August 15, 2025

Healgen Scientific LLC
% Jenny Xia
Director
LSI International Inc
504E Diamond Ave., Suite H
Gaithersburg, Maryland 20877

Re: K251972
Trade/Device Name: Healgen® AccuFluor Fentanyl Fluorescence Immunoassay (FIA)Test Kit - Qualitative; Healgen® Immunofluorescence Analyzer (OG-H180)
Regulation Number: 21 CFR 862.3650
Regulation Name: Opiate test system
Regulatory Class: Class II
Product Code: DJG, KHO
Dated: June 26, 2025
Received: June 26, 2025

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: 2025.08.15 10:28:52 -04'00'

Joseph Kotarek
Branch Chief
Division of Chemistry and
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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)*
K251972

Device Name
Healgen® AccuFluor Fentanyl Fluorescence Immunoassay (FIA)Test Kit - Qualitative;
Healgen® Immunofluorescence Analyzer (OG-H180)

Indications for Use *(Describe)*
The Healgen® AccuFluor Fentanyl Fluorescence Immunoassay (FIA) Test Kit-Qualitative 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 Healgen® Immunofluorescence analyzer OG-H180. This in vitro diagnostic device is for prescription use only.

This assay provides only a preliminary analytical test result. A more specific alternate chemical method must be used to obtain a confirmed analytical result. Gas Chromatography-Mass Spectrometry (GC-MS) and Liquid Chromatography-Mass Spectrometry (LC-MS) are the preferred confirmatory methods. Clinical consideration and professional judgment should be applied to a Fentanyl test result, particularly when a preliminary positive result is obtained.

The Healgen® Immunofluorescence analyzer OG-H180 is a portable fluorescence instrument for in vitro diagnostic use only. The analyzer is designed to detect test results from in vitro diagnostic tests on clinical specimens. This analyzer can be used in a laboratory or 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.

510(k) SUMMARY

K251972

1. Date: August 12, 2025

2. Submitter: Healgen Scientific LLC.
3818 Fuqua Street
Houston, TX 77047

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: Healgen AccuFluor Fentanyl Fluorescence Immunoassay (FIA) Test Kit - Qualitative
Healgen Immunofluorescence Analyzer OG-H180

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:

BioSieve™ Fentanyl FIA Test Kit, K240124
BioSieve™ ToxiSmart FIA Reader, K240124

6. Indications for Use

Healgen AccuFluor Fentanyl Fluorescence Immunoassay (FIA) Test Kit - Qualitative 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 Healgen® Immunofluorescence analyzer OG-H180. This in vitro diagnostic device is for prescription use only.

This assay provides only a preliminary analytical test result. A more specific alternate chemical method must be used to obtain a confirmed analytical result. Gas Chromatography-Mass Spectrometry (GC-MS) and Liquid Chromatography-Mass Spectrometry (LC-MS) are the preferred confirmatory methods. Clinical consideration and professional judgment should be applied to a Fentanyl test result, particularly when a preliminary positive result is obtained.

The Healgen Immunofluorescence analyzer OG-H180 is a portable fluorescence instrument for in vitro diagnostic use only. The analyzer is designed to detect test results from in vitro diagnostic tests on clinical specimens. This analyzer can be used in a laboratory or point-of-care setting.

7. Device Description

The AccuFluor Fentanyl FIA Test Kit-Qualitative is a rapid fluorescence immunoassay based on the principle of competitive binding, which uses fluorescent microspheres-labeled antibody as the

indicator marker to qualitatively detect fentanyl in human urine. Drugs which may be present in the urine specimen compete against the drug conjugate for binding sites on the antibody.
During testing, a urine specimen migrates upward by capillary action. Fentanyl, if present in the urine specimen below 1.0 ng/mL, will not saturate the binding sites of antibody-coated particles in the test device. The antibody coated fluorescence particles will then be captured by immobilized Fentanyl conjugate, and the signal will be detected in the test line (T) region to show a negative result. The signal will not be detected in the test line (T) region if the Fentanyl level exceeds 1.0 ng/mL because all the binding sites for the anti-Fentanyl antibodies will be saturated and the result will show as positive. To serve as a procedural control, a signal will be detected at the control line (C) region indicating the proper volume of specimen has been added and membrane wicking has occurred. The test is interpreted by the Healgen® Immunofluorescence analyzer OG-H180 and the result will be interpreted by the analyzer.

