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

Re: K231978
Trade/Device Name: BioSieve™ Marijuana Test Panel 50; BioSieve™ Marijuana Test Strip 50; BioSieve™ Dx Marijuana Test Strip 20; BioSieve™ Dx Marijuana Test Strip 50; BioSieve™ Dx Marijuana Test Panel 20; BioSieve™ Dx Marijuana Test Panel 50
Regulation Number: 21 CFR 862.3870
Regulation Name: Cannabinoid Test System
Regulatory Class: Class II
Product Code: NFW
Dated: June 27, 2023
Received: July 3, 2023

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,

Joseph A. Kotarek -S
Digitally signed by Joseph A. Kotarek -S
Date: 2023.08.31 16:55:57 -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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K231978

Device Name
BioSieve™ Dx Marijuana Test Panel 20; BioSieve™ Dx Marijuana Test Panel 50
BioSieve™ Dx Marijuana Test Strip 20
BioSieve™ Dx Marijuana Test Strip 50

Indications for Use *(Describe)*
BioSieve™ Dx Marijuana Test Panel 20 is competitive binding, lateral flow immunochromatographic assay for qualitative detection of Marijuana in human urine at the cutoff concentrations of 20 ng/mL.
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.
For in vitro diagnostic use only.

BioSieve™ Dx Marijuana Test Strip 20 is competitive binding, lateral flow immunochromatographic assay for qualitative detection of Marijuana in human urine at the cutoff concentrations of 20 ng/mL.
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.
For in vitro diagnostic use only.

BioSieve™ Dx Marijuana Test Panel 50 is competitive binding, lateral flow immunochromatographic assay for qualitative detection of Marijuana in human urine at the cutoff concentrations of 50 ng/mL.
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.
For in vitro diagnostic use only.

BioSieve™ Dx Marijuana Test Strip 50 is competitive binding, lateral flow immunochromatographic assay for qualitative detection of Marijuana in human urine at the cutoff concentrations of 50 ng/mL.
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.
For in vitro diagnostic use only.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K231978

Device Name
BioSieve™ Marijuana Test Panel 50
BioSieve™ Marijuana Test Strip 50

Indications for Use *(Describe)*
BioSieve™ Marijuana Test Panel 50 is competitive binding, lateral flow immunochromatographic assay for qualitative detection of Marijuana in human urine at the cutoff concentrations of 50 ng/mL.
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.
For in vitro diagnostic use only.

BioSieve™ Marijuana Test Strip 50 is competitive binding, lateral flow immunochromatographic assay for qualitative detection of Marijuana in human urine at the cutoff concentrations of 50 ng/mL.
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.
For in vitro diagnostic use only.

Type of Use *(Select one or both, as applicable)*

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510(k) SUMMARY

K231978

1 Date August 31, 2023

2 Submitter VivaChek Biotech (Hangzhou) Co., Ltd.
Level 2, Block 2, 146 East Chaofeng Rd.
Hangzhou, China

3 Contact Person Joe Shia
LSI International Inc.
504 East Diamond Ave., Suite J
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Telephone: 240-505-7880
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4 Device Name BioSieve™ Dx Marijuana Test Panel 20
BioSieve™ Dx Marijuana Test Panel 50
BioSieve™ Dx Marijuana Test Strip 20
BioSieve™ Dx Marijuana Test Strip 50
BioSieve™ Marijuana Test Panel 50
BioSieve™ Marijuana Test Strip 50

5 Classification Class II

Product Code Target Drug	Regulation Section	Panel
NFW Cannabinoids	862.3870, Cannabinoids Test System	Toxicology

6. Predicate Device BIOEASY Marijuana Test Dip Card and BIOEASY Marijuana Test Strip **(**K192301)

7. Intended Use

BioSieve™ Dx Marijuana Test Panel 20 is competitive binding, lateral flow immunochromatographic assay for qualitative detection of Marijuana in human urine at the cutoff concentrations of 20 ng/mL. 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.

For in vitro diagnostic use only.

BioSieve™ Dx Marijuana Test Panel 50 is competitive binding, lateral flow immunochromatographic assay for qualitative detection of Marijuana in human urine at the cutoff concentrations of 50 ng/mL. 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.

For in vitro diagnostic use only.

BioSieve™ Dx Marijuana Test Strip 20 is competitive binding, lateral flow immunochromatographic assay for qualitative detection of Marijuana in human urine at the cutoff concentrations of 20 ng/mL. 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.
For in vitro diagnostic use only.

