Co-Innovation Biotech Co.,Ltd.
Hong Feng
Product Manager
No.9 Baihe 3 Street,
Economic And Technological Development East Zone,
Guangzhou, Guangdong 510530
China

Re: K231904
Trade/Device Name: Rapid Fentanyl (FYL) Test Strip, Rapid Fentanyl (FYL) Test Dipcard
Regulation Number: 21 CFR 862.3650
Regulation Name: Opiate Test System
Regulatory Class: Class II
Product Code: DJG
Dated: February 2, 2024
Received: February 2, 2024

Dear Hong Feng:

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.

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: 2024.03.08 11:37:33 -05'00'

Joseph Kotarek
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K231904

Device Name
Rapid Fentanyl (FYL) Test Strip
Rapid Fentanyl (FYL) Test Dipcard

Indications for Use *(Describe)*
The Rapid Fentanyl (FYL) Test Strip is a rapid, screening test for the qualitative detection of Fentanyl (FYL) in human urine at the cut-off concentration of 1 ng/mL.
The tests is intended for in vitro diagnostics use. It is intended for prescription use including point of care sites. This assay provides only a preliminary analytical test result. To obtain a confirmed analytical result, a more specific alternative chemical method must be used. Gas Chromatography/ Mass spectrometry (GC/MS) or Liquid chromatography/Mass spectrometry (LC/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are indicated.

The Rapid Fentanyl (FYL) Test Dipcard is a rapid, screening test for the qualitative detection of Fentanyl (FYL) in human urine at the cut-off concentration of 1 ng/mL.
The tests is intended for in vitro diagnostics use. It is intended for prescription use including point of care sites. This assay provides only a preliminary analytical test result. To obtain a confirmed analytical result, a more specific alternative chemical method must be used. Gas Chromatography/ Mass spectrometry (GC/MS) or Liquid chromatography/Mass spectrometry (LC/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are indicated.

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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Section 5 - 510(k) Summary

Date of Summary Preparation: March 6, 2024
510 (K) number:K231904

1. Submitter's Identifications

Submitter: Co-Innovation Biotech Co., Ltd.
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2. Correspondent’s Identifications

Correspondent’s Name: Co-Innovation Biotech Co., Ltd.
Address: No.9 Baihe 3 Street, Economic And Technological Development East Zone，Guangzhou,510530, Guangdong P.R. CHINA
Contact Person: Hong Feng
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3. Name of the Device

Recommended classification regulation:

21 CFR 862.3650 Opiate test system

Device class: ClassII
Panel: Toxicology (91)
Product code: DJG
Common Name:

Fentanyl (FYL) Test System

Proprietary names:

Rapid Fentanyl (FYL) Test Strip
Rapid Fentanyl (FYL) Test Dipcard

4. The Predicate Devices

K220046 Superbio Fentanyl Urine Detection Kit

5. Device Description

Rapid Fentanyl (FYL) Test Strip and Rapid Fentanyl (FYL) Test Dipcard are competitive binding, lateral flow immunochromatographic assays for qualitatively the detection of fentanyl at or above the cut-off concentration of 1 ng/mL. The tests can be performed without the use of an instrument. Test Strip and Test Dipcard use identical test strips made with same chemical formulation and manufacturing procedures.

6. Intended Use of Device

The Rapid Fentanyl (FYL) Test Strip is a rapid, screening test for the qualitative detection of Fentanyl (FYL) in human urine at the cut-off concentration of 1 ng/mL.
The tests is intended for in vitro diagnostics use. It is intended for prescription use including point of care sites. This assay provides only a preliminary analytical test result. To obtain a confirmed analytical result, a more specific alternative chemical method must be used. Gas Chromatography/ Mass spectrometry (GC/MS) or Liquid chromatography/Mass spectrometry (LC/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are indicated.

