February 20, 2025

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

Re: K250067
Trade/Device Name: Dochek® Multi-Drug Urine Test Cup; Dochek® Multi-Drug Urine Test Cup Pro
Regulation Number: 21 CFR 862.3650
Regulation Name: Opiate test system
Regulatory Class: Class II
Product Code: NGL, NFT, PTH, NFV, NFY, PTG, NGG, NGM, QBF, QAW, NFW
Dated: January 10, 2025
Received: January 10, 2025

Dear Mango Huang:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

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: 2025.02.20 09:07:05 -05'00'

Joseph Kotarek, Ph.D.
Branch Chief
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K250067

Device Name
Dochek® Multi-Drug Urine Test Cup
Dochek® Multi-Drug Urine Test Cup Pro

Indications for Use *(Describe)*
Dochek® Multi-Drug Urine Test Cup is an immunoassay for the qualitative determination of single or multiple drugs in human urine at the following cutoff concentrations.

Drug (Identifier)	Cut-off level
Amphetamine (AMP)	1000 or 500 ng/mL
Secobarbital (BAR)	300 ng/mL
Buprenorphine (BUP)	10 ng/mL
Oxazepam (BZO)	300 ng/mL
Cocaine (COC)	300 or 150 ng/mL
2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP)	300 ng/mL
Methylenedioxymethamphetamine (MDMA)	500 ng/mL
Methamphetamine (MET)	1000 or 500 ng/mL
Morphine (MOP/OPI)	300 or 2000 ng/mL
Methadone (MTD)	300 ng/mL
Oxycodone (OXY)	100 ng/mL
Phencyclidine (PCP)	25 ng/mL
Propoxyphene (PPX)	300 ng/mL
Nortriptyline (TCA)	1000 ng/mL
Cannabinoids (THC)	50 ng/mL
6-Monoacetylmorphine (6-MAM)	10 ng/mL
Fentanyl (FTY)	1 ng/mL

Dochek® Multi-Drug Urine Test Cup offers any combinations from 1 to 17 drugs but only one cutoff concentration under same drug condition will be included per device.
It is intended for over-the-counter (OTC) use. For in vitro diagnostic use only.
The test provides only preliminary results. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly in evaluating a preliminary positive result. To obtain a confirmed analytical result, a more specific alternate chemical method is needed. GC/MS or LC/MS is the recommended confirmatory method.

Dochek® Multi-Drug Urine Test Cup Pro is an immunoassay for the qualitative determination of single or multiple drugs in human urine at the following cutoff concentrations.

Drug (Identifier)	Cut-off level
Amphetamine (AMP)	1000 or 500 ng/mL
Secobarbital (BAR)	300 ng/mL
Buprenorphine (BUP)	10 ng/mL
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Methylenedioxymethamphetamine (MDMA)	500 ng/mL
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Methadone (MTD)	300 ng/mL
Oxycodone (OXY)	100 ng/mL
Phencyclidine (PCP)	25 ng/mL
Propoxyphene (PPX)	300 ng/mL

Nortriptyline (TCA)	1000 ng/mL
Cannabinoids (THC)	50 ng/mL
6-Monoacetylmorphine (6-MAM)	10 ng/mL
Fentanyl (FTY)	1 ng/mL

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For in vitro diagnostic use only.

The test provides only preliminary results. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly in evaluating a preliminary positive result. To obtain a confirmed analytical result, a more specific alternate chemical method is needed. GC/MS or LC/MS is the recommended confirmatory method.

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.

