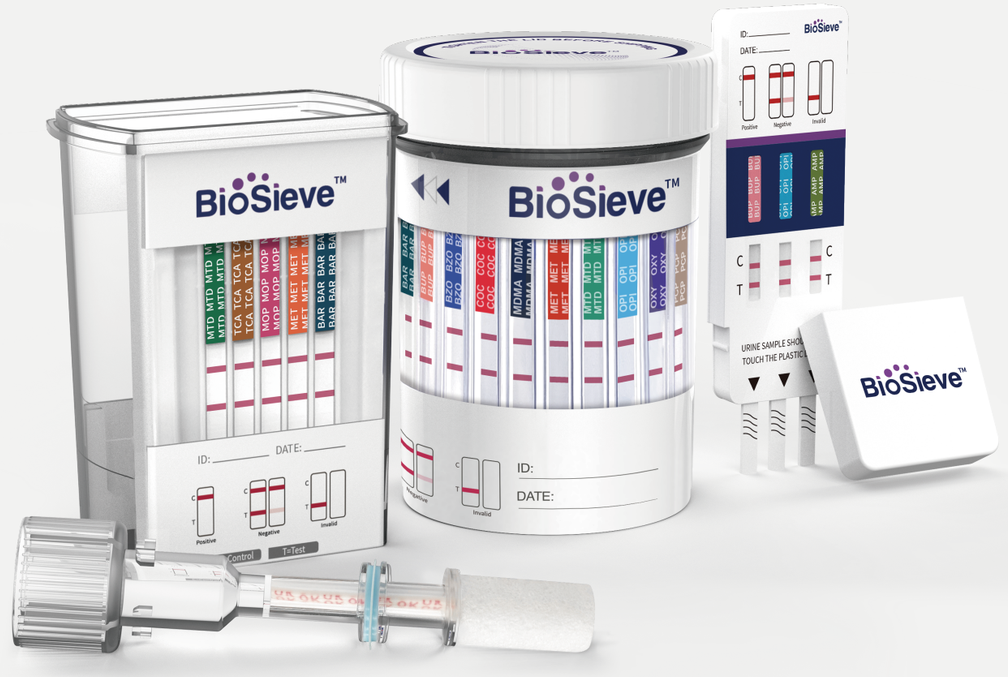
BioSieve™ / VivaChek

Number:
Effective Date:

VivaChek Diagnostics, Inc.
1401 21st St. STER, Sacramento, CA
TEL: 224-360-7669
E-mail: info@vivachek.com
Website: https://vivachekdx.com

VivaChek



BioSieve™

Multi-Drug Test

About VivaChek

The Global leader in Blood Glucose Meter Innovation and Manufacturing is creating its base in the U.S with launch of VivaChek USA based in Sacramento, CA. VivaChek specializes in OEM, ODM and Custom Manufacturing of various Drugs of Abuse Tests in various standard and tailor-made configurations.

We aspire to become a trusted partner in manufacturing for the U.S to cater the Professional and OTC market for DOA products with strategically placed warehouses in the U.S.

