Assure Tech LLC
% Joe Shia
Director
LSI International Inc
504E Diamond Ave., Suite H
Gaithersburg, Maryland 20877

Re: K240351
Trade/Device Name: FaStep™ Fentanyl Rapid Test Device (Urine); FaStep™ Rapid Fentanyl Urine Test (Urine)
Regulation Number: 21 CFR 862.3650
Regulation Name: Opiate test system
Regulatory Class: Class II
Product Code: NGL
Dated: February 2, 2024
Received: February 5, 2024

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 (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: 2024.03.06 09:36:19 -05'00'

Joseph Kotarek
Branch Chief for Toxicology
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: 06/30/2025
See PRA Statement below.

510(k) Number *(if known)*
K240351

Device Name
FaStep™ Fentanyl Rapid Test Device (Urine)
FaStep™ Rapid Fentanyl Urine Test (Urine)

Indications for Use *(Describe)*
The FaStep™ Fentanyl Rapid Test Device (Urine) is a rapid visual immunoassay for the qualitative, presumptive detection of Fentanyl in human urine specimens at a cut-off concentration of 1.0 ng/mL.
It is for in vitro diagnostic use only.
The tests provide 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.

The FaStep™ Rapid Fentanyl Urine Test (Urine) is a rapid visual immunoassay for the qualitative, presumptive detection of Fentanyl in human urine specimens at a cut-off concentration of 1.0 ng/mL. It is for in vitro diagnostic use only.
The tests provide 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. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive.

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
K240351

1. Date: March 5, 2024

2. Submitter:
Assure Tech. LLC.
1521 Concord Pike, Suite 201
Wilmington, DE 19803

3. Contact person:
Joe Shia
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4. Device Names:
FaStep™ Fentanyl Rapid Test Device (Urine)
FaStep™ Rapid Fentanyl Urine Test (Urine)

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 FaStep™ Fentanyl Rapid Test Device (Urine) is a rapid visual immunoassay for the qualitative, presumptive detection of Fentanyl in human urine specimens at a cut-off concentration of 1.0 ng/mL. It is for in vitro diagnostic use only.

The tests provide 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.

The FaStep™ Rapid Fentanyl Urine Test (Urine) is a rapid visual immunoassay for the qualitative, presumptive detection of Fentanyl in human urine specimens at a cut-off concentration of 1.0 ng/mL. It is for in vitro diagnostic use only.

The tests provide 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. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive.

7. Device Description

The FaStep™ Fentanyl Tests are immunoassays intended for the qualitative detection of fentanyl in human urine. Each FaStep™ 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 FaStep™ Fentanyl Test and the predicate devices is provided in following table.

Table 1: Features Comparison of FaStep™ 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 FaStep™ 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 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+	58-/2+	36+/24-	60+/0-	60+/0-	60+/0-	60+/0-
Lot 3	60-/0+	60-/0+	60-/0+	57-/3+	35+/25-	60+/0-	60+/0-	60+/0-	60+/0-

c. Stability

The devices are stable at 36-86F for 24 months based on the real-time 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	Doxepin	Nortriptyline
Acetone (1000 mg/dL)	Ecgonine methyl ester	Noscapine
Acetophenetidin	Ephedrine	O-Hydroxyhippuric acid
Acetylsalicylic acid	Erythromycin	Octopamine
Albumin (100 mg/dL)	Ethanol (1%)	Oxalic acid (100 mg/dL)
Albuterol	Fenoprofen	Oxazepam
Aminopyrine	Fluphenazine	Oxolinic acid
Amitriptyline	Furosemide	Oxymetazoline
Amobarbital	Galactose (10 mg/dL)	Papaverine
Amoxicillin	Gamma globulin (500 mg/dL)	Penicillin G
Ampicillin	Gentisic acid	Perphenazine
Apomorphine	Glucose (3000 mg/dL)	Phencyclidine
Ascorbic Acid	Hemoglobin	Phenelzine
Aspartame	Hydralazine	Phenobarbital
Atropine	Hydrochlorothiazide	Prednisone
Benzilic acid	Hydrocortisone	Propoxyphene
Benzoic acid	Hydroxytyramine	Propranolol
Benzoylecgonine	Ibuprofen	Pseudoephedrine
Bilirubin	Imipramine	Quinine
Boric acid (1% w/v)	Isoproterenol	Ranitidine
Bupropion	Isoxsuprine	Riboflavin (10 mg/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 (300 μg/mL)	Trifluoperazine