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510(k) SUMMARY

510(k) number: K250067

1. **Date:** February 17, 2025

2. **Submitter:** 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: Mango Huang
Contact Email Address: mango.huang@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: Mango Huang
Contact Email Address: mango.huang@dochekbio.com
Telephone: (888) 695-5248

4. **Device Name:** Dochek® Multi-Drug Urine Test Cup Pro
Dochek® Multi-Drug Urine Test Cup

5. **Classification:** Class II

Product Code **Target Drug**	**Regulation Section**	**Panel**
NFT Amphetamine (AMP)	862.3100, Amphetamine Test System	Toxicology
PTH Secobarbital (BAR)	862.3150, Barbiturate Test System	Toxicology
NGL Buprenorphine (BUP) Morphine (MOP/OPI) Oxycodone (OXY) 6-Monoacetylmorphine (6-MAM) Fentanyl (FTY)	862.3650, Opiate Test System	Toxicology
NFV Oxazepam (BZO)	862.3170, Benzodiazepine Test System	Toxicology
NFY Cocaine (COC)	862.3250, Cocaine and cocaine metabolite test system	Toxicology
PTG 2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP) Methadone (MTD)	862.3620, Methadone Test System	Toxicology

NGG Methylenedioxymethamphetamine (MDMA) Methamphetamine (MET)	862.3610, Methamphetamine Test System	Toxicology
NGM Phencyclidine (PCP)	Unclassified	Toxicology
QBF Propoxyphene (PPX)	862.3700 Propoxyphene test system.	Toxicology
QAW Nortriptyline (TCA)	862.3910 Tricyclic antidepressant drugs test system	Toxicology
NFW Cannabinoids (THC)	862.3870, Cannabinoids Test System	Toxicology

6. Purpose for Submission

Modification of previously cleared devices (K232659) to add fentanyl device (1 ng/mL cutoff).

7. Predicate Devices

K232659	Dochek® Multi-Drug Urine Test Cup Rx
	Dochek® Multi-Drug Urine Test Cup

8. Intended Use

Dochek® Multi-Drug Urine Test Cup Pro is an immunoassay for the qualitative determination of single or multiple drugs in human urine at the following cutoff concentrations.

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Amphetamine (AMP)	1000 or 500 ng/mL
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6-Monoacetylmorphine (6-MAM)	10 ng/mL
Fentanyl (FTY)	1 ng/mL

Dochek® Multi-Drug Urine Test Cup Pro offers any combinations from 1 to 17 drugs but only one cutoff concentration under same drug condition will be included per device.
For in vitro diagnostic use only.

The test provides only preliminary results. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly in evaluating a preliminary positive result. To obtain a confirmed analytical result, a more specific alternate chemical method is needed. GC/MS or LC/MS is the recommended confirmatory method.

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Cannabinoids (THC)	50 ng/mL
6-Monoacetylmorphine (6-MAM)	10 ng/mL
Fentanyl (FTY)	1 ng/mL

Dochek® Multi-Drug Urine Test Cup offers any combinations from 1 to 17 drugs but only one cutoff concentration under same drug condition will be included per device.
It is intended for over-the-counter (OTC) use. For in vitro diagnostic use only.

The test provides only preliminary results. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly in evaluating a preliminary positive result. To obtain a confirmed analytical result, a more specific alternate chemical method is needed. GC/MS or LC/MS is the recommended confirmatory method.

9. Device Description

Dochek® Multi-Drug Urine Test Cup Pro and Dochek® Multi-Drug Urine Test Cup are immunochromatographic assays that use a lateral flow system for the qualitative detection of single or multiple drugs in human urine at or above the cut-off levels as indicated. The products are single-

use in vitro diagnostic medical devices.
This device is a cup format, with the test strips integrated into the plastic cup provided, and the urine sample is collected directly into the cup containing the strips. Each cup device is sealed in an aluminum foil pouch with two sachets of desiccant. The device is in a ready-to-use format and no longer requires assembly before use.