Milestones

2023
VivaChek Diagnostics Inc. USA Established.
Products Available in 120+ countries,
150+ patents

2022
DOA urine cup of 15 Drugs: 510(k) cleared,
CLIA Waived & OTC approved

2021
Revenue reached 180+ million USD

2019
Blood Ketone+ BGM dual system
510(k) cleared

2017
1st BGM 510(k) cleared

2013
VivaChek established

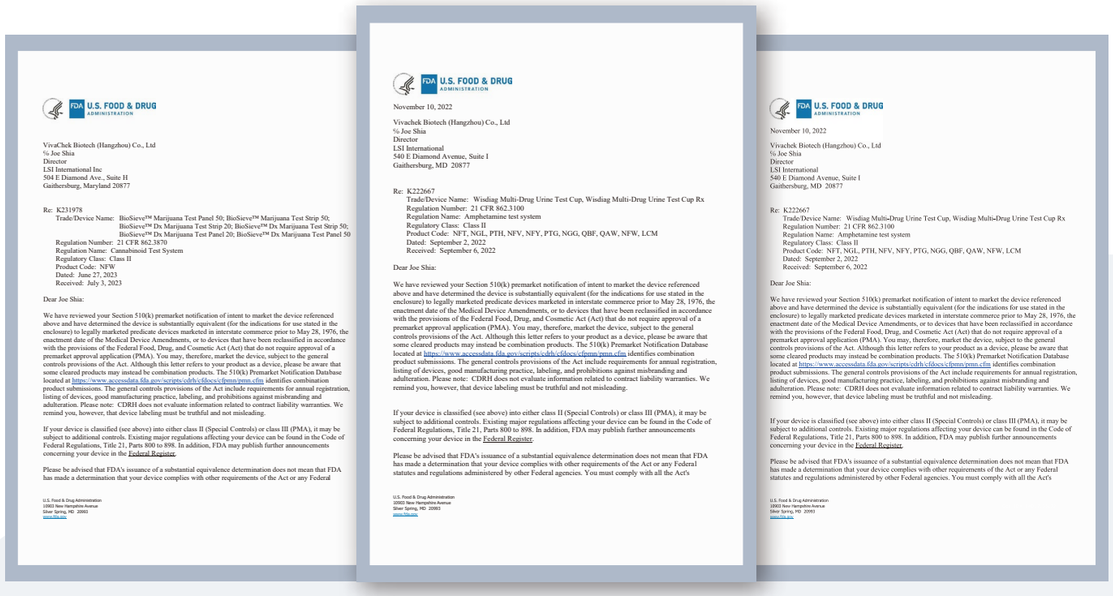
Product Catalogue

Urine Drug Test

510 (k) Cleared, CLIA Waived & OTC Approved

- Multi-Drug Urine Test Cup/Panel
- Marijuana Single Dip Panel/Strip

- Any combination up to 15 drugs
- Convenient & Reliable
- Results within 5 minutes
- Long expiration dating



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

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

November 10, 2022

Vivachek Biotech (Hangzhou) Co., Ltd
℅ Joe Shia
Director
LSI International
540 E Diamond Avenue, Suite I
Gaithersburg, MD 20877

Re: K222667
Trade/Device Name: Wisdiag Multi-Drug Urine Test Cup, Wisdiag Multi-Drug Urine Test Cup Rx
Regulation Number: 21 CFR 862.3100
Regulation Name: Amphetamine test system
Regulatory Class: Class II
Product Code: NFT, NGL, PTH, NFV, NFY, PTG, NGG, QBF, QAW, NFW, LCM
Dated: September 2, 2022
Received: September 6, 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.

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01

Multi-Drug Urine Test Cup

- 510 (k) Cleared, CLIA Waived & OTC Approved

Products Information

Drug Test	Cut-off (ng/mL)
2-ethylidene-1,5dimethyl-3,3-diphenylpyrrolidine (EDDP)	300
Amphetamine(AMP)	500,1000
Buprenorphine(BUP)	10
Cocaine (COC)	150, 300
Marijuana (THC)	50
Methylenedioxymethamphetamine (MDMA)	500
Methadone(MTD)	300
Methamphetamine(MET)	500, 1000
Morphine(MOP)	300
Morphine(OPI)	2000
Nortriptyline (TCA)	1000
Oxazepam(BZO)	300
Opiate (OPI)	2000
Oxycodone (OXY)	100
Phencyclidine (PCP)	25
Propoxyphene(PPX)	300
Secobarbital (BAR)	300

