Hangzhou AllTest Biotech Co., Ltd.
℅ Joe Shia
Director
LSI International Inc
504 E Diamond Ave., Suite H
Gaithersburg, Maryland 20877

Re: K231698
Trade/Device Name: AllTest Fentanyl Rapid Test (Urine)
Regulation Number: 21 CFR 862.3650
Regulation Name: Opiate test system
Regulatory Class: Class II
Product Code: DJG
Dated: June 11, 2023
Received: June 12, 2023

Dear Joe Shia:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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: 2023.07.31 15:54:12 -04'00'

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

k231698

Device Name
AllTest Fentanyl Rapid Test (Urine)

Indications for Use *(Describe)*
AllTest Fentanyl Rapid Test (Urine) is an immunoassay intended for the qualitative detection of fentanyl in human urine at a cutoff concentration of 1.0 ng/mL. This in vitro diagnostic device is for prescription use only.

The test provides only preliminary test results. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. 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.

510(k) SUMMARY (K231698)

1. Date: June 11, 2023
2. Submitter: Hangzhou Alltest Biotech Co.,Ltd
   #550, Yinhai Street
   Hangzhou, zhejiang, China 310018
3. Contact person: Joe Shia
   LSI International Inc.
   504E Diamond Ave., Suite H
   Gaithersburg, MD 20877
   Telephone: 240-505-7880
   Email: shiajl@yahoo.com
4. Device Names: AllTest Fentanyl Rapid Test (Urine)

Classification: Class 2

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

5. Predicate Devices:

   Superbio Fentanyl Urine Detection Kit (K220046)

6. Indications for Use

   AllTest Fentanyl Rapid Test (Urine) is an immunoassay intended for the qualitative detection of fentanyl in human urine at a cutoff concentration of 1.0 ng/mL. This in vitro diagnostic device is for prescription use only.

   The test provides only preliminary test results. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. GC/MS or LC/MS is the preferred confirmatory method.

7. Device Description

   AllTest Fentanyl Rapid Test (Urine) is an immunoassay intended for the qualitative detection of fentanyl in human urine. Each AllTest Fentanyl Rapid Test (Urine) device consists of a Test Cassette 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 AllTest Fentanyl Rapid Test (Urine) and the predicate devices is provided in following table.

Table 1: Features Comparison of AllTest Fentanyl Rapid Test (Urine) and the Predicate Devices

Item	Device	Predicate – K220046

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 prescription use	Same
Configurations	Cassette	Dip Card
Platform Required	None	Fluorescence analyzer
Storage	4-30˚C	Same

9. Test Principle

AllTest Fentanyl Rapid Test (Urine) is a competitive and immunochromatography assay, and uses monoclonal antibody as the indicator marker to qualitatively detect fentanyl in human urine. The test cassette contains fentanyl test strip. The nitrocellulose membrane test area (T) of the test strip is correspondingly coated with fentanyl-bovine serum albumin conjugate, and the quality control area (C) is coated with goat anti-rabbit IgG polyclonal antibody. When the concentration of fentanyl in the sample is higher than or equal to the cut-off of the product, it will compete with the corresponding conjugate coated on the test area (T) to bind to the monoclonal antibody, the test line is inhibited and the result is positive; while when the sample does not contain fentanyl or its concentration is lower than the cut-off of the product, the corresponding conjugate on the test line reacts with sufficient monoclonal antibodies, the test line will be visible and the result is negative. No matter whether the sample contains the corresponding analyte or not, the quality control area (C) will develop a colored line, which is the criteria for judging whether the chromatography process is normal or not.

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 day for 10 days per device lot 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+	35+/25-	60+/0-	60+/0-	60+/0-	60+/0-
Lot 2	60-/0+	60-/0+	60-/0+	59-/1+	28+/32-	60+/0-	60+/0-	60+/0-	60+/0-
Lot 3	60-/0+	60-/0+	60-/0+	60-/0+	26+/34-	60+/0-	60+/0-	60+/0-	60+/0-

c. Stability

The devices are stable at 2-30 °C for 24 months based on the real time stability.

