December 13, 2022

Shenzhen Superbio Technology Co., Ltd.
% Joe Shia, Director
LSI
504 E Diamond Ave., Suite I
Gaithersburg, MD 20877

Re: K220046
Trade/Device Name: Superbio Fentanyl Urine Detection Kit, Superbio Immunofluorescence Analyzer EASY-11
Regulation Number: 21 CFR 862.3650
Regulation Name: Opiate Test System
Regulatory Class: Class II
Product Code: DJG, KHO
Dated: August 29, 2022
Received: August 29, 2022

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,

Paula Caposino -S

Digitally signed by Paula Caposino -S
Date: 2022.12.13 17:19:25 -05'00'

Paula V. Caposino, Ph.D.
Acting Deputy Director
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
k220046

Device Name
Superbio Fentanyl Urine Detection Kit
Superbio Immunofluorescence Analyzer EASY-11

Indications for Use *(Describe)*
The Superbio Fentanyl Urine Detection Kit is a fluorescence immunoassay intended for the qualitative detection of fentanyl in human urine at a cutoff concentration of 1.0 ng/mL. The assay is intended for use with Superbio Immunofluorescence Analyzer EASY-11. 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.

The Superbio Immunofluorescence Analyzer EASY-11 is a portable fluorescence instrument for in vitro diagnostic use only. The analyzer is designed to perform in vitro diagnostic tests on clinical specimens. This analyzer can be used in a laboratory or in a point-of-care setting.

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
K220046

1. Date: December 2, 2022

2. Submitter: Shenzhen Superbio Technology Co., Ltd.
Building B, Xinzheng, 71 Area, Xinan Sub-District, Baoan
Shenzhen, China 518101

3. Contact person: Joe Shia
LSI International Inc.
504E Diamond Ave., Suite I
Gaithersburg, MD 20877
Telephone: 240-505-7880
Email: shiajl@yahoo.com

4. Device Names: Superbio Fentanyl Urine Detection Kit
Superbio Immunofluorescence Analyzer EASY-11

Classification: Class 2

Product Code	Classification	Regulation Section	Panel
DJG	II	21 CFR § 862.3650 Opiate Test System	Toxicology (91)
KHO	I	21 CFR § 862.2560 Fluorometer for clinical use	Clinical Chemistry

5. Predicate Devices:

The ARK™ Fentanyl Assay K180427;
TRIAGE STATMETER K973547

6. Indications for Use

The Superbio Fentanyl Urine Detection Kit is a fluorescence immunoassay intended for the qualitative detection of fentanyl in human urine at a cutoff concentration of 1.0 ng/mL. The assay is intended for use with Superbio Immunofluorescence Analyzer EASY-11. 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.

The Superbio Immunofluorescence Analyzer EASY-11 is a portable fluorescence instrument for in vitro diagnostic use only. The analyzer is designed to perform in vitro diagnostic tests on clinical specimens. This analyzer can be used in a laboratory or in a point-of-care setting.

7. Device Description

This test uses a lateral flow design with location-dependent lines and zones. The Immunofluorescence Analyzer EASY-11 scans the test strip and displays results. The sample is added to the sample well of the test card, and the sample is drawn by capillary action into and through the fluorescent labeled pad, through the nitrocellulose strip and into the adsorption pad.

Within the fluorescent labeled pad, the specimen comes into contact with antibodies conjugated with fluorescent microspheres. During this interaction, if the amount of fentanyl antigen in the sample is greater than or equal to the detection limit, the antigen in the sample and the fluorescence-labeled antibody bind to the FTY antigen-antibody complex when the sample passes through a pad of fluorescence-microbead-labeled antibody conjugate. As the sample flows and reaches the FTY antigen coated by the T-line of nitrocellulose membrane, the FTY antigen coated by the T-line and the antigen in the sample competitively bind the FTY antibody labeled with fluorescence, then the T-line captures no fluorescence signal. When the samples do not contain fentanyl antigen or levels below the detection limit, as the sample flow, fluorescent microsphere labeled antibody to nitrocellulose membrane T line captures fluorescent signal. Whether or not FTY antigen was present in the sample, the rabbit IgG fluorescent microsphere conjugate not bound to the test line continued to flow with the rest of the sample and soon encountered a control line composed of sheep anti-rabbit IgG. The position of C-line will accumulate fluorescence signal. The C-line control area was scanned to confirm that adequate sample flow had occurred. High resolution, narrow band SMD LED was used as light source in the Immunofluorescence Analyzer. The central wavelength of the excitation spectrum is 365nm. The central response wavelength is 610nm.