10. Substantial Equivalence Information

<table>
<tr><th colspan="4">Similarities</th></tr>
<tr><th>Item</th><th colspan="2">Candidate device</th><th>Predicate device (K232659)</th></tr>
<tr><td>Indication for use</td><td colspan="2">Qualitative detection of drugs of abuse in urine.</td><td>Same</td></tr>
<tr><td>Intended use</td><td colspan="2">For medical and other professional use, or over-the-counter use.</td><td>For prescription use or over-the-counter use.</td></tr>
<tr><td>Methodology</td><td colspan="2">Competitive binding, lateral flow immunochromatographic assay based on antigen-antibody reaction</td><td>Same</td></tr>
<tr><td>Type of Test</td><td colspan="2">Qualitative</td><td>Same</td></tr>
<tr><td>Specimen Type</td><td colspan="2">Human urine</td><td>Same</td></tr>
<tr><td rowspan="19">Target Drug and Cutoff Value</td><td>Target Drug</td><td>Cutoff (ng/mL)</td><td rowspan="19">Same except Fentanyl (FTY) 1 ng/mL</td></tr>
<tr><td>Amphetamine (AMP)</td><td>1000 or 500</td></tr>
<tr><td>Secobarbital (BAR)</td><td>300</td></tr>
<tr><td>Buprenorphine (BUP)</td><td>10</td></tr>
<tr><td>Oxazepam (BZO)</td><td>300</td></tr>
<tr><td>Cocaine (COC)</td><td>300 or 150</td></tr>
<tr><td>2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP)</td><td>300</td></tr>
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<tr><td>Methamphetamine (MET)</td><td>1000 or 500</td></tr>
<tr><td>Morphine (MOP300/OPI2000)</td><td>2000 or 300</td></tr>
<tr><td>Methadone (MTD)</td><td>300</td></tr>
<tr><td>Oxycodone (OXY)</td><td>100</td></tr>
<tr><td>Phencyclidine (PCP)</td><td>25</td></tr>
<tr><td>Propoxyphene (PPX)</td><td>300</td></tr>
<tr><td>Nortriptyline (TCA)</td><td>1000</td></tr>
<tr><td>Cannabinoids (THC)</td><td>50</td></tr>
<tr><td>6-Monoacetylmorphine (6-MAM)</td><td>10</td></tr>
<tr><td>Fentanyl (FTY)</td><td>1</td></tr>
<tr><td>Configurations</td><td colspan="2">Test cup</td><td>Same</td></tr>
<tr><td colspan="4">Differences</td></tr>
<tr><td>Number of drugs detected</td><td colspan="2">17
(Add fentanyl device with 1 ng/mL cutoff)</td><td>16</td></tr>
</table>

11. Standard/Guidance Document Reference (if applicable)

None referenced.

12. Test Principle

Dochek® Multi-Drug Urine Test Cup Pro or Dochek® Multi-Drug Urine Test Cup is a competitive immunoassay that is used to screen for the presence of various drugs and drug metabolites in urine. It is chromatographic absorbent device in which, drugs within a urine sample, competitively combined to a limited number of drug monoclonal antibody (mouse) conjugate binding sites.

When the test is activated, the urine is absorbed into each test strip by capillary action, mixes with the respective drug monoclonal antibody conjugate, and flows across a pre-coated membrane. When drug in the urine sample is below the detection level of the test, respective drug monoclonal antibody conjugate binds to the respective drug-protein conjugate immobilized in the Test Region (T) of the test strip. This produces a colored Test line in the Test Region (T) of the strip, which, regardless of its intensity, indicates a negative test result.

When drug level is at or above the detection level of the test, the free drug in the sample binds to the respective drug monoclonal antibody conjugate, preventing the respective drug monoclonal antibody conjugate from binding to the respective drug-protein conjugate immobilized in the Test Region (T) of the device. This prevents the development of a distinct colored band in the test region, indicating a preliminary positive result.

To serve as a procedure control, a colored line will appear at the Control Region (C) of each strip, if the test has been performed properly.

