Co-Innovation Biotech Co., Ltd.
Hong Feng
Product Manager
No. 9 Baihe 3 Street
Economic And Technological Development East Zone
Guangzhou, Guangdong 510530
China

Re: K232732
Trade/Device Name: Rapid Marijuana (THC) Test Strip 20, Rapid Marijuana (THC) Test Dipcard 20, Rapid Marijuana (THC) Test Strip 50, Rapid Marijuana (THC) Test Dipcard 50
Regulation Number: 21 CFR 862.3870
Regulation Name: Cannabinoid test system
Regulatory Class: Class II
Product Code: LDJ
Dated: December 11, 2023
Received: December 11, 2023

Dear Hong Feng:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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: 2024.01.17 17:24:10 -05'00'

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)*
K232732

Device Name
Rapid Marijuana (THC) Test Strip 20, Rapid Marijuana (THC) Test Dipcard 20 ,
Rapid Marijuana (THC) Test Strip 50, Rapid Marijuana (THC) Test Dipcard 50

Indications for Use *(Describe)*
Rapid Marijuana (THC) Test Strip 20 and Rapid Marijuana (THC) Test Dipcard 20 is a rapid, screening test for the qualitative detection of Marijuana and their metabolites in human urine at the cut-off concentration of 20 ng/mL.

Rapid Marijuana (THC) Test Strip 50 and Rapid Marijuana (THC) Test Dipcard 50 is a rapid, screening test for the qualitative detection of Marijuana and their metabolites in human urine at the cut-off concentration of 50 ng/mL.

The tests contain two formats:1) Test Strip and 2) Test Dipcard. The tests are intended for in vitro diagnostics use. They are intended for over-the-counter use.

The tests provide only a preliminary result. To obtain a confirmed analytical result, a more specific alternative chemical method must be used. Gas Chromatography/Mass spectrometry (GC/MS) or Liquid chromatography/Mass spectrometry (LC/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are obtained.

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.

Co-Innovation Biotech Co.,Ltd.

Section 5 - 510(k) Summary

K232732

Date of Summary Preparation: 17/1/2024

1. Submitter's Identifications

Submitter: Co-Innovation Biotech Co.,Ltd.
Address: No.9 Baihe 3 Street, Economic And Technological Development East Zone，Guangzhou,510530, Guangdong P.R. CHINA
Contact Person: Hong Feng
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Telephone: + 86 -20-82109823
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2. Correspondent’s Identifications

Correspondent’s Name: Co-Innovation Biotech Co.,Ltd.
Address: No.9 Baihe 3 Street, Economic And Technological Development East Zone，Guangzhou,510530, Guangdong P.R. CHINA
Contact Person: Hong Feng
Contact Email Address: fenghongfda@126.com
Telephone: + 86 -20-82109823
Fax: + 86 -20-82109823

3. Name of the Device

Recommended classification regulation:

21 CFR 862.3870 Cannabinoid test system

Device class: ClassII
Panel: Toxicology (91)
Product code: LDJ
Common Name:

Cannabinoid (THC) Test System

Proprietary names:

Rapid Marijuana (THC) Test Strip 20
Rapid Marijuana (THC) Test Dipcard 20
Rapid Marijuana (THC) Test Strip 50
Rapid Marijuana (THC) Test Dipcard 50

4. The Predicate Devices

5. Device Description

Rapid Marijuana (THC) Test Strip 20 and Rapid Marijuana (THC) Test Dipcard 20 are competitive binding, lateral flow immunochromatographic assays for qualitatively the detection of Marijuana and their metabolites at or above the cut-off concentration of 20 ng/mL. The tests can be performed without the use of an instrument.
Rapid Marijuana (THC) Test Strip 50 and Rapid Marijuana (THC) Test Dipcard 50 are competitive binding, lateral flow immunochromatographic assays for qualitatively the detection of Marijuana and their metabolites at or above the cut-off concentration of 50 ng/mL. The tests can be performed without the use of an instrument.
Test Strip and Test Dipcard use identical test strips made with same chemical formulation and manufacturing procedures.

6. Intended Use of Device

Rapid Marijuana (THC) Test Strip 20 and Rapid Marijuana (THC) Test Dipcard 20 is a rapid, screening test for the qualitative detection of Marijuana and their metabolites in human urine at the cut-off concentration of 20 ng/mL.

