October 11, 2019

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

Re: K192515
Trade/Device Name: BIOEASY Marijuana Test Dip Card 40, BIOEASY Marijuana Test Dip Card 20, BIOEASY Marijuana Test Strip 40, BIOEASY Marijuana Test Strip 20
Regulation Number: 21 CFR 862.3870
Regulation Name: Cannabinoid test system
Regulatory Class: Class II
Product Code: LDJ
Dated: September 3, 2019
Received: September 13, 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,

Kellie Kelm, Ph.D.
Acting 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)*
k192515

Device Name
BIOEASY Marijuana Test Dip Card 40; BIOEASY Marijuana Test Dip Card 20; BIOEASY Marijuana Test Strip 40; BIOEASY Marijuana Test Strip 20

Indications for Use *(Describe)*

BIOEASY Marijuana Test Dip Card 40 is competitive binding, lateral flow immunochromatographic assay for qualitative detection of Marijuana in human urine at the cutoff concentrations of 40 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.

BIOEASY Marijuana Test Strip 40 is competitive binding, lateral flow immunochromatographic assay for qualitative detection of Marijuana in human urine at the cutoff concentrations of 40 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.

BIOEASY Marijuana Test Dip Card 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.

BIOEASY 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.

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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K192515

510(k) SUMMARY

1. Date: October 10, 2019

2. Submitter:
Shenzhen Bioeasy Biotechnology Co., Ltd.
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Baoan District
Shenzhen, China 518101

3. Contact person:
Joe Shia
LSI International Inc.
504E Diamond Ave., Suite I
Gaithersburg, MD 20877
Telephone: 240-505-7880
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4. Device Name:
BIOEASY Marijuana Test Dip Card 20
BIOEASY Marijuana Test Strip 20
BIOEASY Marijuana Test Dip Card 40
BIOEASY Marijuana Test Strip 40

Classification: Class 2

Product Code	Classification	Regulation Section	Panel
LDJ Cannabinoids	II	21 CFR § 862.3870, Cannabinoids Test System	Toxicology (91)

5. Predicate Devices: K182530

The Bioeasy Multi-Drug Test Cup

6. Indications for Use

BIOEASY Marijuana Test Dip Card 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.

BIOEASY Marijuana Test Dip Card 40 is competitive binding, lateral flow immunochromatographic assay for qualitative detection of Marijuana in human urine at the cutoff concentrations of 40 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.

BIOEASY 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.

BIOEASY Marijuana Test Strip 40 is competitive binding, lateral flow immunochromatographic assay for qualitative detection of Marijuana in human urine at the cutoff concentrations of 40 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.

7. Device Description

The BIOEASY Marijuana Test Dip Card and the BIOEASY Marijuana Test 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

8. Substantial Equivalence Information

A summary comparison of features of the BIOEASY Marijuana Test devices and the predicate devices is provided in following table.

Table 1: Features Comparison of BIOEASY Marijuana Test devices and the Predicate Devices

Item	Device	Predicate - K182530
Indication(s) for Use	For the qualitative determination of marijuana in human urine.	Same (but the number of drugs detected is different)
Calibrator and Cut-Off Values	Marijuana (THC) 20 ng/ml or 40 ng/ml	50 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 prescription use	For over-the-counter
Configurations	Dip Card and Strip	Cup

9. Test Principle

The BIOEASY Marijuana Test Dip Card and the BIOEASY Marijuana Test Strip tests are rapid tests for the qualitative detection of Marijuana in urine samples. The tests are lateral flow

chromatographic immunoassays. During testing, a urine specimen migrates upward by capillary action. If the target drug present in the urine specimen is 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 11-Nor-△9-THC-9-COOH in negative samples. Each 11-Nor-△9-THC-9-COOH 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 six runs per day for 10 days per device lot in a randomized order. The results obtained are summarized in the following tables.