13. Performance Characteristics

13.1. Analytical Performance

A. Precision/Reproducibility

Precision studies were carried out for samples with concentrations of +100% cutoff, +75% cutoff, +50% cutoff, +25% cutoff, cutoff, -25% cutoff, -50% cutoff, -75% cutoff and -100% cutoff. Samples with concentration of -100% cutoff were drug-free urines samples. Other samples were prepared by spiked target drug in drug-free urine samples. Each drug concentration was confirmed by LC-MS/MS. For each concentration, tests were performed two runs per day for 25 days using three lots of candidate device. The results for Fentanyl (FTY) are summarized in the following table. The precision data for Amphetamine (AMP), Secobarbital (BAR), Buprenorphine (BUP), Oxazepam (BZO), Cocaine (COC), 2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP), Methamphetamine (MET), Methylenedioxymethamphetamine (MDMA), Morphine (MOP300/OPI2000), Methadone (MTD), Oxycodone (OXY), Phencyclidine (PCP), Propoxyphene (PPX), Nortriptyline (TCA), Cannabinoids (THC) and 6-Monoacetylmorphine (6-MAM) were reported in k232659.

Drug	Lot Number	+100% cutoff	+75% cutoff	+50% cutoff	+25% cutoff	Cutoff	-25% cutoff	-50% cutoff	-75% cutoff	-100% cut-off
FTY	Lot I	0-/50+	0-/50+	0-/50+	0-/50+	12-/38+	50-/0+	50-/0+	50-/0+	50-/0+
	Lot II	0-/50+	0-/50+	0-/50+	0-/50+	11-/39+	50-/0+	50-/0+	50-/0+	50-/0+
	Lot III	0-/50+	0-/50+	0-/50+	0-/50+	11-/39+	50-/0+	50-/0+	50-/0+	50-/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 36 months based on real time stability study.

D. Detection Limit

Not applicable.

E. Analytical specificity/Interference

a. Specificity and Cross-Reactivity

Analytical specificity for this device was determined through adding the potential interfering substances to drug-free urine samples. The relative cross-reactivity represents the minimum concentration necessary to yield a result similar to the cutoff level of the respective assay. The table below shows the minimum concentration of each compound that produced a positive result and its percent cross-reactivity. The cross-reactivity data for Amphetamine (AMP), Secobarbital (BAR), Buprenorphine (BUP), Oxazepam (BZO), Cocaine (COC), 2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP), Methamphetamine (MET), Methylenedioxymethamphetamine (MDMA), Morphine (MOP300/OPI2000), Methadone (MTD), Oxycodone (OXY), Phencyclidine (PCP), Propoxyphene (PPX), Nortriptyline (TCA), Cannabinoids (THC) and 6-Monoacetylmorphine (6-MAM) were reported in k232659.

Drug/Cutoff	Compound	Concentration (ng/mL)	% Cross-Reactivity
Fentanyl (FTY) (Cutoff = 1 ng/mL)	Fentanyl	1.0	100%
	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%

b. Interfering Substances

To evaluate the potential interference, non-structurally related compounds were added to drug-free urine and to urine samples containing the target drugs at 25% below and 25% above each corresponding cutoff level. Compounds that show no interference at a concentration of 100μg/mL are summarized in the following table.

Acetaminophen	Dopamine HCl	Noscapine
Acetone (1000 mg/dL)	Doxepin (except TCA test)	Octopamine
Acetylsalicylic acid	Duloxetine	O-Hydroxyhippuric acid
Acyclovir	Ecgonine methyl ester	Omeprazole
Albumin (100 mg/dL)	Ephedrine (except MET test)	Oxalic acid (100 mg/dL)
Albuterol sulfate (Proair HFA)	Erythromycin	Oxazepam (except BZO test)
Aminophylline	Esomeprazole Magnesium	Oxolinic acid
Aminopyrine	Ethanol (1%)	Oxymetazoline
Amitriptyline (except TCA test)	Fenoprofen	Paliperidone (except FTY test)
Amobarbital (except BAR test)	Fluoxetine Hydrochloride	Papaverine
Amoxicillin	Fluphenazine	Penicillin G
Ampicillin	Furosemide	PenicillinV Potassium
Apomorphine	Gabapentin	Perphenazine
Aripiprazole	Galactose (10 mg/dL)	Phenacetin (Acetophenetidin)
Aspartame	Gamma Globulin (500mg/dL)	Phencyclidine (except PCP test)
Atomoxetine	Gentisic acid	Phenelzine
Atorvastatin Calcium	Glucose (3000 mg/dL)	Phenobarbital (except BAR test)
Atropine	Hemoglobin	Prednisone
Azithromycin	Hydralazine	Pregablin
Benzilic acid	Hydrochlorothiazide	Propoxyphene (except PPX test)
Benzocaine	Hydrocortisone	Propranolol
Benzoic acid	Ibuprofen	Pseudoephedrine
Benzoylecgonine (except COC test)	Imipramine (except TCA test)	Quinine
Bilirubin	Isoproterenol	Ranitidine
Boric Acid (1%)	Isoxsuprine	Rifampicin