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	Doxepin	Nortriptyline
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	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	Quinine
Boric Acid (1%)	Isoproterenol	Ranitidine
Bupropion	Isoxsuprine	Riboflavin (10mg/dL)
Caffeine	Ketamine	Salicylic acid
Carbamazepine	Ketoprofen	Secobarbital
Chloral hydrate	Labetalol	Serotonin (5-Hydroxytyramine)
Chloramphenicol	Lidocaine	Sulfamethazine
Chlorothiazide	Loperamide	Sulindac
Chlorpromazine	Maprotiline	Tetrahydrocortisone 3-(β-Dglucuronide)
Cholesterol	Meperidine	Tetrahydrocortisone 3-acetate
Clomipramine	Meprobamate	Tetrahydrozoline
Clonidine	Methapyrilene	Thiamine
Cortisone	Methaqualone	Thioridazine
Cotinine	Methoxyphenamine	Triamterene
Creatinine	Metronidazole (300ug/ml)	Trifluoperazine
Cyclobenzaprine	N-Acetylprocainamide	Trimethoprim
Deoxycorticosterone	NaCl (4000mg/dL)	Tyramine
Desipramine	Nalidixic acid	Urea (2000mg/dL)
Dextromethorphan	Naloxone	Uric acid
Diclofenac	Naltrexone	Valproic acid (250ug/ml)

Diflunisal	Naproxen	Venlafaxine
Digoxin	Niacinamide	Verapamil
Diphenhydramine	Nicotine	Zomepirac
DL-Tryptophan	Nifedipine	β-Estradiol
DL-Tyrosine	Norethindrone	

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
ω-1-Hydroxyfentanyl	20000	0.005
Isobutyryl fentanyl	1	100
Ocfentanil	2.5	40.00
Butyryl fentanyl	2.5	40.00
Furanyl fentanyl	5	20.00
Valeryl fentanyl	10	10.00
(±) β-hydroxythiofentanyl	2	50.00
4-Fluoro-isobutyrylfentanyl	50	2.00
Para-fluorobutyryl fentanyl	4	25.00
Para-fluoro fentanyl	3	33.33
(±)-3-cis-methyl fentanyl	50	2.00
Carfentanil	2	50.00
Sufentanil	7.5	13.33
Alfentanil	5000	0.02
Despropionyl fentanyl (4-ANPP)	2500	0.04
Remifentanil	>100000	/
Norfentanyl	>100000	/
Acetyl norfentanyl	>100000	/
Norcarfentanil	>100000	/

The following opioids compounds were tested at a concentration of 100ug/mL. Negative results were obtained for all these compounds. There is no cross-reactivity for these compounds using the Alltest Fentanyl Rapid Test (Urine).

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

Trazodone showed 0.1% cross-reactivity as a positive result was observed at 1000 ng/mL.

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 Alltest Fentanyl Rapid Test (Urine) were performed at three different testing sites. 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%)
Site 1	Positive	0	0	3	22	16
	Negative	9	16	12	2	0
Site 2	Positive	0	0	3	22	16
	Negative	9	16	12	2	0
Site 3	Positive	0	0	2	21	16
	Negative	9	16	13	3	0

Discordant Results

Site	Sample Number	LC-MS/MS Result	ALLTEST Result
Site 1	M41	1.079	Negative
Site 1	M40	0.906	Positive
Site 1	M2	1.013	Negative
Site 1	M58	0.822	Positive
Site 1	M59	0.920	Positive
Site 2	M14	1.015	Negative
Site 2	M2	1.013	Negative
Site 2	M63	0.917	Positive
Site 2	M59	0.920	Positive

Site	Sample Number	LC-MS/MS Result	ALLTEST Result
Site 2	M49	0.842	Positive
Site 3	M41	1.079	Negative
Site 3	M59	0.920	Positive
Site 3	M2	1.013	Negative
Site 3	M14	1.015	Negative
Site 3	M63	0.917	Positive

3. Clinical Studies

Not applicable.

11. Conclusion

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