The Rapid Fentanyl (FYL) Test Dipcard is a rapid, screening test for the qualitative detection of Fentanyl (FYL) in human urine at the cut-off concentration of 1 ng/mL.
The tests is intended for in vitro diagnostics use. It is intended for prescription use including point of care sites. This assay provides only a preliminary analytical test result. To obtain a confirmed analytical result, a more specific alternative chemical method must be used. Gas Chromatography/ Mass spectrometry (GC/MS) or Liquid chromatography/Mass spectrometry (LC/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are indicated.

7. Comparison to Predicate Devices:

A summary comparison of features of the Rapid Fentanyl (FYL) Test Strip and Rapid Fentanyl (FYL) Test Dipcard and the predicate devices is provided in the following Table：

Item	Device	Predicate （K220046）
Indication for use	Qualitative detection of fentanyl in urine	Same
Intended Users	Prescription Use	Same
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 and Dipcard	Same
Platform Required	No	Immunofluorescence Analyzer
Storage	4-30˚C	Same

Remark:

The subject devices have all features of the predicate device except Platform Required.

8. Performance Data:

8.1 Cross-reactivity with structurally similar compounds

To test the cross reactivity of the test, 3 lots of test Strip and test Dipcard was used to test with drug metabolites and drug structurally similar compounds in urine. All the components were added to drug-free normal human urine. Each sample was tested in 3 replicates using 3 lots of Strip and test Dipcard. If any positive result was observed, the compounds were further diluted with known drug-free urine specimen sequentially to different concentrations and tested in quintuplicate, until the highest concentration that generates a negative result was identified. The cross reacting substances with the lowest concentration that produced a positive result was identified and is listed in the table below.

Compound	Lowest Concentration (ng/mL)	% Cross-reactivity
Norfentanyl	10,000	0.01
Acetyl fentanyl	1.2	83.3
Acetyl norfentanyl	10,000	0.01
Acrylfentanyl	1.5	66.7
Butyryl fentanyl	1.6	62.5
Carfentanil	500	0.2
(±)-3-cis-methylfentanyl	5	20
4-Fluoro-isobutyrylfentanyl	3	33.3
Furanyl fentanyl	1.8	55.6
ω-1-Hydroxyfentanyl	20,000	0.01
(±) β-hydroxythiofentanyl	2.8	35.7
Isobutyryl fentanyl	1.5	66.7
Ocfentanil	1.8	55.6

Para-fluorobutyrylfentanyl (p-FBF)	3	33.3
Para-fluoro fentanyl	3	33.3
Sufentanil	625	0.16
Valeryl fentanyl	2.5	40

8.2 Interference

Clinical urine samples may contain substances that could potentially interfere with the test. The following compounds were added to drug-free urine and target drug fentanyl urine with concentrations at 50% below and 50% above Cut-Off levels. All potential interfering substances were added at a concentration of 100μg/mL (despropionyl fentanyl (4-ANPP) at 50 ug/mL, norcarfentanil at 5 ug/mL and remifentanil at 10 ug/ mL) or specified concentrations are summarized in the following tables. The urine specimens were tested with 3 lots of test Strip and test Dipcard. None of the compounds listed below were shown to interfere.

Opioids compounds

6-Acetyl morphine	EDDP	Methadone	Normeperidine	Tapentadol
Alfentanil	EMDP	Morphine	Normorphine	Thioridazine
Amphetamine	Fluoxetine	Morphine-3-glucuronide	Noroxycodone	Tilidine
Buprenorphine	Heroin	Naloxone	Oxycodone	Tramadol
Buprenorphineglucuronide	Hydrocodone	Naltrexone	Oxymorphone	Tramadol-O-Desmethyl
Codeine	Hydromorphone	Norbuprenorphine	Pentazocine (Talwin)	Tramadol-N-Desmethyl
Despropionyl fentanyl (4-ANPP) (50ug/mL)	Ketamine	Norcarfentanil (5ug/mL)	Pipamperone	Trazodone
Dextromethorphan	Levorphanol	Norcodeine	Remifentanil (10ug/mL)	
Dihydrocodeine	Meperidine	Norketamine	Risperidone	

