November 8, 2024

Hangzhou Clongene Biotech Co.,Ltd.
℅ Jenny Xia
Director
LSI International Inc
504E Diamond Ave., Suite H
Gaithersburg, Maryland 20877

Re: K242802
Trade/Device Name: CLUNGENE Fentanyl Home Test Cassette; CLUNGENE Fentanyl Test Cassette
Regulation Number: 21 CFR 862.3650
Regulation Name: Opiate Test System
Regulatory Class: Class II
Product Code: NGL
Dated: September 14, 2024
Received: September 17, 2024

Dear Jenny Xia:

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: 2024.11.08 08:51:37 -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)*
K242802

Device Name
CLUNGENE Fentanyl Home Test Cassette;
CLUNGENE Fentanyl Test Cassette

Indications for Use *(Describe)*
The CLUNGENE Fentanyl Home Test Cassette is competitive binding, lateral flow immunochromatographic assay for the qualitative detection of Fentanyl in human urine at the cut off concentration of 1.0 ng/mL.
This test provides only a preliminary result. A more specific alternative chemical method must be used to obtain a confirmed analytical result. Gas Chromatography-Mass Spectrometry (GC-MS) or Liquid Chromatography-Mass Spectrometry (LC-MS) is the preferred confirmatory method. Evaluate preliminary positive results carefully. For in vitro diagnostic use only.

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This test provides only a preliminary result. A more specific alternative chemical method must be used to obtain a confirmed presumptive positive result. Gas Chromatography-Mass Spectrometry (GC-MS), Liquid Chromatography-Mass Spectrometry (LC-MS), and their tandem mass-spectrometer versions are the preferred confirmatory methods. Careful consideration and judgment should be applied to any drugs of abuse screen test result, particularly when evaluating preliminary positive results. For in vitro diagnostic use only.

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.

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510(k) SUMMARY
K242802

1. Date: September 13, 2024

2. Submitter: Hangzhou Clongene Biotech Co., Ltd.
No.1 Yichuang Road, Yuhang District
Hangzhou, China

3. Contact person: Jenny Xia
LSI International Inc.
504E Diamond Ave., Suite H
Gaithersburg, MD 20877
Telephone: 301-525-6856
Email: jxia@lsi-consulting.org

4. Device Names: CLUNGENE Fentanyl Home Test Cassette
CLUNGENE Fentanyl Test Cassette

Classification: Class 2

Product Code	Classification	Regulation Section	Panel
NGL	II	21 CFR § 862.3650 Opiate Test System	Toxicology (91)

5. Predicate Devices:

AllTest Fentanyl Urine Test Cassette (K233417)

6. Indications for Use

The CLUNGENE Fentanyl Home Test Cassette is competitive binding, lateral flow immunochromatographic assay for the qualitative detection of Fentanyl in human urine at the cut off concentration of 1.0 ng/mL.

This test provides only a preliminary result. A more specific alternative chemical method must be used to obtain a confirmed analytical result. Gas Chromatography-Mass Spectrometry (GC-MS) or Liquid Chromatography-Mass Spectrometry (LC-MS) is the preferred confirmatory method. Evaluate preliminary positive results carefully. For in vitro diagnostic use only.

The CLUNGENE Fentanyl Test Cassette is competitive binding, lateral flow immunochromatographic assay for the qualitative detection of Fentanyl in human urine at the cut off concentration of 1.0 ng/mL.

This test provides only a preliminary result. A more specific alternative chemical method must be used to obtain a confirmed presumptive positive result. Gas Chromatography-Mass Spectrometry (GC-MS), Liquid Chromatography-Mass Spectrometry (LC-MS), and their tandem mass-spectrometer versions are the preferred confirmatory methods. Careful consideration and judgment should be applied to any drugs of abuse screen test result, particularly when evaluating preliminary positive results. For in vitro diagnostic use only.