Rapid Marijuana (THC) Test Strip 50 and Rapid Marijuana (THC) Test Dipcard 50 is a rapid, screening test for the qualitative detection of Marijuana and their metabolites in human urine at the cut-off concentration of 50 ng/mL.

The tests contain two formats:1) Test Strip and 2) Test Dipcard. The tests are intended for in vitro diagnostics use. They are intended for over-the-counter use.

The tests provide only a preliminary result. To obtain a confirmed analytical result, a more specific alternative chemical method must be used. Gas Chromatography/Mass spectrometry (GC/MS) or Liquid chromatography/Mass spectrometry (LC/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are obtained.

7. Comparison to Predicate Devices:

A summary comparison of features of the Rapid Marijuana (THC) Test and the predicate devices is provided in the following Table：

Item	Device	Predicate （K192515）

Indication for use	Qualitative detection of Marijuana in urine	Same
Intended Use	Over-the-counter use	Prescription Use
Specimen	Urine	Same
Cutoff	20 ng/mL or 50 ng/mL	20 ng/mL or 40 ng/mL
Results	Qualitative	Same
Methodology	Competitive binding, Lateral flow immunochromatographic assay based on the principle of antigen antibody immunochemistry	Same
Configuration	Strip and Dipcard	Same
Platform Required	No	Same
Storage	4-30˚C	Same

Remark:

The subject devices have all features of the predicate device except the Cutoff concentration and Intended Use.

8. Performance Data:

8.1 Cross-reactivity with structurally similar compounds

To test the cross reactivity of the test, 3 lots of test Strip and test Dipcard was used to test with drug metabolites and drug structurally similar compounds in urine. All the components were added to drug-free normal human urine. Each sample was tested in 3 replicates using 3 lots of Strip and test Dipcard. If any positive result was observed, the compounds were further diluted with known drug-free urine specimen sequentially to different concentrations and tested in quintuplicate, until the highest concentration that generates a negative result was identified. The cross reacting substances with the lowest concentration that produced a positive result was identified and is listed in the table below.

For cut-off 20ng/mL

Compound	Lowest Concentration (ng/mL)	% Cross-reactivity
11-nor-Δ^9-THC-9-COOH	20	100%
11-nor-Δ^8-THC-9-COOH	20	100%
11-Nor-△9-THC-carboxy glucuronide	30	66.7%
11-Hydroxy-△	20	100%

9-Tetrahydrocannabinol		
(-)-11-nor-9-carboxy-Δ 9-THC	20	100%
Δ^9-THC	6000	0.3%
Δ^8-THC	4000	0.5%
Cannabinol	8000	0.3%
Cannabidiol	＞100000	Not detected

For cut-off 50ng/mL

Compound	Lowest Concentration (ng/mL)	% Cross-reactivity
11-nor-Δ^9-THC-9-COOH	50	100%
11-nor-Δ^8-THC-9-COOH	50	100%
11-Nor-△9-THC-carboxy glucuronide	75	66.7%
11-Hydroxy-△ 9-Tetrahydrocannabinol	50	100.0%
(-)-11-nor-9-carboxy-Δ 9-THC	50	100.0%
Δ^9-THC	10,000	0.5%
Δ^8-THC	15,000	0.3%
Cannabinol	20,000	0.3%
Cannabidiol	＞100,000	Not detected

8.2 Interference

Clinical urine samples may contain substances that could potentially interfere with the test. The following compounds were added to drug-free urine and target drug (-)-11-nor-9-Carboxy-Δ^9-THC urine with concentrations at 50% below and 50% above Cut-Off levels. All potential interfering substances were added at a concentration of 100μg/mL (albumin was tested at 100 mg/dL and ethanol was tested at 1%). The urine specimens were tested with 3 lots of test Strip and test Dipcard. None of the compounds listed below were shown to interfere.