BioSieve™ Dx Marijuana Test Strip 50 is competitive binding, lateral flow immunochromatographic assay for qualitative detection of Marijuana in human urine at the cutoff concentrations of 50 ng/mL. 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.
For in vitro diagnostic use only.

BioSieve™ Marijuana Test Panel 50 is competitive binding, lateral flow immunochromatographic assay for qualitative detection of Marijuana in human urine at the cutoff concentrations of 50 ng/mL. 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.
For in vitro diagnostic use only.

BioSieve™ Marijuana Test Strip 50 is competitive binding, lateral flow immunochromatographic assay for qualitative detection of Marijuana in human urine at the cutoff concentrations of 50 ng/mL. 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.
For in vitro diagnostic use only.

8. Device Description

The BioSieve™ Marijuana Test Panel (Strip) and the BioSieve™ Dx Marijuana Test Panel (Strip) tests are immunochromatographic assays that use a lateral flow system for the qualitative detection of Marijuana in human urine. The products are single-use in vitro diagnostic devices. Each test kit contains a Test Device and a package insert. Each test device is sealed with a desiccant in an aluminum pouch.

9. Substantial Equivalence Information

Item	**Proposed Device**	**Predicate (K192301)**
Indication(s) for use	For the qualitative determination of marijuana in human urine.	Same

Methodology	Competitive binding, lateral flow immunochromatographic assay based on antigen-antibody reaction	Same
Type of Test	Qualitative	Same
Specimen Type	Human urine	Same
Calibrator and Cut-Off Values	11-Nor-△9-THC-9-COOH 20 ng/mL or 50 ng/mL	Same 50 ng/mL
Configurations	Strip and Panel	Same
Intended Use	Prescription Use and over-the-counter use	Over-the-counter

10. Test Principle

The BioSieve™ Marijuana Test Panel and the BioSieve™ Marijuana Test Strip tests are rapid tests for the qualitative detection of marijuana in urine samples. They are lateral flow chromatographic immunoassay. When urine sample is added to the device, urine is absorbed into the test strip and migrates upwards by capillary action. If the concentration of target drug presented in the urine sample is below the cutoff level, the target drug will not saturate the binding sites of its specific monoclonal antibody-coated particles. The antibody-coated particles will then be captured by immobilized drug-conjugate and a visible colored band will be formed on the test line region. If the concentration of target is beyond the cutoff level, the target drug will saturate the binding sites of its specific monoclonal antibody-particles, thus the antibody-coated particles will not be captured by immobilized drug-conjugate hence no colored band will be formed on the test line region.

A band should be formed on the control line region regardless of the presence of target drug or metabolite in the sample to indicate that the tests have been performed properly.

11. 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, cutoff, +25% cut off, +50% cut off, +75% cut off and +100% cut off at three different testing sites. Samples with concentration of -100% cutoff were drug-free urines samples. Other samples were prepared by spiking 11-Nor-△9-THC-9-COOH in drug-free urine samples. Each 11-Nor-△9-THC-9-COOH concentration was confirmed by LC/MS. For each concentration, tests were performed two runs per day at each site for each lot for 10 days. The results obtained are summarized in the following tables:

For Strip Format of 20 ng/mL Cut-off:

Result / drug	-100% cut off	-75% cut off	-50% cut off	-25% cut off	cut off	+25% cut off	+50% cut off	+75% cut off	+100% cut off
Lot 1	60-/0+	60-/0+	60-/0+	42-/18+	32+/28-	46+/14-	60+/0-	60+/0-	60+/0-
Lot 2	60-/0+	60-/0+	60-/0+	43-/17+	35+/25-	42+/18-	60+/0-	60+/0-	60+/0-
Lot 3	60-/0+	60-/0+	60-/0+	41-/19+	33+/27-	45+/15-	60+/0-	60+/0-	60+/0-

For Panel Format 20 ng/mL Cut-off:

Result / drug	-100% cut off	-75% cut off	-50% cut off	-25% cut off	cut off	+25% cut off	+50% cut off	+75% cut off	+100% cut off
Lot 1	60-/0+	60-/0+	60-/0+	43-/17+	34+/26-	44+/16-	60+/0-	60+/0-	60+/0-
Lot 2	60-/0+	60-/0+	60-/0+	44-/16+	35+/25-	46+/14-	60+/0-	60+/0-	60+/0-
Lot 3	60-/0+	60-/0+	60-/0+	43-/17+	37+/23-	45+/15-	60+/0-	60+/0-	60+/0-

For Strip Format of 50 ng/mL Cut-off:

