VivaChek Biotech (Hangzhou) Co., Ltd
℅ Jenny Xia
LSI International Inc
504E Diamond Ave., Suite H
Gaithersburg, Maryland 20877

Re: K241869
Trade/Device Name: BioSieve™ Fentanyl FIA Home Test Kit; BioSieve™ Fentanyl FIA Pro Test Kit; BioSieve™ Toxismart Reader
Regulation Number: 21 CFR 862.3650
Regulation Name: Opiate Test System
Regulatory Class: Class II
Product Code: NGL; KHO
Dated: June 27, 2024
Received: June 27, 2024

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: 2024.10.04 13:18:32 -04'00'

Joseph Kotarek, PhD
Toxicology 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)*
K241869

Device Name
BioSieve™ Fentanyl FIA Home Test Kit
BioSieve™ Fentanyl FIA Pro Test Kit
BioSieve™ Toxismart Reader

Indications for Use *(Describe)*

BioSieve™ Fentanyl FIA Home Test Kit is a fluorescence immunoassay (FIA) for the qualitative determination of fentanyl in human urine at a cutoff concentration of 1.0 ng/mL. The assay is intended for use with BioSieve™ Toxismart Reader.
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.

BioSieve™ Fentanyl FIA Pro Test Kit is a fluorescence immunoassay (FIA) for the qualitative determination of fentanyl in human urine at a cutoff concentration of 1.0 ng/mL. The assay is intended for use with BioSieve™ Toxismart Reader. It is for in vitro diagnostic use only.
The tests provide only preliminary results. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Gas Chromatography/Mass Spectrometry (GC/MS) or Liquid Chromatography/Tandem Mass Spectrometry (LC/MS-MS) is the preferred confirmatory method.
Clinical consideration and professional judgment should be exercised with any drug test result, particularly when the preliminary test result is positive.

BioSieve™ Toxismart Reader is a portable fluorescence instrument for in vitro diagnostic use only. The Reader is designed to perform in vitro diagnostic tests on urine specimens. This Reader is intended for OTC use.

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
K241869

1. Date: September 27, 2024

2. Submitter: VivaChek Biotech (Hangzhou) Co., Ltd.
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Yuhang Economy Development Zone
Hangzhou, Zhejiang, China 311100

3. Contact person: Jenny Xia
LSI International Inc.
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Telephone: 301-525-6856
Email:jxia@lsi-consulting.org

4. Device Name: BioSieve™ Fentanyl FIA Home Test Kit
BioSieve™ Fentanyl FIA Pro Test Kit
BioSieve™ Toxismart Reader

Classification: Class II

Product Code	Classification	CFR #	Panel
NGL	II	21 CFR § 862.3650 Opiate Test System	Toxicology
KHO	I	21 CFR § 862.2560 Fluorometer for clinical use	Clinical Chemistry

5. Predicate Devices: K240124
BioSieve™ Fentanyl FIA Test Kit
BioSieve™ Toxismart FIA Reader

6. Intended Use:
BioSieve™ Fentanyl FIA Home Test Kit is a fluorescence immunoassay (FIA) for the qualitative determination of fentanyl in human urine at a cutoff concentration of 1.0 ng/mL. The assay is intended for use with BioSieve™ Toxismart Reader.
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.

BioSieve™ Fentanyl FIA Pro Test Kit is a fluorescence immunoassay (FIA) for the qualitative determination of fentanyl in human urine at a cutoff concentration of 1.0 ng/mL. The assay is intended for use with BioSieve™ Toxismart Reader.
It is for in vitro diagnostic use only.
The tests provide only preliminary results. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Gas Chromatography/Mass Spectrometry (GC/MS) or Liquid Chromatography/Tandem Mass Spectrometry (LC/MS-MS) is the preferred confirmatory method.
Clinical consideration and professional judgment should be exercised with any drug test result, particularly when the preliminary test result is positive.

BioSieve™ Toxismart Reader is a portable fluorescence instrument for in vitro diagnostic use only. The Reader is designed to perform in vitro diagnostic tests on urine specimens. This Reader is intended for OTC use.

7. Device Description:

BioSieve™ Fentanyl FIA Home Test Kit and BioSieve™ Fentanyl FIA Pro Test Kit are immunoassays intended for the qualitative detection of fentanyl in human urine. These candidate test kits are the same physical devices as the predicate device cleared in K240124. Each BioSieve™ Fentanyl Test Kit consists of a test cassette and a package insert. Each test cassette is sealed with sachets of desiccant in an aluminum pouch.

BioSieve™ Toxismart Reader is a portable fluorescence instrument that is intended for use with the BioSieve™ Fentanyl FIA Home Test Kit and BioSieve™ Fentanyl FIA Pro Test Kit. The Reader scans the test cassettes included in the Test Kits and displays the results.

8. Substantial Equivalence Information

Table 1: Features Comparison of BioSieve™ Fentanyl FIA Home/Pro Test Kit to the Predicate Device

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	Over-The-Counter Use	For prescription use
Configurations	Cassette	Same
Storage	2-30˚C	Same

Table 2: Features Comparison of BioSieve™ Toxismart Reader to the Predicate Device

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 Quality control test device is supplied with the Reader and used to check the Reader optics and calculation systems.	Same
Development Modes	One basic assay development mode: • Standard test: In standard test, the user inserts into the Reader immediately after adding the sample, and the Reader will display the test result when the countdown is finished.	Two basic assay development modes: • Standard test: In standard test, the user inserts into the Reader immediately after adding the sample, and the Reader will display the test result when the countdown is finished. • Quick test: In the quick test, the user inserts into the Reader after the reaction time is completed, and the Reader will display test results in a few seconds.
User interface	1.54 inch LCD Screen display	Same

Barcode scanner (sample)	Not equipped with a barcode scanner	Same
Assay/instrument interface	Drawer	Same
Light Source	LED Light	Same
Power Supply	Powered by a 3.7V lithium-ion battery Two charging methods: 1.Type C & USB 2 in 1 cable (computer charging) 2.Type C & USB 2 in 1 cable with the AC adapter (wall charging) Input: 100-240V~, 50/60Hz, 0.2A Max; Output: 5.0V⎓, 1.0A	Same
Dimensions	12.45 cm x 7.25 cm x 4 cm	Same
Weight	~0.36 lbs	Same
Bluetooth	Disabled	Enabled

9. Test Principle

   BioSieve™ Fentanyl Test Kit 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 were 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 fluorescent-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 BioSieve™ ToxiSmart Reader.

10. Performance Characteristics

1. Analytical Performance: See analytical performance in predicate K240124.
2. Comparison Studies: See studies in predicate K240124
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	0.248	0	20	100
-50% Cutoff	20	0.504	0	20	100
-25% Cutoff	20	0.745	0	20	100
+25% Cutoff	20	1.267	20	0	100
+50% Cutoff	20	1.508	20	0	100
+75% Cutoff	20	1.768	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 8.

4. Clinical Studies

   Not applicable.

11. Conclusion

Based on the test principle and performance characteristics of the device, it's concluded that BioSieve™ Fentanyl FIA Home Test Kit and BioSieve™ Fentanyl FIA Pro Test Kit and BioSieve™ Toxismart Reader are substantially equivalent to the predicate.