Dip Card of 20ng/mL Cut-off

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	60-/0+	60-/0+	60-/0+	58-/2+	32-/28+	59+/1-	60+/0-	60+/0-	60+/0-
Lot 2	60-/0+	60-/0+	60-/0+	59-/1+	29-/31+	59+/1-	60+/0-	60+/0-	60+/0-
Lot 3	60-/0+	60-/0+	60-/0+	59-/1+	30-/30+	58+/2-	60+/0-	60+/0-	60+/0-

Strip of 20ng/mL Cut-off

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	60-/0+	60-/0+	60-/0+	59-/1+	30-/30+	58+/2-	60+/0-	60+/0-	60+/0-
Lot 2	60-/0+	60-/0+	60-/0+	58-/2+	32-/28+	58+/2-	60+/0-	60+/0-	60+/0-
Lot 3	60-/0+	60-/0+	60-/0+	59-/1+	31-/29+	57+/3-	60+/0-	60+/0-	60+/0-

Dip Card of 40ng/mL Cut-off

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	60-/0+	60-/0+	60-/0+	59-/1+	31-/29+	58+/2-	60+/0-	60+/0-	60+/0-
Lot 2	60-/0+	60-/0+	60-/0+	57-/3+	28-/32+	59+/1-	60+/0-	60+/0-	60+/0-
Lot 3	60-/0+	60-/0+	60-/0+	58-/2+	29-/31+	59+/1-	60+/0-	60+/0-	60+/0-

Strip of 40ng/mL Cut-off

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	60-/0+	60-/0+	60-/0+	58-/2+	32-/28+	59+/1-	60+/0-	60+/0-	60+/0-
Lot 2	60-/0+	60-/0+	60-/0+	59-/1+	29-/31+	57+/3-	60+/0-	60+/0-	60+/0-

Lot 3	60-/0+	60-/0+	60-/0+	58-/2+	31-/29+	58+/2-	60+/0-	60+/0-	60+/0-

c. Stability

The devices are stable at 4-30 °C for 24 months based on the accelerated stability study at 45 °C and real time stability determinations 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 50% below and 50% above Cut-Off levels. These urine samples were tested using three batches of each device. Compounds that showed 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 tables. There were no differences observed for both the strip and dip card formats at the two different cut-offs.

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 specificity, drug metabolites and other components that are likely to interfere in urine samples were tested using three batches of each device format. The lowest concentration that caused a positive result for each compound are listed below. There are no differences for different device formats.

For cut-off 20ng/mL

THC(Cannabinoids) (11-nor-Δ9-THC-9-COOH, Cut-off = 20 ng/mL)	**Result**	**% Cross-Reactivity**
11-nor-Δ9-THC-9-COOH	Positive at 20 ng/mL	100%
11-Hydroxy-△9-Tetrahydrocannabinol	Positive at 20 ng/mL	100%
11-Nor-△8-Tetrahydrocannabinol-9-COOH	Positive at 20 ng/mL	100%
Cannabinol	Positive at 8000 ng/mL	0.25%
△8-Tetrahydrocannabinol	Positive at 6000 ng/mL	0.33%
△9-Tetrahydrocannabinol	Positive at 6000 ng/mL	0.33%
Cannabidiol	Positive＞ 100000 ng/mL	＜0.02%
11-Nor-△9-THC-carboxy glucuronide	Positive at 30 ng/mL	66.7%
(-)-11-nor-9-carboxy-Δ 9-THC	Positive at 20 ng/mL	100%

For cut-off 40ng/mL

THC(Cannabinoids) (11-nor-Δ9-THC-9-COOH, Cut-off = 40 ng/mL)	**Result**	**% Cross-Reactivity**
11-nor-Δ9-THC-9-COOH	Positive at 40 ng/mL	100%
11-Hydroxy-△9-Tetrahydrocannabinol	Positive at 40 ng/mL	100%
11-Nor-△8-Tetrahydrocannabinol-9-COOH	Positive at 40 ng/mL	100%
Cannabinol	Positive at 16000 ng/mL	0.25%
△8-Tetrahydrocannabinol	Positive at 12000 ng/mL	0.33%
△9-Tetrahydrocannabinol	Positive at 12000 ng/mL	0.33%
Cannabidiol	Positive＞ 100000 ng/mL	＜0.04%
11-Nor-△9-THC-carboxy glucuronide	Positive at 60 ng/mL	66.7%
(-)-11-nor-9-carboxy-Δ 9-THC	Positive at 40 ng/mL	100%

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 50% below and 50% above Cut-Off levels. These samples were tested using three lots of each device format. Results were all positive for samples at and above +50% Cut-Off and all negative for samples at and below -50% Cut-Off. There were no differences observed for different device formats of the two different cutoffs.

