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

Re: K241100
Trade/Device Name: Rapid Urine Fentanyl (FYL) Test Strip; Rapid Urine Fentanyl (FYL) Test Dipcard
Regulation Number: 21 CFR 862.3650
Regulation Name: Opiate test system
Regulatory Class: Class II
Product Code: NGL
Dated: April 22, 2024
Received: April 22, 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: 2024.05.22 12:02:56 -04'00'

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)*
K241100

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

Indications for Use *(Describe)*
Rapid Urine 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.
For in vitro diagnostic use only.
This assay provides only a preliminary analytical test result. 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.

Rapid Urine 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.
For in vitro diagnostic use only.
This assay provides only a preliminary analytical test result. 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.

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.

Section 5 - 510(k) Summary

Date of Summary Preparation: May 22, 2024
510 (K) number:K241100

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
Contact Email Address: fenghongfda@126.com
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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: NGL
Common Name:
Fentanyl (FYL) Test System
Proprietary names:
Rapid Urine Fentanyl (FYL) Test Strip
Rapid Urine Fentanyl (FYL) Test Dipcard

4. The Predicate Devices

K231904	Rapid Fentanyl (FYL) Test Strip
	Rapid Fentanyl (FYL) Test Dipcard

5. Device Description

Rapid Urine Fentanyl (FYL) Test Strip and Rapid Urine 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

Rapid Urine 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.
For in vitro diagnostic use only.
This assay provides only a preliminary analytical test result. 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.

Rapid Urine 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.
For in vitro diagnostic use only.
This assay provides only a preliminary analytical test result. 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.

7. Substantial Equivalence Information:

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

Item	Device	Predicate （K231904）
Indication for use	Qualitative detection of fentanyl in urine	Same
Intended Use	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	Same

	immunochemistry	
Configuration	Strip and Dipcard	Same
Platform Required	No	Same
Storage	4-30˚C	Same

Remark:

The subject devices have all features of the predicate device except Intended Use.

8. Performance Characteristics:

8.1 Analytical Performance Clearance of candidate device is for addition of OTC claim. See analytical performance in predicate K231904.

8.2 Comparison Studies See studies in predicate K231904.

8.3 Lay User Study

A lay user study was performed at three intended user sites with 360 lay persons. They had diverse educational and professional backgrounds and ranged in age from 18 to 65 years. Urine samples were prepared at the following concentrations: 0, +/- 50% cutoff, +/- 25% cutoff and +100% 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:

Rapid Urine Fentanyl (FYL) Test Strip:

Approximate concentration of sample	% of cutoff	Number of determinations per lot	Layer user Results		Agreement (%)
			Positive	Negative	
0ng/ml	Negative	30	0	30	100%
0.5ng/ml	-50%cutoff	30	0	30	100%
0.75ng/ml	-25%cutoff	30	2	28	93%
1.25ng/ml	+25%cutoff	30	29	1	97%
1.5ng/ml	+50%cutoff	30	30	0	100%
2ng/ml	+100%cutoff	30	30	0	100%

Rapid Urine Fentanyl (FYL) Test Dipcard:

Approximate concentration	% of cutoff	Number of determinati	Layer user Results		Agreement (%)
			Positive	Negative	

of sample		ons per lot			
0ng/ml	Negative	30	0	30	100%
0.5ng/ml	-50%cutoff	30	0	30	100%
0.75ng/ml	-25%cutoff	30	1	29	97%
1.25ng/ml	+25%cutoff	30	27	3	90%
1.5ng/ml	+50%cutoff	30	30	0	100%
2ng/ml	+100%cutoff	30	30	0	100%

9. Conclusion:

Based on the test principle and performance characteristics of the device, it's concluded that Rapid Urine Fentanyl (FYL) Test is substantially equivalent to the predicate