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

Re: K240295
Trade/Device Name: InstaStrip Fentanyl Rapid Test (Urine); InstaStrip Fentanyl Dipstick Test (Urine)
Regulation Number: 21 CFR 862.3650
Regulation Name: Opiate Test System
Regulatory Class: Class II
Product Code: NGL
Dated: January 24, 2024
Received: February 1, 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: 2024.03.28 11:12:32 -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: 07/31/2026
*See PRA Statement below.*

510(k) Number *(if known)*
K240295

Device Name
InstaStrip Fentanyl Rapid Test (Urine)
InstaStrip Fentanyl Dipstick Test (Urine)

Indications for Use *(Describe)*
InstaStrip Fentanyl Rapid Test (Urine) is intended for the qualitative detection of fentanyl in human urine at the cutoff value of 1.0 ng/mL. The test is intended for over-the-counter (OTC) use.
The assay provides only a preliminary analytical result. A more specific alternative chemical method (e.g., gas or liquid chromatography and mass spectrometry) must be used in order to obtain a confirmed analytical result. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary test result is positive.

The InstaStrip Fentanyl Dipstick Test (Urine) is intended for the qualitative detection of fentanyl in human urine at the cutoff value of 1.0 ng/mL.
The assay provides only a preliminary analytical result. A more specific alternative chemical method (e.g., gas or liquid chromatography and mass spectrometry) must be used in order to obtain a confirmed analytical result. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary test 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
K240295

1. Date: March 25, 2024

2. Submitter:
Instanosis Inc.
1004 w 9th Avenue, Suite 10
King of Prussia, PA 19406

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: InstaStrip Fentanyl Rapid Test (Urine)
InstaStrip Fentanyl Dipstick Test (Urine)

Classification: Class 2

| Product Code | Classification | Regulation Section | Panel |
|---|---|---|---|
| NGL | II | 21 CFR § 862.3650<br>Opiate Test System | Toxicology (91) |

5. Predicate Devices:

AllTest Fentanyl Urine Test Cassette (K233417)

6. Indications for Use

InstaStrip Fentanyl Rapid Test (Urine) is intended for the qualitative detection of fentanyl in human urine at the cutoff value of 1.0 ng/mL. The test is intended for over-the-counter (OTC) use.

The assay provides only a preliminary analytical result. A more specific alternative chemical method (e.g., gas or liquid chromatography and mass spectrometry) must be used in order to obtain a confirmed analytical result. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary test result is positive.

The InstaStrip Fentanyl Dipstick Test (Urine) is intended for the qualitative detection of fentanyl in human urine at the cutoff value of 1.0 ng/mL.

The assay provides only a preliminary analytical result. A more specific alternative chemical method (e.g., gas or liquid chromatography and mass spectrometry) must be used in order to obtain a confirmed analytical result. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary test result is positive.

7. Device Description

InstaStrip Fentanyl Test is an immunoassay intended for the qualitative detection of fentanyl in human urine. Each InstaStrip Fentanyl Test device consists of a Test Strip, a Test Tube, a Dropper and a package insert. Each Test Strip is sealed with sachets of desiccant in an aluminum pouch.

8. Substantial Equivalence Information

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

**Table 1: Features Comparison of InstaStrip 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)<br>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** | Strip | Cassette |
| **Storage** | 15-30˚C | 4-30˚C |

9. Test Principle

The InstaStrip-Fentanyl Rapid Test is an immunoassay technique that is based on competitive lateral flow immunoassay to detect the presence of fentanyl in human urine samples. The urine sample is added to a provided test tube containing dried rabbit monoclonal antibody-gold nanoparticle (Ab-AuNP) conjugates. This mixture is applied to the InstaStrip-Fentanyl test strip. The pre-immobilized fentanyl-BSA on the test line competes with fentanyl in the urine sample for binding to the Ab-AuNPs. The device is designed so that when the fentanyl concentration in the urine sample exceeds 1 ng/mL, the test line is no longer visible. The test line will be visible and the result is negative when the fentanyl concentration in the urine sample is less than 1 ng/mL. 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 six 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+ | 54-/6+ | 32+/28- | 60+/0- | 60+/0- | 60+/0- | 60+/0- |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| Lot 2 | 60-/0+ | 60-/0+ | 60-/0+ | 55-/5+ | 30+/30- | 60+/0- | 60+/0- | 60+/0- | 60+/0- |
| Lot 3 | 60-/0+ | 60-/0+ | 60-/0+ | 55-/5+ | 34+/26- | 60+/0- | 60+/0- | 60+/0- | 60+/0- |