7. Device Description

The CLUNGENE Fentanyl Tests are immunoassays intended for the qualitative detection of fentanyl in human urine. Each CLUNGENE Fentanyl Test device consists of a Test Cassette, a

Dropper and a package insert. Each Test Cassette is sealed with sachets of desiccant in an aluminum pouch.

8. Substantial Equivalence Information

A summary comparison of features of the CLUNGENE Fentanyl Test and the predicate device is provided in following table.

Table 1: Features Comparison of CLUNGENE Fentanyl Test and the Predicate Device

Item	Device	Predicate – K233417
Indication(s) for Use	For the qualitative determination of fentanyl in human urine.	Same
Calibrator and Cut-Off Values	Fentanyl (FTY) 1 ng/ml	Same
Methodology	Competitive binding, lateral flow immunochromatographic assays based on the principle of antigen antibody immunochemistry.	Same
Type of Test	Qualitative	Same
Specimen Type	Human Urine	Same
Intended Use	For OTC use	Same
Configurations	Cassette	Same
Storage	4-30˚C	Same

9. Test Principle

The CLUNGENE Fentanyl Tests are immunoassays based on the principle of competitive binding.

During testing, a 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 fentanyl conjugate and a visible colored line will show up in the test line region. The colored line will not form in the test line region if the fentanyl level exceeds 1 ng/mL because it will saturate all the binding sites of anti-fentanyl antibodies.

To serve as a procedural control, a colored line will always appear at the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

10. Performance Characteristics

1. Analytical Performance

a. Precision

Precision studies were carried out for samples with concentrations of -100% cut off, -75% cut off, -50% cut off, -25% cut off, cut off, +25% cut off, +50% cut off, +75% cut off and +100% cut off. These samples were prepared by spiking fentanyl in negative samples. Each fentanyl concentration was confirmed by LC/MS. All sample aliquots were blindly labeled by the person who prepared the samples and didn't take part in the

sample testing. For each concentration, tests were performed two tests per lot per day per operator for 10 days in a randomized order.

Lot Number	-100% cut off	-75% cut off	-50% cut off	-25% cutoff	cut off	+25% cut off	+50% cut off	+75% cut off	+100% cut off
Lot 1	60-/0+	60-/0+	60-/0+	58-/2+	33-/27+	60+/0-	60+/0-	60+/0-	60+/0-
Lot 2	60-/0+	60-/0+	60-/0+	60-/0+	26-/34+	60+/0-	60+/0-	60+/0-	60+/0-
Lot 3	60-/0+	60-/0+	60-/0+	58-/2+	32-/28+	60+/0-	60+/0-	60+/0-	60+/0-

c. Stability

The devices are stable at 39-86° F for 24 months based on the accelerated stability study.

d. Interference

Potential interfering substances found in human urine of physiological or pathological conditions were added to drug-free urine and target drug fentanyl urine with concentrations at 50% below and 50% above Cut-Off levels. These urine samples were tested using three batches of each device. Compounds that showed no interference at a concentration of 100µg/mL or specified concentrations are summarized in the following tables.

Acetaminophen	Erythromycin	Octopamine
Acetone (1000 mg/dL)	Ethanol (1%)	O-Hydroxyhippuric acid
Acetophenetidin	Fenofibrate	Olanzapine
Acetylsalicylic acid	Fenoprofen	Omeprazole
Acyclovir	Fluphenazine	Oxalic acid (100 mg/dL)
Albumin (100mg/dL)	Furosemide	Oxazepam
Albuterol	Galactose (10 mg/dL)	Oxolinic acid
Aminopyrine	Gamma globulin (500 mg/dL)	Oxymetazoline
Amitriptyline	Gatifloxacin	Papaverine
Amobarbital	Gentisic acid	Penicillin G
Amoxicillin	Glibenclamide	Perphenazine
Ampicillin	Gliclazide	Phencyclidine
Apomorphine	Glucose (3000 mg/dL)	Phenelzine
Ascorbic acid	Hemoglobin	Phenobarbital
Aspartame	Hydralazine	Prednisone
Atropine	Hydrochlorothiazide	Procaine
Benzilic acid	Hydrocortisone	Promethazine
Benzoic acid	Hydroxytyramine	Propoxyphene (50 mg/dL)
Benzoylecgonine	Ibuprofen	Propranolol
Bilirubin	Imipramine	Propylthiouracil
Boric acid (1%)	Isoproterenol	Pseudoephedrine
Bupropion	Isoxsuprine	Quinine
Caffeine	Ketamine	Ranitidine
Captopril	Ketoprofen	Ribavirin
Carbamazepine	Labetalol	Riboflavin (10 mg/dL)
Chloral hydrate	Levonorgestrel	Rifampicin
Chloramphenicol	Lidocaine	Salicylic acid
Chlorothiazide	Loperamide	Secobarbital
Chlorpheniramine	Maprotiline	Serotonin (5-Hydroxytyramine)
Chlorpromazine	MDMA	Simvastatin
Cholesterol	Meperidine	Sulfamethazine
Clarithromycin	Meprobamate	Sulindac
Clomipramine	Methamphetamine	Tetrahydrocortisone 3-(β- Dglucuronide)

