January 31, 2020

Shenzhen Bioeasy Biotechnology Co., Ltd.
% Joe Shia
Director
LSI
504E Diamond Ave., Suite I
Gaithersburg, MD 20877

Re: k193480
Trade/Device Name: BIOEASY Multi-Drug Test Cup
Regulation Number: 21 CFR 862.3650
Regulation Name: Opiate test system
Regulatory Class: Class II
Product Code: NGL, NGI, NFW, NFY, NGG, NFT, NFV, PTH, NGM, PTG, QAW, QBF
Dated: December 11, 2019
Received: December 16, 2019

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,

Marianela Perez-Torres, M.T., Ph.D.
Acting Deputy Director
Division of Chemistry
and Toxicology Devices
OHT7: Office of In Vitro Diagnostics
and Radiological Health
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K193480

Device Name
BIOEASY Multi-Drug Test Cup

Indications for Use *(Describe)*
BIOEASY Multi-Drug Test Cup Tests are competitive binding, lateral flow immunochromatographic assays for qualitative and simultaneous detection of Amphetamine, Oxazepam, Cocaine, Marijuana, Methamphetamine, Morphine, Oxycodone, Secobarbital, Buprenorphine, Methylenedioxy-methamphetamine, Phencyclidine, Methadone, Nortriptyline and d-Propoxyphene in human urine at the cutoff concentrations of:

Drug(Identifier)	Cut-off level
Amphetamine	1000 ng/mL
Oxazepam	300 ng/mL
Cocaine	300 ng/mL
Marijuana	50 ng/mL
Methamphetamine	1000 ng/mL
Morphine	300 ng/mL or 2000 ng/mL
Oxycodone	100 ng/mL
Secobarbital	300 ng/mL
Buprenorphine	10 ng/mL
Methylenedioxy-methamphetamine	500 ng/mL
Phencyclidine	25 ng/mL
Methadone	300 ng/mL
Nortriptyline	1000 ng/mL
d-Propoxyphene	300 ng/mL

Configuration of the BIOEASY Multi-Drug Test Cup tests can consist of any combination of the above listed drug analytes.

The test may yield positive results for the prescription drugs Buprenorphine, Nortriptyline, Oxazepam, Secobarbital, Propoxyphene and Oxycodone when taken at or above prescribed doses. It is not intended to distinguish between prescription use or abuse of these drugs. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive. 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.

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K193480

510(k) SUMMARY

1. Date: January 27, 2020

2. Submitter: Shenzhen Bioeasy Biotechnology Co., Ltd.
No.2-1, Liuxian 1st Road
Baoan District
Shenzhen, China 518101

3. Contact person: Joe Shia
LSI International Inc.
504 East Diamond Ave.
Gaithersburg, MD 20877
Telephone: 240-505-7880
Email: shiajl@yahoo.com

4. Device Name: BIOEASY Multi-Drug Test Cup

Classification: Class 2

Product Code	Classification	Regulation Section	Panel
NFT Amphetamine	II	21 CFR § 862.3100, Amphetamine Test System	Toxicology (91)
NFW Cannabinoids	II	21 CFR § 862.3870, Cannabinoids Test System	Toxicology (91)
NFY Cocaine	II	21 CFR § 862.3250, Cocaine and Cocaine Metabolites Test System	Toxicology (91)
NGG Methamphetamine	II	21 CFR § 862.3610, Methamphetamine Test System	Toxicology (91)
NGI Morphine	II	21 CFR § 862.3640, Morphine Test System	Toxicology (91)
NFV Oxazepam	II	21 CFR § 862.3170, Benzodiazepine Test System	Toxicology (91)
NGL Oxycodone	II	21 CFR § 862.3650, Opiate Test System	Toxicology (91)
PTH Secobarbital	II	21 CFR § 862.3150, Barbiturate Test System	Toxicology (91)
NGL Buprenorphine	II	21 CFR § 862.3650, Opiate Test System	Toxicology (91)
NGG Methylenedioxy-methamphetamine	II	21 CFR § 862.3610, Methamphetamine Test System	Toxicology (91)
NGM Phencyclidine	unclassified	Enzyme Immunoassay Phencyclidine	Toxicology (91)
PTG Methadone	II	21 CFR § 862.3620, Methadone Test System	Toxicology (91)
QAW Nortriptyline	II	21 CFR, 862.3910 Tricyclic Antidepressant Drugs Test System	Toxicology (91)
QBF Propoxyphene	II	21 CFR, 862.3700 Propoxyphene Test System	Toxicology (91)