c. Stability

The devices are stable at room temperature 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 (500 µg/mL) | Doxepin | Nortriptyline |
| Acetone (1000 mg/dL) | Ecgonine methyl ester | Noscapine |
| Acetophenetidin | Ephedrine | O-Hydroxyhippuric acid |
| Acetylsalicylic acid | Erythromycin | Octopamine |
| Albumin (500 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 (560 mg/dL) | Hemoglobin (500 mg/dL) | Phenelzine |
| Aspartame | Hydralazine | Phenobarbital |
| Atropine | Hydrochlorothiazide | Prednisone |
| Benzilic acid | Hydrocortisone | Propoxyphene |
| Benzoic acid | Hydroxytyramine | Propranolol |
| Benzoylecgonine | Ibuprofen (500 µg/mL) | Pseudoephedrine |
| Bilirubin | Imipramine | Quinine (15 µg/mL) |
| Boric acid (1% w/v) | Isoproterenol | Ranitidine |
| Bupropion | Isoxsuprine (20 µg/mL) | Riboflavin (10 mg/dL) |
| Caffeine | Ketamine | Salicylic acid |
| Carbamazepine | Ketoprofen | Secobarbital |
| Chloral hydrate | Labetalol (15 µg/mL) | Serotonin (5-hydroxytyramine) |
| Chloramphenicol | Lidocaine | Sulfamethazine |
| Chlorothiazide | Loperamide | Sulindac |
| Chlorpromazine | Maprotiline | Tetrahydrocortisone 3-(β-D-glucuronide) |
| Cholesterol | Meperidine | Tetrahydrocortisone 3-acetate |
| Clomipramine | Meprobamate | Tetrahydrozoline |
| Clonidine | Methapyrilene | Thiamine |
| Cortisone | Methaqualone | Thioridazine |
| Cotinine | Methoxyphenamine | Triamterene |
| Creatinine (500 mg/dL) | 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 (20 µg/mL) |
| 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 |
| Acetyl norfentanyl | >10000 | <0.01 |
| Acrylfentanyl | 1.8 | 56 |
| Alfentanil | >10000 | <0.01 |
| Benzodioxole fentanyl | 4.8 | 21 |
| Butyryl fentanyl | 1 | 100 |
| Carfentanil | >10000 | <0.01 |
| Crotonyl fentanyl | 1 | 100 |
| Despopionyl 2' fluoro-ortho- | >10000 | <0.01 |
| Despropionyl fentanyl (4-ANPP) | 10000 | 0.01 |
| Furanyl fentanyl | 1.9 | 53 |
| (±) β-hydroxythiofentanyl | 7.5 | 13 |
| Isobutyryl fentanyl | 1.7 | 59 |
| N-benzyl furanyl norfentanyl | >10000 | <0.01 |
| N-benzyl parafluoro cyclopropyl | >10000 | <0.01 |
| (±)-3-cis-methyl fentanyl | 9.2 | 11 |
| Norcarfentanil | >10000 | <0.01 |
| Norfentanyl | >10000 | <0.01 |
| o-Fluorofentanyl | 1 | 100 |
| 4-Fluoro-isobutyryl fentanyl | 1 | 100 |
| Ocfentanil | 2.2 | 45 |
| Para-chloroisobutyrul fentanyl | 1.8 | 56 |
| Para-fluoro fentanyl | 2.8 | 36 |
| Para-fluorobutyryl fentanyl (p-FBF) | 2.5 | 40 |
| Remifentanil | >10000 | <0.01 |
| Sufentanil | >10000 | <0.01 |
| Tetrahydrofyranyl fentanyl | 2.3 | 43 |
| Valeryl fentanyl | 2.9 | 34 |
| β-hydroxyfentanyl | 7.5 | 13 |

| | | |
|---|---|---|
| ω-1-Hydroxyfentanyl | 7.5 | 13 |

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 InstaStrip Fentanyl Test.

| | |
|---|---|
| 6-Acetyl morphine | Morphine |
| Amphetamine | Morphine-3-glucuronide |
| Buprenorphine | Naloxone |
| Buprenorphine glucuronide | Naltrexone |
| Ceftriaxone | Norbuprenorphine |
| M-Chlorophenylpiperazine | Norcodeine |
| Ciprofloxacin | Norketamine |
| Cocaine | Normeperidine |
| Codeine | Normorphine |
| Dextromethorphan | Noroxycodone |
| Dihydrocodeine | Ofloxacin |
| Diphehydramine | Oxycodone |
| Duloxetine | Oxymorphone |
| EDDP | Pentazocine (Talwin) |
| EMDP | Pipamperone |
| Fluoxetine | 1-(3-chlorophenyl) Piperazine (hydrochloride) |
| Haloperidol | Quinidine |
| Heroin | Risperidone |
| Hydrocodone | Tapentadol |
| Hydromorphone | Thioridazine |
| Ketamine | Tilidine |
| Levorphanol | Tramadol |
| MDMA | Tramadol-O- Desmethyl |
| Meperidine | Tramadol-N- Desmethyl |
| Methadone | Trazodone |
| Methamphetamine | |

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 InstaStrip Fentanyl Test were performed using three different lots of the device. Operators ran 85 (42 negative and 43 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%) |
|---|---|---|---|---|---|---|
| Lot 1 | Positive | 0 | 0 | 1 | 7 | 36 |
| | Negative | 11 | 21 | 9 | 0 | 0 |
| Lot 2 | Positive | 0 | 0 | 0 | 7 | 36 |
| | Negative | 11 | 21 | 10 | 0 | 0 |
| Lot 3 | Positive | 0 | 0 | 0 | 6 | 36 |
| | Negative | 11 | 21 | 10 | 1 | 0 |

**Discordant Results**

| Lot | Sample Number | LC-MS/MS Result | InstaStrip Result |
|---|---|---|---|
| Lot 1 | 310-13724 | 0.9 | Positive |
| Lot 3 | 280-06705 | 1.0 | Negative |

3. Lay-user study

A lay user study was performed at three intended user sites with 140 lay persons. They had diverse educational and professional backgrounds and ranged in age from 18 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 | 0.19 | 0 | 20 | 100 |
| **-50% Cutoff** | 20 | 0.50 | 0 | 20 | 100 |
| **-25% Cutoff** | 20 | 0.69 | 1 | 19 | 95 |
| **+25% Cutoff** | 20 | 1.15 | 20 | 0 | 100 |
| **+50% Cutoff** | 20 | 1.44 | 20 | 0 | 100 |
| **+75% Cutoff** | 20 | 1.69 | 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.