Bupropion (except FTY test)	Ketamine	Risperidone (except FTY test)
Caffeine	Ketoprofen	Salicylic acid
Captopril	Labetalol	Secobarbital (except BAR test)
Carbamazepine	Levofloxacin Hydrochloride	Serotonin (5-Hydroxytyramine)
Cefradine	Levonorgestrel	Sertraline Hydrochloride
Cephalexin	Levothyroxine Sodium	Sildenafil Citrate
Chloral hydrate	Lidocaine	Simvastatin
Chloramphenicol	Lisinopril	Sulfamethazine
Chlorothiazide	Loperamide	Sulindac
Chlorpheniramine	Loratadine	Tetrahydrocortisone 3-(β-D-glucuronide)
Chlorpromazine	Magnesium	Tetrahydrocortisone 3-acetate
Cholesterol	Maprotiline (except TCA test)	Tetrahydrozoline
Ciprofloxacin Hydrochloride	Meperidine	Theophylline
Citalopram	Meprobamate	Thiamine
Clarithromycin	Methapyrilene	Thioridazine
Clomipramine (except TCA test)	Methaqualone	Tramadol Hydrochloride
Clonidine	Methoxyphenamine (except MET test)	Trazodone Hydrochloride
Clozapine	Metoprolol Tartrate	Triamterene
Conjugated Estrogens	Metronidazole	Trifluoperazine
Cortisone	Mifepristone	Trimethoprim
Cotinine	N-Acetylprocainamide	Tyramine (except AMP test)
Creatinine	NaCl (4000 mg/dL)	Urea (2000 mg/dL)
Cyclobenzaprine (except TCA test)	Nalidixic acid	Uric acid
D,L-Tryptophan	Naloxone	Valproic acid (250 ug/mL)
D,L-Tyrosine	Naltrexone	Venlafaxine
Deoxycorticosterone	Naproxen	Verapamil
Desipramine (except TCA test)	Niacinamide	Vitamin B2
Dextromethorphan	Nicotine	Vitamin C (Ascorbic acid)
Diclofenac	Nifedipine	Zomepirac
Diflunisal	Nitroglycerin	β-Estradiol
Digoxin	Norethindrone	

Diphenhydramine	Nortriptyline (except TCA test)	

c. Effect of Urinary pH and Specific Gravity

Interference by pH and specific gravity were also evaluated using pooled urine specimens with concentrations of 0 (drug-free), at 25% below and 25% above each corresponding cutoff. The results demonstrated that pH levels of 4 to 9 and specific gravity levels of 1.000 to 1.035 do not affect the results of the assays.