8. Substantial Equivalence Information

A summary comparison of features of the Healgen AccuFluor Fentanyl Fluorescence Immunoassay (FIA) Test Kit - Qualitative and the predicate devices is provided in following table.

Table 1: Features Comparison of Healgen AccuFluor Fentanyl Fluorescence Immunoassay (FIA) Test Kit - Qualitative and the Predicate Devices

Item	Device	Predicate - K240124
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	Same
Platform Required	Immunofluorescence Analyzer	Same
Storage	2-30˚C	Same

Table 2: Instrument Similarities and Differences

Item	Device	Predicate - K240124
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	Competitive immunofluorescence immunoassay	Same
Calibration Check	A self-test card is supplied with the analyzer and used to check instrument functions including QR code recognition and test cassette scanning.	A Quality control test device is supplied with the Reader and used to check the Reader optics and calculation systems.
Test Modes	Standard test Non-standard test (Quick test).	Same
User interface	2.8 inch LCD Screen display	1.54 inch LCD Screen display
Light Source	LED Light	Same
Power Supply	Rechargeable 3.7V - 2200mA Li-ion Battery	Same
Dimensions	13.52 cm x 8.38 cm x 4.3 cm	12.45 cm x 7.25 cm x 4 cm
Weight	~0.54 lbs	~0.36 lbs

9. Test Principle

The AccuFluor Fentanyl FIA Test Kit-Qualitative uses the principle of competitive and fluorescence immunochromatography assay. 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 lgG polyclonal antibody. Both Fentanyl monoclonal antibody and rabbit lgG polyclonal antibody labeled with fluorescent microspheres are embedded on the conjugate pad. The labeled antibody will flow forward with the sample, when the urine sample is applied to the sample well of the test device. 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 signal 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 signal and the result is negative. The quality control area (C) will develop fluorescence signal, which is the criteria for judging whether the test process is normal or not. Signal intensity of fluorescence is detected by Healgen Immunofluorescence analyzer OG-H180.

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-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 replicates per day for 10 days using three device lots in a randomized order. Each device was read on one Healgen Immunofluorescence analyzer. 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+	57-/3+	22-/38+	60+/0-	60+/0-	60+/0-	60+/0-
Lot 2	60-/0+	60-/0+	60-/0+	57-/3+	24-/36+	60+/0-	60+/0-	60+/0-	60+/0-
Lot 3	60-/0+	60-/0+	60-/0+	56-/4+	23-/37+	60+/0-	60+/0-	60+/0-	60+/0-

c. Stability

The devices are stable at 2-30°C for 27 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 (100mg/dL)	Ethanol (1%)	Oxalic acid (100mg/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
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-D-glucuronide)

Cholesterol	Meperidine	Tetrahydrocortisone 3-acetate
Clomipramine	Meprobamate	Tetrahydrozoline
Clonidine	Methapyrilene	Thiamine
Cortisone	Methaqualone	Thioridazine
Cotinine	Methoxyphenamine	Triamterene
Creatinine	Metronidazole (300μg/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 (250μg/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.