8. Substantial Equivalence Information

A summary comparison of features of the Superbio Fentanyl Urine Detection Kit and the predicate devices is provided in following table.

Table 1: Features Comparison of Superbio Fentanyl Urine Detection Kit and the Predicate Devices

Item	Device	Predicate - K180427
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.	Homogenous enzyme immunoassay (EIA)
Type of Test	Qualitative	Same
Specimen Type	Human Urine	Same
Intended Use	For prescription use	Same
Configurations	Dip Card and Strip	Cup
Platform Required	Immunofluorescence Analyzer	Automated clinical chemistry analyzer
Storage	4-30˚C	2-8˚C

Table 2: Instrument Similarities and Differences

Item	Predicate – K973547	Subject Device

Intended Use/ Indication for Use	Immunofluorescence analyzer designed to perform in vitro diagnostic tests on clinical specimens including drug urine test.	Same
Principles of Assay Operation	Sandwich immunofluorescence immunoassay	Same
Calibration Check	Run two levels or POS and NEG external liquid control samples as appropriate with each new lot of reagents and once every 30 days with continued use of the same reagent lot number	A Quality control card is supplied with Easy-11 and used for check Easy-11 optics and calculation. systems.
Development Modes	one test mode ● Run Test	Two basic assay development modes: • Standard test: In standard test, the user immediately inserts Test Cassette into Easy-11 and click "start test". Easy-11 automatically counts the time. • Quick test: Manually timing, then insert the test card into Easy-11, and click "Start Test". The instrument will read the results.
User interface	4 inch LCD Screen display	8 inch Color LCD touchscreen display
Barcode scanner (sample)	External Barcode Scanner (optional)	Same
Assay/instrument interface	Drawer	Same
Light Source	Laser Diode	LED Light
Power Supply	6v DC at 1 amp – supplied via 4 AA batteries or AC/DC Converter	AC100-240V
Dimensions	22.5 cm x 19 cm x 7 cm	24.5 cm x 27 cm x 16 cm
Weight	~1.5 lbs	~4.5 lbs

9. Test Principle
   Superbio Fentanyl Urine Detection Kit is a competitive and fluorescence immunochromatography assay, and uses fluorescence microspheres-labeled monoclonal antibody as the indicator marker to qualitatively detect fentanyl in human urine.

The test card 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. Both Fentanyl monoclonal antibody and rabbit IgG polyclonal antibody labeled with fluorescent microspheres were embedded on the conjugate pad. 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 fluorescently-labeled monoclonal antibody, the fluorescence rendering of 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 fluorescently-labeled monoclonal antibodies, the test line will have fluorescence and the result is negative. No matter whether the sample contains the corresponding analyte or not, the quality control area (C) will develop fluorescence, which is the criteria for judging whether the chromatography process is normal or not. The test card is tested by the Superbio Immunofluorescence Analyzer EASY-11 and the results are interpreted by the analyzer.

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, +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 runs per day for 10 days per device lot in a randomized order. Each device was read on one Superbio Immunofluorescence Analyzer EASY-11. The results obtained are summarized in the following tables.

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+	56-/4+	27-/33+	56+/4-	60+/0-	60+/0-	60+/0-
Lot 2	60-/0+	60-/0+	60-/0+	57-/3+	32-/28+	57+/3-	60+/0-	60+/0-	60+/0-
Lot 3	60-/0+	60-/0+	60-/0+	56-/4+	27-/33+	55+/5-	60+/0-	60+/0-	60+/0-

c. Stability

The devices are stable at 4-30 °C for 12 months based on the accelerated stability study at 45 °C. The real time stability study is ongoing.