2. Comparison Studies

Method comparison studies for the BIOEASY Marijuana test devices were performed in-house with three laboratory assistants for each device format. Operators ran 80 (40 negative and 40 positive) unaltered clinical samples. The samples were blind labeled and compared to LC/MS results. The results are presented in the tables below.

Strip Format of 20ng/mL Cut-off

		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%)
Operator	Positive	0	0	2	18	20

A	Negative	6	16	16	2	0
Operator B	Positive	0	0	3	18	20
	Negative	6	16	15	2	0
Operator C	Positive	0	0	2	18	20
	Negative	6	16	16	2	0

Discordant Results

Operator	Sample Number	LC/MS Result	BIOEASY Results
Operator A	THCC473	19.1	Positive
Operator A	THCC356	18.4	Positive
Operator B	THCC312	17.5	Positive
Operator B	THCC473	19.1	Positive
Operator B	THCC500	16.2	Positive
Operator C	THCC312	17.5	Positive
Operator C	THCC356	18.4	Positive
Operator A	THCC373	20.3	Negative
Operator A	THCC350	22.6	Negative
Operator B	THCC385	21.6	Negative
Operator B	THCC342	22.9	Negative
Operator C	THCC373	20.3	Negative
Operator C	THCC350	22.6	Negative

Dip Card Format of 20ng/mL Cut-off

		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%)
Operator D	Positive	0	0	2	18	20
	Negative	6	16	16	2	0
Operator E	Positive	0	0	2	19	20
	Negative	6	16	16	1	0
Operator F	Positive	0	0	3	18	20
	Negative	6	16	15	2	0

Discordant Results

Operator	Sample Number	LC/MS Result	BIOEASY Results
Operator D	THCC312	17.5	Positive
Operator D	THCC473	19.1	Positive
Operator E	THCC473	19.1	Positive
Operator E	THCC356	18.4	Positive
Operator F	THCC312	17.5	Positive
Operator F	THCC473	19.1	Positive
Operator F	THCC356	18.4	Positive
Operator D	THCC373	20.3	Negative
Operator D	THCC350	22.6	Negative

Operator E	THCC385	21.6	Negative
Operator F	THCC373	20.3	Negative
Operator F	THCC350	22.6	Negative

Strip Format of 40ng/mL Cut-off

		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%)
Operator A	Positive	0	0	1	17	22
	Negative	6	13	20	1	0
Operator B	Positive	0	0	1	16	22
	Negative	6	13	20	2	0
Operator C	Positive	0	0	1	17	22
	Negative	6	13	20	1	0

Discordant Results

Operator	Sample Number	LC/MS Result	BIOEASY Results
Operator A	THCC365	39.35	Positive
Operator B	THCC412	38	Positive
Operator C	THCC412	38	Positive
Operator A	THCC371	40.95	Negative
Operator B	THCC371	40.95	Negative
Operator B	THCC374	41.45	Negative
Operator C	THCC379	43.15	Negative

Dip Card Format of 40ng/mL Cut-off

		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%)
Operator D	Positive	0	0	2	17	22
	Negative	6	13	19	1	0
Operator E	Positive	0	0	1	16	22
	Negative	6	13	20	2	0
Operator F	Positive	0	0	2	16	22
	Negative	6	13	19	2	0

Discordant Results

Operator	Sample Number	LC/MS Result	BIOEASY Results
Operator D	THCC365	39.35	Positive
Operator D	THCC433	37.1	Positive
Operator E	THCC412	38	Positive

Operator F	THCC412	38	Positive
Operator F	THCC365	39.35	Positive
Operator D	THCC371	40.95	Negative
Operator E	THCC371	40.95	Negative
Operator E	THCC374	41.45	Negative
Operator F	THCC379	43.15	Negative
Operator F	THCC374	41.45	Negative

3. Clinical Studies

Not applicable.

11. Conclusion

Based on the test principle and acceptable performance characteristics including precision, cut-off, interference, specificity, and method comparison studies of the devices, it's concluded that the BIOEASY Marijuana Test Dip Card and BIOEASY Marijuana Test Strip tests are substantially equivalent to the predicate.