Result / drug	-100% cut off	-75% cut off	-50% cut off	-25% cut off	cut off	+25% cut off	+50% cut off	+75% cut off	+100% cut off
Lot 1	60-/0+	60-/0+	60-/0+	60-/0+	24-/36+	60+/0-	60+/0-	60+/0-	60+/0-
Lot 2	60-/0+	60-/0+	60-/0+	60-/0+	22-/38+	60+/0-	60+/0-	60+/0-	60+/0-
Lot 3	60-/0+	60-/0+	60-/0+	60-/0+	23-/37+	60+/0-	60+/0-	60+/0-	60+/0-

For Panel Format 50 ng/mL Cut-off:

Result / drug	-100% cut off	-75% cut off	-50% cut off	-25% cut off	cut off	+25% cut off	+50% cut off	+75% cut off	+100% cut off
Lot 1	60-/0+	60-/0+	60-/0+	60-/0+	30-/30+	60+/0-	60+/0-	60+/0-	60+/0-
Lot 2	60-/0+	60-/0+	60-/0+	60-/0+	26-/34+	60+/0-	60+/0-	60+/0-	60+/0-
Lot 3	60-/0+	60-/0+	60-/0+	60-/0+	28-/32+	60+/0-	60+/0-	60+/0-	60+/0-

The following cutoff values are verified:

Test Device	**Cut-off values**
BioSieve™ Marijuana Test Panel	20 or 50 ng/mL
BioSieve™ Marijuana Test Strip	20 or 50 ng/mL

b. Linearity

Not applicable

c. Stability

The devices are stable at 4-30℃ for 24 months based on accelerated and real time stability studies.

d. Interference

Potential interfering substances were added to drug-free urine sample and samples with target drugs of -25% cutoff and +25% cutoff level and tested with 50ng/mL cut-off strip and panel devices. Potential interfering substances were added to drug-free urine sample and samples with target drugs of -50% cutoff and +50% cutoff level and tested with 20ng/mL cut-off strip and panel devices.

Compounds that show no interference at a concentration of 100μg/mL (albumin was tested at 100 mg/dL and ethanol was tested at 1%) are summarized in the following table.

Acetaminophen	β-Estradiol	Oxalic acid
Acetophenetidin	Erythromycin	Oxolinic acid
N-Acetylprocainamide	Ethanol (1%v/v)	Oxymetazoline

Acetylsalicylic acid	Fenoprofen	Papaverine
Albumin (100 mg/dL)	Furosemide	Penicillin G
Aminopyrine	Gentisic acid	Perphenazine
Amoxicillin	Hemoglobin	Phenelzine
Ampicillin	Hydralazine	Prednisone
Apomorphine	Hydrochlorothiazide	(±)-Propranolol
Ascorbic acid	Hydrocortisone	Pseudoephedrine
Aspartame	O-Hydroxyhippuric acid	Quinine
Atropine	3-Hydroxytyramine	Ranitidine
Benzilic acid	Ibuprofen	Salicylic acid
Benzoic acid	Isoproterenol	Serotonin (5- Hydroxytyramine)
Bilirubin	Isoxsuprine	Sulfamethazine
Chloral hydrate	Ketamine	Sulindac
Chloramphenicol	Ketoprofen	Tetrahydrocortisone 3-(β-Dglucuronide)
Chlorothiazide	Labetalol	Tetrahydrocortisone 3-acetate
Chlorpromazine	Loperamide	Tetrahydrozoline
Cholesterol	Meperidine	Thiamine
Clonidine	Meprobamate	Thioridazine
Cortisone	Methoxyphenamine	Triamterene
(-)-Cotinine	Nalidixic acid	Trifluoperazine
Creatinine	Naloxone	Trimethoprim
Deoxycorticosterone	Naltrexone	DL-Tryptophan
Dextromethorphan	Naproxen	Tyramine
Diclofenac	Niacinamide	DL-Tyrosine
Diflunisal	Nifedipine	Uric acid
Digoxin	Norethindrone	Verapamil
Diphenhydramine	Noscapine	Zomepirac
Ecgonine methyl ester	(±)-Octopamine	

e. Specificity

To test the specificity, drug metabolites and other components that are likely to cross-react in urine samples were spiked into drug-free urine. These urine samples were tested using three lots of each device.