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 (50ug/ml)	Nortriptyline (25ug/ml)
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 (35ug/ml)	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 (30ug/ml)	Quinine
Boric Acid (1%)	Isoproterenol	Ranitidine
Bupropion (50ug/ml)	Isoxsuprine	Riboflavin (7.5mg/dL)
Caffeine	Ketamine	Salicylic acid
Carbamazepine	Ketoprofen	Secobarbital
Chloral hydrate	Labetalol	Serotonin (5-Hydroxytyramine)
Chloramphenicol	Lidocaine (50ug/ml)	Sulfamethazine
Chlorothiazide	Loperamide	Sulindac
Chlorpromazine	Maprotiline (50ug/ml)	Tetrahydrocortisone 3-(β-Dglucuronide)
Cholesterol	Meperidine	Tetrahydrocortisone 3-acetate
Clomipramine (50ug/ml)	Meprobamate	Tetrahydrozoline
Clonidine	Methapyrilene (10ug/ml)	Thiamine
Cortisone	Methaqualone (50ug/ml)	Thioridazine
Cotinine	Methoxyphenamine	Triamterene
Creatinine	Metronidazole (300ug/ml)	Trifluoperazine
Cyclobenzaprine (10ug/ml)	N-Acetylprocainamide	Trimethoprim
Deoxycorticosterone	NaCl (4000mg/dL)	Tyramine
Desipramine (50ug/ml)	Nalidixic acid	Urea (2000mg/dL)
Dextromethorphan	Naloxone	Uric acid
Diclofenac	Naltrexone	Valproic acid (250ug/ml)
Diflunisal	Naproxen	Venlafaxine
Digoxin	Niacinamide	Verapamil
Diphenhydramine	Nicotine (10ug/ml)	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**
Norfentanyl	10000	0.01
Acetyl fentanyl	1.20	83.33

Acrylfentanyl	1.20	83.33
ω-1-Hydroxyfentanyl	20000	0.005
Isobutyryl fentanyl	1.50	66.67
Ocfentanil	1.50	66.67
Butyryl fentanyl	1.60	62.50
Furanyl fentanyl	1.75	57.14
Valeryl fentanyl	2.50	40.00
(±) β-hydroxythiofentanyl	2.80	35.71
4-Fluoro-isobutyrylfentanyl	3.00	33.33
Para-fluorobutyrylfentanyl (p-FBF)	3.00	33.33
Para-fluoro fentanyl	3.00	33.33
(±)-3-cis-methylfentanyl	5.00	20.00
Carfentanil	500	0.20
Sufentanil	625	0.16
Acetyl norfentanyl	10,000	0.01

The following opioids compounds were tested at a concentration of 100ug/mL (despropionyl fentanyl (4-ANPP) was tested at 50 ug/mL, norcarfentanil was tested at 5 ug/mL and remifentanil was tested at 10 ug/mL). Negative results were obtained for all these compounds. There is no cross-reactivity for these compounds using the Superbio Fentanyl Urine Detection Kit.

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	Alfentanil
Despropionyl fentanyl (4-ANPP) (50 ug/mL)	Norcarfentanil (5 ug/mL)
Norcarfentanil (10 ug/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 Superbio Fentanyl Urine Detection Kit 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	21	16
	Negative	7	17	13	3	0
Site 2	Positive	0	0	3	21	16
	Negative	7	17	13	3	0
Site 3	Positive	0	0	3	22	16
	Negative	7	17	13	2	0

Discordant Results

Operator	Sample Number	LC/MS Result	SUPERBIO Results
Site 1	FM015	0.984	Positive
Site 1	FM026	0.866	Positive
Site 1	FM058	0.921	Positive
Site 1	FM031	1.05	Negative
Site 1	FM051	1.18	Negative
Site 1	FM065	1.07	Negative
Site 2	FM012	0.833	Positive
Site 2	FM015	0.984	Positive
Site 2	FM026	0.866	Positive
Site 2	FM013	1.09	Negative
Site 2	FM074	1.1	Negative
Site 2	FM098	1.14	Negative
Site 3	FM012	0.833	Positive
Site 3	FM016	0.953	Positive
Site 3	FM032	0.815	Positive
Site 3	FM065	1.07	Negative
Site 3	FM091	1.12	Negative

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.