Cyclobenzaprine	N-Acetylprocainamide	Trimethoprim
Deoxycorticosterone	NaCl (4000 mg/dL)	Tyramine
Desipramine	Nalidixic acid	Urea (2000 mg/dL)
Dextromethorphan	Naloxone	Uric acid
Diclofenac	Naltrexone	Valproic acid (250 µg/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	5	20.00
Acrylfentanyl	5	20.00
ω-1-Hydroxyfentanyl	50000	0.002
Isobutyryl fentanyl	5	20.00
Ocfentanil	100	1.00
Butyryl fentanyl	25	4.00
Furanyl fentanyl	10	10.00
Valeryl fentanyl	50	2.00
(±) β-hydroxythiofentanyl	5	20.00
4-Fluoro-isobutyrylfentanyl	50	2.00
Para-fluorobutyryl fentanyl	25	4.00
Para-fluoro fentanyl	25	4.00
(±)-3-cis-methyl fentanyl	50	2.00
Carfentanil	10000	0.01
Despropionyl fentanyl (4-ANPP)	50000	0.002
Sufentanil	>10000	<0.01
Alfentanil	>100000	<0.001
Remifentanil	>10000	<0.01
Norfentanyl	>100000	<0.001
Acetyl norfentanyl	>100000	<0.001
Norcarfentanil	>10000	<0.01

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 FaStep™ Fentanyl Test.

6-Acetyl morphine	Naltrexone
Amphetamine	Norbuprenorphine
Buprenorphine	Norcodeine
Buprenorphineglucuronide	Norketamine

Codeine	Normeperidine
Dextromethorphan	Normorphine
Dihydrocodeine	Noroxycodone
EDDP	Oxycodone
EMDP	Oxymorphone
Fluoxetine	Pentazocine (Talwin)
Heroin	Pipamperone
Hydrocodone	Risperidone
Hydromorphone	Tapentadol
Ketamine	Thioridazine
Levorphanol	Tilidine
Meperidine	Tramadol
Methadone	Tramadol-O-Desmethyl
Morphine	Tramadol-N-Desmethyl
Morphine-3-glucuronide	Trazodone
Naloxone	

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 FaStep™ Fentanyl Test were performed using three different lots of the device. Operators ran 82 (42 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	2	16	22
	Negative	5	16	19	2	0
Operator 2	Positive	0	0	2	16	22
	Negative	5	16	19	2	0
Operator 3	Positive	0	0	3	17	22
	Negative	5	16	18	1	0

Discordant Results

Operator	Sample ID	LC/MS Result (ng/mL)	Rapid Test Result
Operator 1	F0031	0.89	+
Operator 1	F0094	0.94	+
Operator 1	F0001	1	-

Operator 1	F0084	1.1	-
Operator 2	F0048	0.93	+
Operator 2	F0094	0.94	+
Operator 2	F0001	1	-
Operator 2	F0084	1.1	-
Operator 3	F0031	0.89	+
Operator 3	F0048	0.93	+
Operator 3	F0094	0.94	+
Operator 3	F0001	1	-

3. Lay-user study

A lay user study was performed at three testing sites with 140 lay persons. They had diverse educational and professional backgrounds and ranged in age from 20 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	0.28	0	20	100
-50% Cutoff	20	0.51	0	20	100
-25% Cutoff	20	0.73	1	19	95
+25% Cutoff	20	1.23	20	0	100
+50% Cutoff	20	1.48	20	0	100
+75% Cutoff	20	1.75	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 a substantial equivalence decision.