August 16, 2019

Safecare Biotech (Hangzhou) Co., Ltd.
% Joe Shia, Manager
LSI International
504 E Diamond Ave., Suite I
Gaithersburg, MD 20877

Re: K191924
Trade/Device Name: SAFECARE® THC Urine Strip Test
Regulation Number: 21 CFR 862.3870
Regulation Name: Cannabinoid test system
Regulatory Class: Class II
Product Code: NFW
Dated: July 16, 2019
Received: July 18, 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 B. 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)*
k191924

Device Name
SAFECARE® THC Urine Strip Test

Indications for Use *(Describe)*
SAFECARE® THC Urine Strip Test is a 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.

The test is intended for over-the-counter use.

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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K191924

510(k) SUMMARY

1. Date: August 15, 2019

2. Submitter: Safecare Biotech (Hangzhou) Co., Ltd.
18 Haishu Road, Yuhang District
Hangzhou, China

3. Contact person: Joe Shia
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4. Device Name: SAFECARE® THC Urine Strip Test

Classification: Class II

Product Code	**CFR #**	**Panel**
NFW	21 CFR, 862.3870 Cannabinoid Test System	Toxicology

5. Predicate Devices:
K153646
SAFECARE Urine Test Marijuana

6. Intended Use
SAFECARE® THC Urine Strip Test is a 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.
The test is intended for over-the-counter use.

7. Device Description
SAFECARE® THC Urine Strip Test devices are immunochromatographic assays for the qualitative detection of 11-nor-Δ9-THC-9 COOH (target analyte) in human urine. The product is a single-use in

vitro diagnostic device. It 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 SAFECARE THC Urine Strip Test and the predicate device is provided in Table 1.

Table 1: Features Comparison of SAFECARE Marijuana Test and the Predicate Device

Item	Device	Predicate - K153646
Indication(s) for Use	For the qualitative determination of 11-nor-Δ9-THC-9 COOH in human urine.	Same
Calibrator	11-nor-Δ9-THC-9 COOH	Same
Methodology	Competitive binding, lateral flow immunochromatographic assays based on the principle of antigen antibody immunochemistry.	Same
Specimen Type	Human Urine	Same
Cut-Off Values	50 ng/mL	Same
Intended Population	For over-the-counter use.	For over-the-counter use and prescription uses.
Configurations	Strip	Cup, Dip Card, Cassette

9. Test Principle

SAFECARE THC Urine Strip Test devices are rapid tests for the qualitative detection of 11-nor-Δ9-THC-9 COOH in urine samples. Each assay test is a lateral flow chromatographic immunoassay. During testing, a urine specimen migrates upward by capillary action. If target drug THC is present in the urine specimen below its cut-off concentration, it will not saturate the binding sites of its specific antibody (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.

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, at the 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. THC drug concentration was confirmed by LC/MS. All sample aliquots were blinded labeled and randomized. For each concentration, tests were performed two runs per day for 25 days. The results obtained are summarized in the following tables:

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	**50-/0+**	**50-/0+**	**50-/0+**	**50-/0+**	**25-/25+**	**50+/0-**	**50+/0-**	**50+/0-**	**50+/0-**
Lot 2	**50-/0+**	**50-/0+**	**50-/0+**	**50-/0+**	**25-/25+**	**50+/0-**	**50+/0-**	**50+/0-**	**50+/0-**
Lot 3	**50-/0+**	**50-/0+**	**50-/0+**	**50-/0+**	**26-/24+**	**50+/0-**	**50+/0-**	**50+/0-**	**50+/0-**

The cut-off value of 50 ng/mL is verified for the device.

   b. Linearity

   Not applicable, these are visually read devices.

   c. Stability

   The devices are stable at 4-30℃ (39-86°F) for 24 months based on the accelerated stability study at 50℃.

   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 concentration 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 are summarized in the following tables.

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	D-Pseudoephedrine
Aspartame	O-Hydroxyhippuric acid	Quinine
Atropine	3-Hydroxytyramine	Ranitidine
Benzilic acid	Ibuprofen	Salicylic acid
Benzoic acid	D,L-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 interfere in urine samples were tested using three batches of the device. The obtained lowest detectable concentration was used to calculate the cross-reactivity.

Drugs	Cross Reactivity Cut off(ng/ml)	% Cross-Reactivity
11-Nor-$\triangle^9$-Tetrahydrocannabinol-9-COOH	50	100%
11-Hydroxy-$\triangle^9$-Tetrahydrocannabinol	5000	1%
11-Nor-$\triangle^8$-Tetrahydrocannabinol-9-COOH	50	100%

Cannabinol	20000	0.25%
$\triangle^8$-Tetrahydrocannabinol	10000	0.5%
$\triangle^9$-Tetrahydrocannabinol	10000	0.5%
Cannabidiol	20000	0.25%
11-Nor-△9-THC-carboxy glucuronide	2500	2%
(-)-11-nor-9-carboxy-Δ 9-THC	2500	2%

f. Effect of Urine Specific Gravity and Urine pH

To investigate the effect of urine specific gravity and urine pH, urine samples with of 1.000 to 1.035 specific gravity or urine samples with pH 4 to 9 were spiked with target drug THC at 25% below and 25% above cut-off levels. These samples were tested using three batches of device. Results were all positive for samples at and above +25% cut-off and all negative for samples at and below -25% Cut-Off.

2. Comparison Studies

The method comparison studies for the SAFECARE THC Urine Strip Test were performed by three different laboratory assistants. 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:

Safecare THC Urine Strip Test		Negative	Low Negative by LC/MS (less than -50%)	Near Cutoff Negative by LC/MS (Between -50% and cut-off)	Near Cutoff Positive by LC/MS (Between the cut-off and +50%)	High Positive by LC/MS (greater than +50%)
Viewer A	Positive	0	0	1	18	20
	Negative	10	10	19	2	0
Viewer B	Positive	0	0	1	19	20
	Negative	10	10	19	1	0
Viewer C	Positive	0	0	0	19	20
	Negative	10	10	20	1	0

Discordant Results

Viewer	Sample Number	LC/MS Result	Viewer Results
Viewer A	MT540	49	Positive
Viewer B	MT630	48	Positive
Viewer A	MT299	51	Negative
Viewer A	MT527	52	Negative
Viewer B	MT527	52	Negative
Viewer C	MT527	52	Negative

Lay-user study

A lay user study was performed at three intended user sites with 140 lay persons testing the devices. A total of 69 females and 71 males tested the marijuana samples. They had diverse educational and professional backgrounds and ranged in age from 21 to > 50 years. Urine samples were prepared at the following concentrations; negative, +/-75%, +/-50%, +/-25% of the cutoff by spiking drug THC 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. The results are summarized below.

Comparison between LC/MS and Lay Person Results

% of Cutoff	Number of samples	11-nor-D9-THC-9-COOH 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	13	0	20	100
-50% Cutoff	20	25	0	20	100
-25% Cutoff	20	37	2	18	90
+25% Cutoff	20	63	19	1	95
+50% Cutoff	20	76	20	0	100
+75% Cutoff	20	88	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, interference, specificity and method comparison of the device, it's concluded that the SAFECARE THC Urine Strip Test devices are substantially equivalent to the predicate.