13.2 Method Comparison Study

A method comparison study for the candidate device was performed in-house by three operators. Operators ran 80 (40 negative and 40 positive) unaltered urine clinical samples for each drug. The samples were blind labeled and compared to LC-MS/MS results. The fentanyl results are presented in the table below. The accuracy data for Amphetamine (AMP), Secobarbital (BAR), Buprenorphine (BUP), Oxazepam (BZO), Cocaine (COC), 2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP), Methamphetamine (MET), Methylenedioxymethamphetamine (MDMA), Morphine (MOP300/OPI2000), Methadone (MTD), Oxycodone (OXY), Phencyclidine (PCP), Propoxyphene (PPX), Nortriptyline (TCA), Cannabinoids (THC) and 6-Monoacetylmorphine (6-MAM) were reported in k232659.

Drug test	Test Cup Result		Drug-Free	Low Negative by LC-MS/MS (less than -50%)	Near Cutoff Negative by LC-MS/MS (Between -50% and the Cutoff)	Near Cutoff Positive by LC-MS/MS (Between the cutoff and +50%)	High Positive by LC-MS/MS (greater than +50%)
FTY	Viewer A	+	0	0	0	25	13
		-	10	14	16	2	0
	Viewer B	+	0	0	0	25	13
		-	10	14	16	2	0
	Viewer C	+	0	0	1	25	13
		-	10	14	15	2	0

Discordant results for fentanyl (FTY 1 ng/mL) are summarized below.

Drug	Operator	Sample ID	LC-MS/MS Result (ng/mL)	Dochek Result
FTY	Viewer C	F046	0.945	+
	Viewer A, B, C	F062	1.012	—
	Viewer A, C	F083	1.020	—
	Viewer B	F049	1.044	—

13.3. Lay Person Study

A lay user study was conducted at three intended user sites by 280 lay users using three lots of the candidate device. The lay users had diverse educational and professional backgrounds and ranged in age from 21 to >50 years. 68 male and 72 female tested the Dochek® Multi-Drug Urine Test Cup for Configuration 1; 74 male and 64 female tested the Dochek® Multi-Drug Urine Test Cup for Configuration 2. Urine samples were prepared at the following concentrations; -100%, +/-75%, +/-50%, +/-25% of the cutoff by spiking drug(s) into drug free-pooled urine specimens. The concentrations of the drugs in these samples were confirmed by LC-MS/MS. Each sample was aliquoted into individual containers and blind-labeled. Each participant was provided with the package insert, 1 blind labeled sample and a device. The results are summarized below.

Results of Dochek® Multi-Drug Urine Test Cup for Configuration 1:

Drug	**Cutoff (ng/mL)**	**Results**	**Drug Concentration**						
			-100% cutoff	**-75% cutoff**	**-50% cutoff**	**-25% cutoff**	**+25% cutoff**	**+50% cutoff**	**+75% cutoff**
AMP	**1000**	**Negative**	20	20	20	20	0	0	0
		Positive	0	0	0	0	20	20	20
		Total	20	20	20	20	20	20	20
		Percentage of correct results (%)	100%	100%	100%	100%	100%	100%	100%
BAR	**300**	**Negative**	20	20	20	20	1	0	0
		Positive	0	0	0	0	19	20	20
		Total	20	20	20	20	20	20	20
		Percentage of correct results (%)	100%	100%	100%	100%	95%	100%	100%
BUP	**10**	**Negative**	20	20	20	19	0	0	0
		Positive	0	0	0	1	20	20	20
		Total	20	20	20	20	20	20	20
		Percentage of correct results (%)	100%	100%	100%	95%	100%	100%	100%
BZO	**300**	**Negative**	20	20	20	20	0	0	0
		Positive	0	0	0	0	20	20	20
		Total	20	20	20	20	20	20	20
		Percentage of correct results (%)	100%	100%	100%	100%	100%	100%	100%
COC	**300**	**Negative**	20	20	20	19	0	0	0