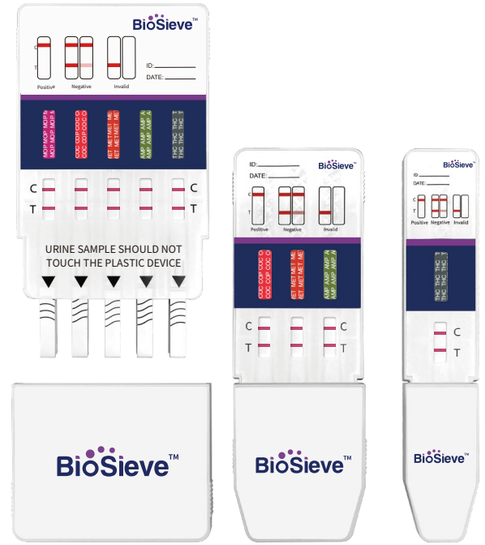
02

Multi-Drug Urine Test Panel

- 510 (k) Cleared, CLIA Waived & OTC Approved

Products Information

Drug Test	Cut-off (ng/mL)
2-ethylidene-1,5-dimethyl-3, 3-diphenylpyrrolidine (EDDP)	300
Amphetamine (AMP)	500, 1000
Barbiturates (BAR)	300
Buprenorphine (BUP)	10
Cocaine (COC)	150, 300
Ecstasy (MDMA)	500
Marijuana (THC)	50
Methadone (MTD)	300
Methamphetamine (MET)	500, 1000
Morphine (MOP/OPI)	300, 2000
Nortriptyline (TCA)	1000
Oxazepam (BZO)	300
Oxycodone (OXY)	100
Phencyclidine (PCP)	25
Propoxyphene (PPX)	300



03

Marijuana Single Dip Panel/Strip

Product Information

Drug Test

Marijuana (THC)

Cut-off (ng/mL)

20 - 510 (k) Cleared, CLIA Moderate
50 - 510 (k) Cleared, CLIA Waived & OTC Approved

BioSieve

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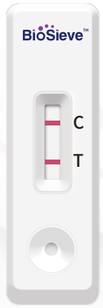
Urine Drug Test - FUO

Products Information

Drug Test	Cut-off (ng/mL)
6-MAM	10
7-Aminoclonazepam (7-ACL)	100, 200, 300
AB-Pinaca (ABP)	10
Acetaminophen (ACE)	5000
Alprazolam (ALP)	100
Caffeine (CAF)	1000
Cathine (CAT)	150
Carfentanyl (CFYL)	500
Clonazepam (CLO)	150, 400
Cannabinol (CNB)	500
Cotinine (COT)	10, 50, 100, 200
Diazepam (DIA)	300
Ethyl Glucuronide (EtG)	500, 1000
Fentanyl (FYL)	10, 20
Gabapentin (GAB)	2000
γ-Hydroxybutyric acid (GHB)	10 μg/mL
Synthetic Marijuana (K2)	25, 30, 50
Ketamine (KET)	100, 300, 500, 1000
LSD	20
Methcathinone (MCAT)	500
Tenamfetamine (MDA)	500
MDPV	1000
Mephedrone HCl (MEP)	100
Methylphenidate (MPD)	300, 1000
Meperidine (MPRD)	100
Methaqualone (MQL)	300
Pregabalin (PGB)	50000
Tramadol (TML)	100,300
Tropicmide (TRO)	350
Trazodone (TZD)	200
Urine Alcohol	0.02%
Xylazine (XYL)	500
Zolpidem (ZOL)	50
α-Pyrrolidinovalerophenone (α-PVP)	300, 500, 1000

05

Oral Fluid Drug Test - FUO



Products Information

Drug Test	Cut-off (ng/mL)
AB-Pinaca (ABP)	10
Amphetamine (AMP)	300, 500
Benzodiazepines (BZO)	100, 200
Cannabinoids (THC)	25, 50
Clonazepam (CLO)	100
Cocaine (COC)	100, 150
Cotinine (COT)	200
EDDP	100
Ethyl Glucuronide (EtG)	500
Fentanyl (FYL)	200
Ketamine (KET)	1000
MDPV	1000
Methamphetamine (MET)	300, 500
Methadone (MTD)	200, 300
Methaqualone (MQL)	300
Methylphenidate (MPD)	300
Monoacetylmorphine (6-MAM)	10
Morphine (MOP/OPI)	100
Pregabalin (PGB)	1000
Synthetic Cannabisnoid (K2)	50
Tramadol (TML)	100, 200, 300

06

Accessories & Related Products

BioSieve™
DOA Controls
- 2 x 10 mL/box

BioSieve™
Adulteration Test Strips
- 25 strips/box

DOA FIA Test Kit *

* Coming soon

07

FIA Testing System

BioSieve™ FIA Reader

Products Information

Analyzer	Specification
Size	124.5 × 72.5 × 40 mm
Weight	165 g
Screen	1.54″ LCD
Connectivity	Bluetooth
Power	Battery & AC/DC adapter
Printer	External bluetooth printer (optional)
Memory	999 results