Percent cross-reactivity, provided in the below table, was calculated as the cutoff concentration divided by the concentration of analyte tested that yielded a positive result, multiplied by 100; compounds that did not yield a positive result at the highest concentration tested have relative cross reactivity results represented by a dash in the table below:

THC(Cannabinoids) (11-nor-Δ^9-THC-9-COOH, Cut-off = 20 ng/mL)	**Result**	**% Cross-Reactivity**
11-nor-Δ^9-THC-9-COOH	20	100%
11-Hydroxy-Δ^9-Tetrahydrocannabinol	2000	1%

11-Nor-Δ^8-Tetrahydrocannabinol-9-COOH	20	100%
Cannabinol	100000	--
Δ^8-Tetrahydrocannabinol	6000	0.5%
Δ^9-Tetrahydrocannabinol	6000	0.5%
Cannabidiol	100000	--
11-Nor-Δ^9-THC-carboxy glucuronide	40	50%
(-)-11-nor-9-carboxy-Δ^9-THC	20	100%

THC(Cannabinoids) (11-nor-Δ9-THC-9-COOH, Cut-off = 50 ng/mL)	**Result**	**% Cross-Reactivity**
11-nor-Δ^9-THC-9-COOH	50	100%
11-Hydroxy-Δ^9-Tetrahydrocannabinol	5000	1%
11-Nor-Δ^8-Tetrahydrocannabinol-9-COOH	50	100%
Cannabinol	100000	--
Δ^8-Tetrahydrocannabinol	15000	0.5%
Δ^9-Tetrahydrocannabinol	15000	0.5%
Cannabidiol	100000	--
11-Nor-Δ^9-THC-carboxy glucuronide	100	50%
(-)-11-nor-9-carboxy-Δ^9-THC	50	100%

f. Effect of Urine Specific Gravity and Urine pH

To investigate the effect of urine specific gravity, urine samples with specific gravity from 1.000 to 1.035 were spiked with target drugs at +25% cutoff and -25% cutoff levels for the 50 ng/mL cut-off devices. And the same urine specific gravity samples were spiked with target drugs at +50% cutoff and -50% cutoff levels for the 20 ng/mL cut-off devices. Three Operators tested each sample using test devices from three different lots. The results were all positive for samples at +25% cutoff or +50% cutoff and all negative for samples at -25% cutoff or -50% cutoff, indicating that urine specific gravity between 1.000 and 1.035 has no effect on the accuracy and precision of the test devices.

To investigate the effect of urine pH, urine samples with pH value from 4 to 9 were spiked with target drugs at +25% cutoff and -25% cutoff levels for the 50 ng/mL cut-off devices. And the same urine pH samples were spiked with target drugs at +50% cutoff and -50% cutoff levels for the 20 ng/mL cut-off devices. Three Operators tested each sample using test devices from three different lots. The results were all positive for samples at +25% or +50% cutoff and all negative for samples at -25% or -50% cutoff, indicating that urine pH value between 4.0 and 9.0 has no effect on the accuracy and precision of the test device.

2. Comparison Studies

The method comparison studies for BioSieve™ Marijuana Test Panel and BioSieve™ Marijuana Test Strip were performed with six operators. Operators ran 80 (40 negative and 40 positive) unaltered

urine samples. The samples were blind labeled and compared to LC/MS results. The results are presented in the table below:

For BioSieve™ Dx Marijuana Test Strip 20

		Drug-Free	Low Negative by LC-MS/MS (less than -50%)	Near Cutoff Negative by LC-MS/MS (Between -50% and the Cutoff)	Near Cutoff Positive by LC-MS/MS (Between the cutoff and +50%)	High Positive by LC-MS/MS (greater than +50%)
Operator A	Positive	0	0	1	17	22
	Negative	10	16	13	1	0
Operator B	Positive	0	0	2	16	22
	Negative	10	16	12	2	0
Operator C	Positive	0	0	2	16	22
	Negative	10	16	12	2	0

Discordant Results:

Operator	Sample Number	LC/MS Result (ng/mL)	BioSieve™ Result
Operator A	22181	19.6	+
Operator B	22181	19.6	+
Operator B	22042	19.5	+
Operator C	22005	19.3	+
Operator C	22181	19.6	+
Operator A	22006	21.5	-
Operator B	22241	23.1	-
Operator B	22279	23.7	-
Operator C	22006	21.5	-
Operator C	22161	23.2	-

For BioSieve™ Dx Marijuana Test Panel 20

		Drug-Free	Low Negative by LC-MS/MS (less than -50%)	Near Cutoff Negative by LC-MS/MS (Between -50% and the Cutoff)	Near Cutoff Positive by LC-MS/MS (Between the cutoff and +50%)	High Positive by LC-MS/MS (greater than +50%)
Operator A	Positive	0	0	2	16	22
	Negative	10	16	12	2	0
Operator B	Positive	0	0	2	17	22
	Negative	10	16	12	1	0
Operator C	Positive	0	0	1	16	22

	Negative	10	16	13	2	0

Discordant Results:

Operator	Sample Number	LC/MS Result (ng/mL)	BioSieve™ Result
Operator D	22071	19.3	+
Operator D	22073	19.6	+
Operator E	22071	19.3	+
Operator E	22204	19.5	+
Operator F	22073	19.6	+
Operator D	22205	23.7	-
Operator D	22302	21.5	-
Operator E	22302	21.5	-
Operator F	22016	23.2	-
Operator F	22302	21.5	-

For BioSieve™ Marijuana Test Strip 50

		Drug-Free	Low Negative by LC-MS/MS (less than -50%)	Near Cutoff Negative by LC-MS/MS (Between -50% and the Cutoff)	Near Cutoff Positive by LC-MS/MS (Between the cutoff and +50%)	High Positive by LC-MS/MS (greater than +50%)
Operator A	Positive	0	0	2	16	22
	Negative	10	16	12	2	0
Operator B	Positive	0	0	2	16	22
	Negative	10	16	12	2	0
Operator C	Positive	0	0	1	16	22
	Negative	10	16	13	2	0

Discordant Results:

Operator	Sample Number	LC/MS Result (ng/mL)	BioSieve™ Result
Operator A	22172	49.2	+
Operator A	22318	46.8	+
Operator B	22115	47.8	+
Operator B	22172	49.2	+
Operator C	22172	49.2	+
Operator A	22013	50.5	-
Operator A	22237	50.9	-
Operator B	22237	50.9	-
Operator B	22284	53.9	-
Operator C	22013	50.5	-
Operator C	22237	50.9	-

For BioSieve™ Marijuana Test Panel 50

		Drug-Free	Low Negative by LC-MS/MS (less than -50%)	Near Cutoff Negative by LC-MS/MS (Between -50% and the Cutoff)	Near Cutoff Positive by LC-MS/MS (Between the cutoff and +50%)	High Positive by LC-MS/MS (greater than +50%)
Operator A	Positive	0	0	1	16	22
	Negative	10	16	13	2	0
Operator B	Positive	0	0	1	16	22
	Negative	10	16	13	2	0
Operator C	Positive	0	0	2	16	22
	Negative	10	16	12	2	0

Discordant Results:

Operator	Sample Number	LC/MS Result (ng/mL)	BioSieve™ Result
Operator D	22217	46.8	+
Operator E	22206	49.2	+
Operator F	22017	47.8	+
Operator F	22206	49.2	+
Operator D	22137	50.9	-
Operator D	22152	53.9	-
Operator E	22103	50.5	-
Operator E	22137	50.9	-
Operator F	22103	50.5	-
Operator F	22152	53.9	-

Lay-user study:

A lay user study was performed at three intended user sites with 280 lay persons for the devices. The lay users had diverse educational and professional backgrounds and ranged in age from 18 to > 50 years. Urine samples were prepared at the following concentrations; negative, +/-75%, +/-50%, +/-25% of the 50 ng/mL cutoff by spiking 11-Nor-∆9-THC-9-COOH into drug free-pooled urine specimens. The concentrations of the samples were confirmed by LC/MS. Each sample was aliquoted into individual containers and blind-labeled. Each participant was provided with the package insert, 1 blind labeled sample and a device. Each device was tested. Summary results are shown below.

The results summary for strip format:

% of Cutoff	**Number of samples**	**Drug Concentration by LC/MS/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	12	0	20	100
-50% Cutoff	20	24.5	0	20	100
-25% Cutoff	20	36.2	1	19	95
+25% Cutoff	20	60.9	20	0	100
+50% Cutoff	20	76.2	20	0	100
+75% Cutoff	20	90.5	20	0	100

The results summary for panel format:

% of Cutoff	**Number of samples**	**Drug Concentration by LC/MS/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	12	0	20	100
-50% Cutoff	20	24.5	0	20	100
-25% Cutoff	20	36.2	1	19	95
+25% Cutoff	20	60.9	19	1	95
+50% Cutoff	20	76.2	20	0	100
+75% Cutoff	20	90.5	20	0	100

Participants were given surveys on the ease of understanding the instruction for use. All participants indicated that the device instruction is easy to understand and follow. A Flesch-Kincaid reading analysis was performed on each package insert and the scores revealed a reading Grade Level of 7.

Clinical Studies:

Not applicable.

12. Conclusion

Based on the test principle and performance characteristics of the device including precision, cut-off, interference, specificity, method comparison and lay-user studies of the devices, it's concluded that BioSieve™ Marijuana Test Panel and BioSieve™ Marijuana Test Strip are substantially equivalent to the predicate device.