5. Predicate Devices: K182530

6. Indications for Use

BIOEASY Multi-Drug Test Cup Tests are competitive binding, lateral flow immunochromatographic assays for qualitative and simultaneous detection of Amphetamine, Oxazepam, Cocaine, Marijuana, Methamphetamine, Morphine, Oxycodone, Secobarbital, Buprenorphine, Methylenedioxy-methamphetamine, Phencyclidine, Methadone, Nortriptyline and d-Propoxyphene in human urine at the cutoff concentrations of:

Drug (Identifier)	Cut-off level
Amphetamine	1000 ng/mL
Oxazepam	300 ng/mL
Cocaine	300 ng/mL
Marijuana	50 ng/mL
Methamphetamine	1000 ng/mL
Morphine	300 ng/mL or 2000 ng/mL
Oxycodone	100 ng/mL
Secobarbital	300 ng/mL
Buprenorphine	10 ng/mL
Methylenedioxy-methamphetamine	500 ng/mL
Phencyclidine	25 ng/mL
Methadone	300 ng/mL
Nortriptyline	1000 ng/mL
d-Propoxyphene	300 ng/mL

Configuration of the BIOEASY Multi-Drug Test Cup tests can consist of any combination of the above listed drug analytes.

The test may yield positive results for the prescription drugs Buprenorphine, Nortriptyline, Oxazepam, Secobarbital, Propoxyphene and Oxycodone when taken at or above prescribed doses. It is not intended to distinguish between prescription use or abuse of these drugs. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive. 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.

7. Device Description

The BIOEASY Multi-Drug Test Cup tests are immunochromatographic assays that use a lateral flow system for the qualitative detection of Amphetamine, Oxazepam, Cocaine, Marijuana, Methamphetamine, Morphine, Oxycodone, Secobarbital, Buprenorphine, Methylenedioxy-methamphetamine, Phencyclidine, Methadone, Nortriptyline and Propoxyphene (target analytes) in human urine. The products are single-use in vitro diagnostic devices. Each test kit contains a Test Device, a package insert and a urine cup for sample collection. Each test device is sealed with a desiccant in an aluminum pouch

8. Substantial Equivalence Information

A summary comparison of features of the BIOEASY Multi-Drug Test Cup tests and the predicate devices is provided in following table.

Table 1: Features Comparison of BIOEASY Multi-Drug Test Cup tests and the Predicate Devices

Item	Device	Predicate - K182530
Indication(s) for Use	For the qualitative determination of drugs of abuse in human urine.	Same
Calibrator and Cut-Off Values	Amphetamine (AMP): 1,000 ng/ml Oxazepam (BZO):300 ng/ml Cocaine(COC): 300 ng/ml Marijuana (THC):50 ng/ml Methamphetamine (MET): 1,000 ng/ml Morphine (MOP): 300ng/ml or 2000ng/mL Oxycodone(OXY) : 100 ng/ml Secobarbital (BAR): 300 ng/ml Buprenorphine (BUP): 10 ng/ml Methylenedioxy-methamphetamine(MDMA): 500 ng/ml Phencyclidine (PCP): 25 ng/ml Methadone (MTD): 300 ng/ml Nortriptyline (TCA): 1000 ng/ml Propoxyphene (PPX): 300 ng/ml	Same except for morphine 2000 ng/mL
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 over-the-counter	Same
Configurations	Cup	Same

9. Test Principle

The BIOEASY Multi-Drug Test Cup tests are rapid tests for the qualitative detection of Amphetamine, Oxazepam, Cocaine, Marijuana, Methamphetamine, Morphine, Oxycodone, Secobarbital, Buprenorphine, Methylenedioxy-methamphetamine, Phencyclidine, Methadone, Nortriptyline and Propoxyphene in urine samples. The tests are lateral flow chromatographic immunoassays. During testing, a urine specimen migrates upward by capillary action. If target drugs present in the urine specimen are below the cut-off concentration, it will not saturate the binding sites of its specific monoclonal mouse antibody coated on the particles. The antibody-coated particles will then be captured by immobilized drug-conjugate and a visible colored line will show up in the test line region. The colored line will not form in the test line region if the target drug level exceeds its cutoff-concentration because it will saturate all the binding sites of the antibody coated on the particles. A band should form in the control region of the devices regardless of the presence of drug or metabolite in the sample to indicate that the tests have been

performed properly.

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, +25% cut off, +50% cut off , +75% cut off and +100% cut off. These samples were prepared by spiking drug in negative samples. Each drug concentration was confirmed by LC/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 two runs per day for 25 days per device in a randomized order. The results obtained are summarized in the following table for Morphine 2000 ng/mL. The data for Amphetamine, Oxazepam, Cocaine, Marijuana, Methamphetamine, Morphine, Oxycodone, Secobarbital, Buprenorphine, Methylenedioxy-methamphetamine, Phencyclidine, Methadone, Nortriptyline and Propoxyphene were reported in k182530.