Components	**Concentration (ng/mL)**	**Cross- Reactivity (%)**
Norfentanyl	30,000	0.003%
Carfentanil	8,000	0.013%
Sufentanil	50,000	0.002%
Cyclopropyl fentanyl	1	100%
Furanyl Fentanyl	10	10%
Para-fluorobutyryl fentanyl	10	10%
4-Fluoro-isobutyrylfentanyl	5	20%
O-Fluorofentanyl	10	10%
2'-Fluoro ortho-Fluorofenyanyl	10	10%
Valeryl Fentanyl	5	20%
(±) β-hydroxythiofentanyl	3	33.33%
Tetrahydrofuranyl fentanyl	1.56	64.10%
2-Thiofuranyl fentanyl	5	20%
Methoxyacetyl fentanyl	1.56	64.10%
4-methoxybutyryl fentanyl (para)	20	5%
N-methyl norfentanyl	20,000	0.005%
3',4'-dimethoxy Fentanyl	125	0.8%
Acetyl-α-methyl fentanyl	62.5	1.6%
4'-methyl acetyl fentanyl	125	0.8%
Benzyl fentanyl	125	0.8%
Meta-methoxy Furanyl fentanyl	100	1%
α-methyl fentanyl	62.5	1.6%
Para-fluoro fentanyl	1	100%
Ocfentanil	5	20%
Isobutyryl fentanyl	2.5	40%
Butyryl fentanyl	3	33.33%
Acetyl fentanyl	1	100%

Acrylfentanyl	0.9	111.11%
Risperidone	50,000	0.002%
9-Hydroxyrisperidone	10,000	0.01%
(±)-3-cis-methyl fentanyl	50	2%
Despropionyl fentanyl (4-ANPP)	7000	0.014%
ω-1-Hydroxyfentanyl	50,000	0.002%
Acetyl norfentanyl	> 100 µg/mL	<0.001%
Norcarfentanil	> 100 µg/mL	<0.001%
Remifentanil	> 100 µg/mL	<0.001%
Alfentanil	> 100 µg/mL	<0.001%

The following other Metabolites and opioids compounds were tested at a concentration of 100 µg/mL. Negative results were obtained for all these compounds. There is no cross-reactivity for these compounds using the Healgen AccuFluor Fentanyl Fluorescence Immunoassay (FIA) Test Kit.

6-Acetyl morphine	Ketamine	Noroxycodone
Amphetamine	Levorphanol	Oxycodone
Buprenorphine	Meperidine	Oxymorphone
Buprenorphineglucuronide	Methadone	Pentazocine (Talwin)
Codeine	Morphine	Pipamperone
Dextromethorphan	Morphine-3-glucuronide	Trazodone
Dihydrocodeine	Naloxone	Buspirone
EDDP	Naltrexone	Tapentadol
EMDP	Norbuprenorphine	Thioridazine
Fluoxetine	Norcodeine	Tilidine
Heroin	Norketamine	Tramadol
Hydrocodone	Normeperidine	Tramadol-O- Desmethyl
Hydromorphone	Normorphine	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 by three different operators using three device lots. 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 Healgen AccuFluor Fentanyl Fluorescence Immunoassay (FIA) Test 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/MS results. The results are presented in the tables below.

		Negative	Low Negative by LC-MS/MS (less than -50%)	Near Cutoff Negative by LC-MS/MS (Between -50% and cutoff)	Near Cutoff Positive by LC-MS/MS (Between the cutoff and +50%)	High Positive by LC-MS/MS (greater
Site 1	Positive	0	0	3	21	17
	Negative	7	19	11	2	0

Site 2	Positive	0	0	2	20	17
	Negative	7	19	12	3	0
Site 3	Positive	0	0	2	20	17
	Negative	7	19	12	3	0

Discordant Results

Site	Sample Number	LC-MS/MS Result	Result
Site 1	FENMCS079	0.802	+
Site 2	FENMCS070	0.841	+
Site 3	FENMCS036	0.916	+
Site 1, 2	FENMCS001	0.952	+
Site 1, 3	FENMCS066	0.976	+
Site 2, 3	FENMCS071	1.013	-
Site 1, 2	FENMCS051	1.092	-
Site 2, 3	FENMCS042	1.098	-
Site 1, 3	FENMCS028	1.113	-

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.