510(k) SUMMARY
K241869

1. Date: September 27, 2024

2. Submitter: VivaChek Biotech (Hangzhou) Co., Ltd.
Level 2, Block 2, 146 East Chaofeng Rd.
Yuhang Economy Development Zone
Hangzhou, Zhejiang, China 311100

3. Contact person: Jenny Xia
LSI International Inc.
504 East Diamond Ave., Suite H
Gaithersburg, MD 20877
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.