Commonly ingested medications or substances

Acetaminophen	Doxepin (50ug/ml)	Nortriptyline (25ug/ml)
Acetone (1000mg/dL)	Ecgonine methyl ester	Noscapine
Acetophenetidin	Ephedrine	O-Hydroxyhippuric acid
Acetylsalicylic acid	Erythromycin	Octopamine
Albumin (100mg/dL)	Ethanol (1%)	Oxalic acid (100 mg/dL)
Albuterol	Fenoprofen	Oxazepam
Aminopyrine	Fluphenazine	Oxolinic acid

Amitriptyline (35ug/ml)	Furosemide	Oxymetazoline
Amobarbital	Galactose (10mg/dL)	Papaverine
Amoxicillin	Gamma Globulin (500mg/dL)	Penicillin G
Ampicillin	Gentisic acid	Perphenazine
Apomorphine	Glucose (3000mg/dL)	Phencyclidine
Ascorbic acid	Hemoglobin	Phenelzine
Aspartame	Hydralazine	Phenobarbital
Atropine	Hydrochlorothiazide	Prednisone
Benzilic acid	Hydrocortisone	Propoxyphene (50ug/ml)
Benzoic acid	Hydroxytyramine	Propranolol
Benzoylecgonine	Ibuprofen	Pseudoephedrine
Bilirubin	Imipramine (30ug/ml)	Quinine
Boric Acid (1%)	Isoproterenol	Ranitidine
Bupropion (50ug/ml)	Isoxsuprine	Riboflavin (7.5mg/dL)
Caffeine	Ketamine	Salicylic acid
Carbamazepine	Ketoprofen	Secobarbital
Chloral hydrate	Labetalol	Serotonin (5-Hydroxytyramine)
Chloramphenicol	Lidocaine (50ug/ml)	Sulfamethazine
Chlorothiazide	Loperamide	Sulindac
Chlorpromazine	Maprotiline (50ug/ml)	Tetrahydrocortisone 3-(β-Dglucuronide)
Cholesterol	Meperidine	Tetrahydrocortisone 3-acetate
Clomipramine (50ug/ml)	Meprobamate	Tetrahydrozoline
Clonidine	Methapyrilene (10ug/ml)	Thiamine
Cortisone	Methaqualone (50ug/ml)	Thioridazine
Cotinine	Methoxyphenamine	Triamterene
Creatinine	Metronidazole (300ug/ml)	Trifluoperazine
Cyclobenzaprine(10ug/ml)	N-Acetylprocainamide	Trimethoprim
Deoxycorticosterone	NaCl (4000mg/dL)	Tyramine
Desipramine (50ug/ml)	Nalidixic acid	Urea (2000mg/dL)
Dextromethorphan	Naloxone	Uric acid
Diclofenac	Naltrexone	Valproic acid (250ug/ml)
Diflunisal	Naproxen	Venlafaxine
Digoxin	Niacinamide	Verapamil
Diphenhydramine	Nicotine (10ug/ml)	Zomepirac
DL-Tryptophan	Nifedipine	β-Estradiol
DL-Tyrosine	Norethindrone	

8.3 Effect of urinary pH

The pH of an aliquot negative urine pool is adjusted to a pH range of 3 to 9 in 1 pH unit increments and spiked with target fentanyl at 50% below and 50% above cutoff levels. Each sample was tested by 3 lots of test Strip and test Dipcard. The results demonstrate that varying ranges of pH do not interfere with the performance of the test.

8.4 Effect of Urinary specific gravity

The specific gravity studies were conducted on different specific gravity including 1.000,1.010, 1.020, 1.030, 1.040 specimens and spiked with target drug fentanyl with concentrations at 50% below and 50% above Cut-Off levels. Each sample was tested by 3 lots of test Strip and test Dipcard. The results demonstrate that varying ranges of urinary specific gravity do not affect the test result.