Morphine 2000 ng/mL

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	50-/0+	50-/0+	50-/0+	50-/0+	26-/24+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 2	50-/0+	50-/0+	50-/0+	50-/0+	29-/21+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 3	50-/0+	50-/0+	50-/0+	50-/0+	24-/26+	50+/0-	50+/0-	50+/0-	50+/0-

c. Stability

The devices are stable at 4-30 °C for 24 months based on the real time stability studies at both 4 °C and 30 °C.

d. Interference

Potential interfering substances found in human urine of physiological or pathological conditions were added to drug-free urine and target drugs urine with concentrations at 25% below and 25% above Cut-Off levels. These urine samples were tested using three batches of the device. Compounds that showed no interference at a concentration of 100µg/mL (albumin was tested at 100 mg/dL, ethanol at 1%) are summarized in the following tables.

Acetaminophen	β-Estradiol	Oxalic acid
Acetophenetidin	Erythromycin	Oxolinic acid
N-Acetylprocainamide	Ethanol	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 specificity, drug metabolites and other components that are likely to interfere in urine samples were tested using three batches of each device. The lowest concentration that caused a positive result for each compound are listed below for Morphine 2000 ng/mL cut-off. The data for Amphetamine, Oxazepam, Cocaine, Marijuana, Methamphetamine, Morphine, Oxycodone, Secobarbital, Buprenorphine, Methylenedioxy-methamphetamine, Phencyclidine, Methadone, Nortriptyline and Propoxyphene were reported in k182530

Morphine，Cut-off=2000 ng/mL	**Result**	**%Cross-Reactivity**
Morphine	Positive at 2000 ng/mL	100%
Codeine	Positive at 200 ng/mL	1000%
Ethylmorphine	Positive at 2500 ng/mL	80%
Hydrocodone	Negative at 100000 ng/mL	<2%
Hydromorphone	Positive 4000 ng/mL	50%
Levorphanol	Negative at 100000 ng/mL	<2%
6-Acetylmorphine	Positive at 3000 ng/mL	67%
Morphine-3- β -D-glucuronide	Positive at 6000 ng/mL	33%
Normorphine	Negative at 100000 ng/mL	<2%
Oxycodone	Negative at 100000 ng/mL	<2%
Oxymorphone	Negative at 100000 ng/mL	<2%
Procaine	Negative at 100000 ng/mL	<2%
Thebaine	Negative at 100000 ng/mL	<2%
Heroin	Positive at 3500 ng/mL	57%

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 drugs at 25% below and 25% above Cut-Off levels. These samples were tested using three lots of each device. Results were all positive for samples at and above +25% Cut-Off and all negative for samples at and below -25% Cut-Off. There were no differences observed for different devices.

2. Comparison Studies

Method comparison studies for the BIOEASY Multi-Drug Test Cup tests were performed in-house with three laboratory assistants for each device. Operators ran 80 (40 negative and 40 positive) unaltered clinical samples for each drug. The samples were blind labeled and compared to LC/MS results. The results obtained are summarized in the following table for Morphine 2000 ng/mL. The data for Amphetamine, Oxazepam, Cocaine, Marijuana, Methamphetamine, Morphine, Oxycodone, Secobarbital, Buprenorphine, Methylenedioxy-methamphetamine, Phencyclidine, Methadone, Nortriptyline and Propoxyphene were reported in k182530.

Morphine 2000 ng/mL

		Negative	Low Negative by LC/MS (less than -50%)	Near Cutoff Negative by LC/MS (Between -50% and cutoff)	Near Cutoff Positive by LC/MS (Between the cutoff and +50%)	High Positive by LC/MS (greater than +50%)
Viewer A	Positive	0	0	2	20	18
	Negative	7	15	16	2	0
Viewer B	Positive	0	0	2	21	18
	Negative	7	15	16	1	0
Viewer C	Positive	0	0	2	21	18
	Negative	7	15	16	1	0

Discordant Results

Viewer	Sample Number	LC/MS Result	BIOEASY Cup Viewer Results
Viewer A	OPIC341	1920	Positive
Viewer A	OPIC335	1870	Positive
Viewer B	OPIC450	1860	Positive
Viewer B	OPIC335	1870	Positive
Viewer C	OPIC341	1920	Positive
Viewer C	OPIC450	1860	Positive
Viewer A	OPIC475	2150	Negative
Viewer A	OPIC408	2100	Negative
Viewer B	OPIC408	2100	Negative
Viewer C	OPIC475	2150	Negative

Lay-user study

A lay user study was performed at three intended user sites with 300 lay persons for the device. 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 cutoff by spiking drugs 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 AMP:

% of Cutoff	Number of	Drug Concentration	Lay person Results	The percentage of

	samples	by LC/MS/MS (ng/mL)	No. of Positive	No. of Negative	correct results (%)
-100% Cutoff	20	0	0	20	100
-75% Cutoff	20	261	0	20	100
-50% Cutoff	160	507	0	160	100
-25% Cutoff	20	771	1	19	95
+25% Cutoff	20	1290	20	0	100
+50% Cutoff	40	1560	40	0	100
+75% Cutoff	20	1870	20	0	100

The results summary for BAR:

% 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	75.9	0	20	100
-50% Cutoff	160	150	0	160	100
-25% Cutoff	20	220	1	19	95
+25% Cutoff	20	360	19	1	95
+50% Cutoff	40	429	40	0	100
+75% Cutoff	20	501	20	0	100

The results summary for COC:

% 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	81.5	0	20	100
-50% Cutoff	160	151	0	160	100
-25% Cutoff	20	225	1	19	95
+25% Cutoff	20	395	19	1	95
+50% Cutoff	40	455	40	0	100
+75% Cutoff	20	520	20	0	100

The results summary for BUP:

% 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	2.57	0	20	100
-50% Cutoff	160	5.14	0	160	100
-25% Cutoff	20	6.76	1	19	95
+25% Cutoff	20	12.8	18	2	90
+50% Cutoff	40	15.1	40	0	100
+75% Cutoff	20	17.2	20	0	100

The results summary for MET:

% 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	268	0	20	100
-50% Cutoff	160	526	0	160	100
-25% Cutoff	20	769	1	19	95
+25% Cutoff	20	1270	19	1	95
+50% Cutoff	40	1560	40	0	100
+75% Cutoff	20	1780	20	0	100

The results summary for MTD:

% 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	76.8	0	20	100
-50% Cutoff	160	147	0	160	100
-25% Cutoff	20	226	1	19	95
+25% Cutoff	20	375	19	1	95
+50% Cutoff	40	441	40	0	100
+75% Cutoff	20	504	20	0	100

The results summary for Morphine:

% 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	535	0	20	100
-50% Cutoff	160	1010	0	160	100
-25% Cutoff	20	1580	0	20	100
+25% Cutoff	20	2600	19	1	95
+50% Cutoff	40	3050	40	0	100
+75% Cutoff	20	3240	20	0	100

The results summary for OXY:

% 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	24.5	0	20	100
-50% Cutoff	160	49.3	0	160	100
-25% Cutoff	20	71.1	1	19	95
+25% Cutoff	20	118	19	1	95
+50% Cutoff	40	147	40	0	100
+75% Cutoff	20	169	20	0	100

The results summary for PCP:

% 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	6.27	0	20	100
-50% Cutoff	160	12.5	0	160	100
-25% Cutoff	20	17.9	1	19	95
+25% Cutoff	20	30.8	20	0	100
+50% Cutoff	40	36.4	40	0	100
+75% Cutoff	20	42.8	20	0	100

The results summary for THC:

% 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	13	0	20	100
-50% Cutoff	160	25.3	0	160	100
-25% Cutoff	20	41	2	18	90
+25% Cutoff	20	65	19	1	95
+50% Cutoff	40	79	40	0	100
+75% Cutoff	20	93	20	0	100

The results summary for BZO:

% 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	70.8	0	20	100
-50% Cutoff	160	148	0	160	100
-25% Cutoff	20	224	1	19	95
+25% Cutoff	20	390	19	1	95
+50% Cutoff	40	452	40	0	100
+75% Cutoff	20	504	20	0	100

The results summary for MDMA:

% 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	137	0	20	100
-50% Cutoff	160	250	0	160	100
-25% Cutoff	20	351	1	19	95
+25% Cutoff	20	600	19	1	95
+50% Cutoff	40	745	40	0	100
+75% Cutoff	20	925	20	0	100

The results summary for TCA:

% 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	273	0	20	100
-50% Cutoff	160	509	0	160	100
-25% Cutoff	20	809	1	19	95
+25% Cutoff	20	1190	19	1	95
+50% Cutoff	40	1510	40	0	100
+75% Cutoff	20	1680	20	0	100

The results summary for PPX:

% 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	77.4	0	20	100
-50% Cutoff	160	150	0	160	100
-25% Cutoff	20	227	1	19	95
+25% Cutoff	20	351	19	1	95
+50% Cutoff	40	420	40	0	100
+75% Cutoff	20	492	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 each package insert and the scores revealed a reading Grade Level of 7.

3. Clinical Studies

Not applicable.

11. Conclusion

Based on the test principle and acceptable performance characteristics including precision, cut-off, interference, specificity, method comparison, and lay-user studies of the device, it's concluded that the BIOEASY Multi-Drug Test Cup tests are substantially equivalent to the predicate.