		Positive	0	0	0	1	20	20	20
		Total	20	20	20	20	20	20	20
		Percentage of correct results (%)	100%	100%	100%	95%	100%	100%	100%
EDDP	**300**	**Negative**	20	20	20	20	1	0	0
		Positive	0	0	0	0	19	20	20
		Total	20	20	20	20	20	20	20
		Percentage of correct results (%)	100%	100%	100%	100%	95%	100%	100%
MDMA	**500**	**Negative**	20	20	20	20	1	0	0
		Positive	0	0	0	0	19	20	20
		Total	20	20	20	20	20	20	20
		Percentage of correct results (%)	100%	100%	100%	100%	95%	100%	100%
MET	**1000**	**Negative**	20	20	20	20	0	0	0
		Positive	0	0	0	0	20	20	20
		Total	20	20	20	20	20	20	20
		Percentage of correct results (%)	100%	100%	100%	100%	100%	100%	100%
OPI	**2000**	**Negative**	20	20	20	20	0	0	0
		Positive	0	0	0	0	20	20	20
		Total	20	20	20	20	20	20	20
		Percentage of correct results (%)	100%	100%	100%	100%	100%	100%	100%
MTD	**300**	**Negative**	20	20	20	19	0	0	0
		Positive	0	0	0	1	20	20	20
		Total	20	20	20	20	20	20	20
		Percentage of correct results (%)	100%	100%	100%	95%	100%	100%	100%
OXY	**100**	**Negative**	20	20	20	20	0	0	0
		Positive	0	0	0	0	20	20	20
		Total	20	20	20	20	20	20	20
		Percentage of correct results (%)	100%	100%	100%	100%	100%	100%	100%

PCP	**25**	**Negative**	20	20	20	20	1	0	0
		Positive	0	0	0	0	19	20	20
		Total	20	20	20	20	20	20	20
		Percentage of correct results (%)	100%	100%	100%	100%	95%	100%	100%
PPX	**300**	**Negative**	20	20	20	20	1	0	0
		Positive	0	0	0	0	19	20	20
		Total	20	20	20	20	20	20	20
		Percentage of correct results (%)	100%	100%	100%	100%	95%	100%	100%
TCA	**1000**	**Negative**	20	20	20	18	0	0	0
		Positive	0	0	0	2	20	20	20
		Total	20	20	20	20	20	20	20
		Percentage of correct results (%)	100%	100%	100%	90%	100%	100%	100%
THC	**50**	**Negative**	20	20	20	19	0	0	0
		Positive	0	0	0	1	20	20	20
		Total	20	20	20	20	20	20	20
		Percentage of correct results (%)	100%	100%	100%	95%	100%	100%	100%
6-MAM	**10**	**Negative**	20	20	20	20	0	0	0
		Positive	0	0	0	0	20	20	20
		Total	20	20	20	20	20	20	20
		Percentage of correct results (%)	100%	100%	100%	100%	100%	100%	100%
FTY	**1**	**Negative**	20	20	20	20	0	0	0
		Positive	0	0	0	0	20	20	20
		Total	20	20	20	20	20	20	20
		Percentage of correct results (%)	100%	100%	100%	100%	100%	100%	100%

Results of Dochek® Multi-Drug Urine Test Cup for Configuration 2:

Drug	**Cutoff (ng/mL)**	**Results**	**Drug Concentration**						
			-100% cutoff	**-75% cutoff**	**-50% cutoff**	**-25% cutoff**	**+25% cutoff**	**+50% cutoff**	**+75% cutoff**

