to +50% cutoff)	1.012

C. Lay person study

Lay user studies were 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 data of Dochek® Fentanyl Urine Test Strip

Approximate concentration of sample	% of cutoff	Number of determinations per lot	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 data of Dochek® Fentanyl Urine Test Card (cassette method)

Approximate concentration of sample	% of cutoff	Number of determinations per lot	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 data of Dochek® Fentanyl Urine Test Card (dipcard method)

Approximate concentration of sample	% of cutoff	Number of determinations per lot	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 data of Dochek® Fentanyl Urine Test Cup

Approximate concentration of sample	% of cutoff	Number of determinations per lot	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%

13. Conclusion

Based on the test principle and performance characteristics of the device including precision, cut-off, interference, specificity, method comparison and lay-user studies of the devices, it's concluded a substantial equivalence decision.