8.5 Precision

Precision studies were performed using 3 lots of test Strip and test Dipcard. Drug free specimens were spiked with target drug fentanyl at 0, ±75% cutoff, ±50% cutoff, ±25% cutoff and +100% cutoff of drug. The concentrations of the target drugs were confirmed with LC/MS. Each concentration of the urine specimen was divided into aliquots. Each aliquot was blindly labeled by a nonparticipant. Separate sets of blinded coded samples were assigned and randomized prior to testing. The study was conducted by 6 operators at 3 Point-of-Care sites. Two operators per location tested 3 aliquots at each concentration for each lot per day (3 runs/day) for 10 non-consecutive days using one device lot per location. One operator tested the test strip format and the second operator tested the test dipcard format. There were 1620 observations by 3 sites at 9 concentrations.

Rapid Fentanyl (FYL) Test Strip:

Approximate concentration of sample	% of cutoff	Number of determinations per lot	Result					
			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	6	54
1ng/ml	cutoff	60	36	24	34	26	32	28
1.25ng/ml	+25%cutoff	6	54	6	56	4	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

Rapid Fentanyl (FYL) Test Dipcard:

Approximate concentration of sample	% of cutoff	Number of determinations per lot	Result					
			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	4	56	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

8.6 Accuracy

80 clinical urine specimens were analyzed by LC/MS and by 3 lots of Rapid Fentanyl (FYL) Test Strip and Rapid Fentanyl (FYL) Test Dipcard. Samples were divided by concentration into five categories: drug free, less than half the cutoff, near cutoff negative, near cutoff positive, and high positive. Results were as follows:

Rapid Fentanyl (FYL) Test Strip:

Operator	Co-Innovation Result	Drug free by LC/MS analysis	Less than half the cutoff concentration by LC/MS analysis	Near Cutoff Negative (Between 50% below the cutoff and the cutoff concentration)	Near Cutoff Positive (Between the cutoff and 50% above the cutoff concentration)	High Positive (greater than 50% above the cutoff concentration)	Total
Site1	Positive	0	0	1	8	31	80
	Negative	27	5	7	1	0	
Site2	Positive	0	0	1	8	31	80
	Negative	27	5	7	1	0	
Site3	Positive	0	0	1	8	31	80
	Negative	27	5	7	1	0	

Analysis of Discordant Results Rapid Fentanyl (FYL) Test Strip

Rapid Fentanyl (FYL) Test Strip			LC/MS Analysis	
Operator	Cutoff(ng/mL)	Test Result	Drug Concentration (ng/mL)	Drug in Urine
Site 1	1	Positive	0.76	Fentanyl
	1	Negative	1.04	Fentanyl
Site 2	1	Positive	0.76	Fentanyl
	1	Negative	1.04	Fentanyl
Site 3	1	Positive	0.76	Fentanyl
	1	Negative	1.04	Fentanyl

Rapid Fentanyl (FYL) Test Dipcard:

Operator	Co-Innovation Result	Drug free by LC/MS analysis	Less than half the cutoff concentration by LC/MS analysis	Near Cutoff Negative (Between 50% below the cutoff and the cutoff concentration)	Near Cutoff Positive (Between the cutoff and 50% above the cutoff concentration)	High Positive (greater than 50% above the cutoff concentration)	Total
Site1	Positive	0	0	1	8	31	80
	Negative	27	5	7	1	0	
Site2	Positive	0	0	1	8	31	80
	Negative	27	5	7	1	0	
Site3	Positive	0	0	1	8	31	80
	Negative	27	5	7	1	0	

Analysis of Discordant Results Rapid Fentanyl (FYL) Test Dipcard

Rapid Fentanyl (FYL) Test Dipcard			LC/MS Analysis	
Operator	Cutoff(ng/mL)	Test Result	Drug Concentration (ng/mL)	Drug in Urine
Site 1	1	Positive	0.76	Fentanyl
	1	Negative	1.04	Fentanyl
Site 2	1	Positive	0.76	Fentanyl
	1	Negative	1.04	Fentanyl
Site 3	1	Positive	0.76	Fentanyl

	1	Negative	1.04	Fentanyl

9. Conclusion:

The data collected in the performance and accuracy studies demonstrate that the Rapid Fentanyl (FYL) Test are substantially equivalent to the predicate device.

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