Clonidine	Methapyrilene	Tetrahydrocortisone 3-acetate
Cortisone	Methaqualone	Tetrahydrozoline
Cotinine	Methoxyphenamine	Theophylline
Creatinine	Metoprolol tartrate	Thiamine
Cyclobenzaprine	Metronidazole (300 μg/mL)	Thioridazine
Deoxycorticosterone	Mifepristone	Triamterene
Desipramine	Montelukast sodium	Trifluoperazine
Dextromethorphan	N-Acetylprocainamide	Trimethoprim
Diazepam	NaCl (4000 mg/dL)	Tyramine
Diclofenac	Nalidixic acid	Urea (2000 mg/dL)
Diflunisal	Naloxone	Uric acid
Digoxin	Naltrexone	Valproic acid (250 μg/mL)
Diphenhydramine	Naproxen	Venlafaxine
DL-Tryptophan	Niacinamide	Verapamil
DL-Tyrosine	Nicotine	Zomepirac
Doxepin	Nifedipine	β-Estradiol
Ecgonine methyl ester	Norethindrone	Δ^9-THC
Ephedrine	Nortriptyline	/
Epinephrine hydrochloride	Noscapine	

e. Specificity

To test specificity, drug metabolites and other components that are likely to interfere in urine samples were tested using three batches of device. The lowest concentration that caused a positive result for each compound are listed below.

Fentanyl (Cutoff=1ng/mL)	**Minimum concentration required to obtain a positive result (ng/mL)**	**% Cross-Reactivity**
Acetyl fentanyl	1	100%
Acrylfentanyl	1	100%
Isobutyryl fentanyl	2.5	40%
Ocfentanil	5	20%
Butyryl fentanyl	5	20%
Furanyl fentanyl	10	10%
Valeryl fentanyl	5	20%
(±) β-hydroxythiofentanyl	2.5	40%
4-Fluoro-isobutyrylfentanyl	10	10%
Para-fluorobutyryl fentanyl	5	20%
Para-fluoro fentanyl	2.5	40%
Carfentanil	50	2%
Sufentanil	25	4%
Alfentanil	7500	0.01%
ω-1-Hydroxy fentanyl	2500	0.04%
(±)-3-cis-methyl fentanyl	75	1.33%
Despropionyl fentanyl (4-ANPP)	2000	0.05%
β-hydroxyfentanyl	100	1%
Thiofentanyl	50	2%
Cyclopropyl Fentanyl	10	10%
Trazodone	1000	0.1%
Remifentanil	> 100000	<0.001%

Norcarfentanil	> 100000	<0.001%
Norfentanyl	> 100000	<0.001%
Acetyl norfentanyl	> 100000	<0.001%

The following opioid compounds were tested at a concentration of 100 µg/mL. A negative result was obtained for all these compounds. There is no cross-reactivity for these compounds using the CLUNGENE® Fentanyl Test Cassette.