AMP	**500**	**Negative**	20	20	20	20	1	0	0
		Positive	0	0	0	0	19	20	20
		Total	20	20	20	20	20	20	20
		Percentage of correct results (%)	100%	100%	100%	100%	95%	100%	100%
BAR	**300**	**Negative**	20	20	20	20	0	0	0
		Positive	0	0	0	0	20	20	20
		Total	20	20	20	20	20	20	20
		Percentage of correct results (%)	100%	100%	100%	100%	100%	100%	100%
BUP	**10**	**Negative**	20	20	20	20	0	0	0
		Positive	0	0	0	0	20	20	20
		Total	20	20	20	20	20	20	20
		Percentage of correct results (%)	100%	100%	100%	100%	100%	100%	100%
BZO	**300**	**Negative**	20	20	20	19	0	0	0
		Positive	0	0	0	1	20	20	20
		Total	20	20	20	20	20	20	20
		Percentage of correct results (%)	100%	100%	100%	95%	100%	100%	100%
COC	**150**	**Negative**	20	20	20	20	0	0	0
		Positive	0	0	0	0	20	20	20
		Total	20	20	20	20	20	20	20
		Percentage of correct results (%)	100%	100%	100%	100%	100%	100%	100%
EDDP	**300**	**Negative**	20	20	20	19	0	0	0
		Positive	0	0	0	1	20	20	20
		Total	20	20	20	20	20	20	20
		Percentage of correct results (%)	100%	100%	100%	95%	100%	100%	100%
MDMA	**500**	**Negative**	20	20	20	20	0	0	0
		Positive	0	0	0	0	20	20	20
		Total	20	20	20	20	20	20	20
		Percentage of correct results (%)	100%	100%	100%	100%	100%	100%	100%
MET	**500**	**Negative**	20	20	20	20	1	0	0

		Positive	0	0	0	0	19	20	20
		Total	20	20	20	20	20	20	20
		Percentage of correct results (%)	100%	100%	100%	100%	95%	100%	100%
MOP	**300**	**Negative**	20	20	20	19	0	0	0
		Positive	0	0	0	1	20	20	20
		Total	20	20	20	20	20	20	20
		Percentage of correct results (%)	100%	100%	100%	95%	100%	100%	100%
MTD	**300**	**Negative**	20	20	20	19	1	0	0
		Positive	0	0	0	1	19	20	20
		Total	20	20	20	20	20	20	20
		Percentage of correct results (%)	100%	100%	100%	95%	95%	100%	100%
OXY	**100**	**Negative**	20	20	20	20	2	0	0
		Positive	0	0	0	0	18	20	20
		Total	20	20	20	20	20	20	20
		Percentage of correct results (%)	100%	100%	100%	100%	90%	100%	100%
PCP	**25**	**Negative**	20	20	20	20	0	0	0
		Positive	0	0	0	0	20	20	20
		Total	20	20	20	20	20	20	20
		Percentage of correct results (%)	100%	100%	100%	100%	100%	100%	100%
PPX	**300**	**Negative**	20	20	20	19	0	0	0
		Positive	0	0	0	1	20	20	20
		Total	20	20	20	20	20	20	20
		Percentage of correct results (%)	100%	100%	100%	95%	100%	100%	100%
TCA	**1000**	**Negative**	20	20	20	20	1	0	0
		Positive	0	0	0	0	19	20	20
		Total	20	20	20	20	20	20	20
		Percentage of correct results (%)	100%	100%	100%	100%	95%	100%	100%
THC	**50**	**Negative**	20	20	20	20	0	0	0
		Positive	0	0	0	0	20	20	20

		Total	20	20	20	20	20	20	20
		Percentage of correct results (%)	100%	100%	100%	100%	100%	100%	100%
6-MAM	**10**	**Negative**	20	20	20	20	1	0	0
		Positive	0	0	0	0	19	20	20
		Total	20	20	20	20	20	20	20
		Percentage of correct results (%)	100%	100%	100%	100%	95%	100%	100%
FTY	**1**	**Negative**	20	20	20	19	0	0	0
		Positive	0	0	0	1	20	20	20
		Total	20	20	20	20	20	20	20
		Percentage of correct results (%)	100%	100%	100%	95%	100%	100%	100%

Lay users completed given surveys on the ease of understanding the package insert. All participants indicated that the device instruction is easy to understand and follow. A Flesch-Kincaid reading analysis was performed on each package insert and the scores revealed a reading Grade Level of 7.

13.4 Clinical Studies

Not applicable.

14. 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 that Dochek® Multi-Drug Urine Test Cup Pro and Dochek® Multi-Drug Urine Test Cup are substantially equivalent to the predicate devices.