6-Acetyl morphine	Naloxone
Amphetamine	Naltrexone
Buprenorphine	Norbuprenorphine
Buprenorphineglucuronide	Norcodeine
Codeine	Norketamine
Dextromethorphan	Normeperidine
Dihydrocodeine	Normorphine
EDDP	Noroxycodone
EMDP	Oxycodone
Fluoxetine	Oxymorphone
Heroin	Pentazocine (Talwin)
Hydrocodone	Pipamperone
Hydromorphone	Risperidone
Ketamine	Tapentadol
Levorphanol	Thioridazine
Meperidine	Tilidine
Methadone	Tramadol
Morphine	Tramadol-O-Desmethyl
Morphine-3-glucuronide	Tramadol-N-Desmethyl

f. Effect of Urine Specific Gravity and Urine pH

To investigate the effect of urine specific gravity and urine pH, urine samples, with 1.000 to 1.035 specific gravity or urine samples with pH 4 to 9 were spiked with target fentanyl at 50% below and 50% above Cut-Off levels. These samples were tested using three lots of device. Results were all positive for samples at and above +50% Cut-Off and all negative for samples at and below -50% Cut-Off.

2. Comparison Studies

Method comparison studies for the CLUNGENE Fentanyl Test were performed by three different operators. Operators ran 80 (40 negative and 40 positive) unaltered clinical samples. The samples were blind labeled and compared to LC/MS results. The results are presented in the tables below.

		Negative	Low Negative by LC/MS (less than -50%)	Near Cutoff Negative by LC/MS (Between -50% and cutoff)	Near Cutoff Positive by LC/MS (Between the cutoff and +50%)	High Positive by LC/MS (greater than +50%)
Operator 1	Positive	0	0	1	21	18
	Negative	10	16	13	1	0
Operator 2	Positive	0	0	1	20	18
	Negative	10	16	13	2	0

Operator 3	Positive	0	0	1	20	18
	Negative	10	16	13	2	0

Discordant Results

Operator	Sample ID	LC/MS Result (ng/mL)	Rapid Test Result
Operator 1	FYL57	0.953	Positive
Operator 2	FYL66	0.987	Positive
Operator 3	FYL66	0.987	Positive
Operator 1	FYL38	1.073	Negative
Operator 2	FYL19	1.083	Negative
Operator 2	FYL55	1.004	Negative
Operator 3	FYL24	1.073	Negative
Operator 3	FYL55	1.004	Negative

3. Lay-user study

A lay user study was performed at three testing sites representative of intended use settings with 140 lay persons. They had diverse educational and professional backgrounds and ranged in age from 19 to >50 years. Urine samples were prepared at the following concentrations; -100%, +/-75%, +/-50%, +/-25% of the cut-off by spiking fentanyl into drug free-pooled urine specimens. The concentrations of the samples were confirmed by LC/MS. Each sample was aliquoted into individual containers, blind-labeled and randomized. Each participant was provided with the package insert, 1 blind labeled sample and a device. The results are summarized below:

% of Cutoff	Number of samples	Fentanyl Concentration by LC/MS (ng/mL)	Lay person results		The percentage of correct results (%)
			No. of Positive	No. of Negative	
-100% Cutoff	20	0	0	20	100
-75% Cutoff	20	0.23	0	20	100
-50% Cutoff	20	0.53	0	20	100
-25% Cutoff	20	0.75	1	19	95
+25% Cutoff	20	1.20	20	0	100
+50% Cutoff	20	1.46	20	0	100
+75% Cutoff	20	1.77	20	0	100

Lay-users were also given surveys on the ease of understanding the package insert instructions. All lay users indicated that the device instructions can be easily followed. A Flesch-Kincaid reading analysis was performed on the package insert and the score revealed a reading grade level of less than 7.

4. Clinical Studies

Not applicable.

11. Conclusion

Based on the test principle and acceptable performance characteristics including precision, cut-off, interference, specificity, method comparison and Lay-user studies of the devices, it's concluded that the CLUNGENE Fentanyl Test is substantially equivalent to the predicate.