Acetaminophen	Diphenhydramine	Norethindrone
Acetophenetidin	Ecgonine methyl ester	Noscapine
N-Acetylprocainamide	Ephedrine	d,l-Octopamine
Acetylsalicylic acid	β-Estradiol	Oxalic acid
Albumin (100 mg/dL)	Erythromycin	Oxolinic acid
Aminopyrine	Estrone-3-sulfate	Oxymetazoline
Amoxicillin	Ethanol (1%v/v)	Oxytetracycline

Ampicillin	Ethyl-p-aminobenzoate	Papaverine
Apomorphine	Erythromycin	Penicillin-G
Ascorbic acid	Fenoprofen	Pentazocine
Aspartame	Flucloxacillin	Perphenazine
Aspirin	Fluoxetine	Phenelzine
Atenolol	Furosemide	Prednisolone
Atorvastatin	Gentisic acid	Prednisone
Atropine	Hemoglobin	(±)-Propranolol
Azlocillin	Hydralazine	d-Pseudoephedrine
Benzilic acid	Hydrochlorothiazide	Quinacrine
Benzylpenicillin	Hydrocortisone	Quinine
Benzoic acid	o-Hydroxyhippuric acid	Quindine
Bilirubin	3-Hydroxytyramine	Ranitidine
Benzydamine	Ibuprofen	Salicylic acid
Caffeine	Indomethacin	Serotonin
Carbamazepine	Iproniazid	Sulfamethazine
Cephalexin	d,l-Isoproterenol	Sulindac
Chloralhydrate	Isoxsuprine	Tetracycline
Chloramphenicol	Ketamine	Tetrahydrocortisone 3-(β-Dglucuronide)
Chlorothiazide	Ketoprofen	Tetrahydrocortisone 3-acetate
Chlorpheniramine	Labetalol	Tetrahydrozoline
d,l-Chlorpromazine	Lisinopril	Thiamine
Cholesterol	Loperamide	Thioridazine
Clonidine	Meperidine	Tolbutamine
Cimetidine	Meprobamate	Tolbutamide
Citalopram	Methoxyphenamine	Triamterene
Cortisone	Methylphenidate	Trifluoperazine
(-)-Cotinine	Nadolol	Trimethoprim
Creatinine	Nalidixic acid	DL-Tryptophan
Deoxycorticosterone	Naloxone	Tryptamine
Dexamethasone	Naltrexone	Tyramine
Dextromethorphan	Naproxen	d, l-Thyroxine (DL-Tyrosine)
Diclofenac	Niacinamide	Uric acid
Diflunisal	Nicotine	Verapamil
Digoxin	Nifedipine	Zomepirac

8.3 Effect of urinary pH

The pH of an aliquot negative urine pool is adjusted to a pH range of 3 to 9 in 1 pH unit increments and spiked with target drug (-)-11-nor-9-Carboxy-Δ^9-THC at 50% below and 50% above cutoff levels. Each sample was tested by 3 lots of test Strip and test Dipcard. The results

demonstrate that varying ranges of pH do not interfere with the performance of the test.

8.4 Effect of Urinary specific gravity

The specific gravity studies were conducted on different specific gravity including 1.000, 1.002,1.010, 1.020, 1.030, 1.040 specimens and spiked with target drug (-)-11-nor-9-Carboxy-Δ^9-THC with concentrations at 50% below and 50% above Cut-Off levels. Each sample was tested by 3 lots of test Strip and test Dipcard. The results demonstrate that varying ranges of urinary specific gravity do not affect the test result.

8.5 Precision

Precision studies were performed using 3 lots of test Strip and test Dipcard. Drug free specimens were spiked with target drug (-)-11-nor-9-Carboxy-Δ^9-THC at 0, ±75% cutoff, ±50% cutoff, ±25% cutoff and +100% cutoff of drug. The concentrations of the target drugs were confirmed with LC/MS. Each concentration of the urine specimen was divided into aliquots. Each aliquot was blindly labeled by a nonparticipant. Separate sets of blinded coded samples were assigned and randomized prior to testing. The study was conducted by 6 operators at 3 Point-of-Care sites. Two operators per location tested 3 aliquots at each concentration for each lot per day (3 runs/day) for 10 non-consecutive days using one device lot per location. One operator tested the test strip format and the second operator tested the test dipcard format. There were 1620 observations by 3 sites at 9 concentrations.

Rapid Marijuana (THC) Test Strip 20:

Approximate concentration of sample	% of cutoff	Number of determinations per lot	Result					
			Lot 1		Lot 2		Lot 3	
			Positive	Negative	Positive	Negative	Positive	Negative
0ng/ml	Negative	60	0	60	0	60	0	60
5ng/ml	-75%cutoff	60	0	60	0	60	0	60
10ng/ml	-50%cutoff	60	0	60	0	60	0	60
15ng/ml	-25%cutoff	60	6	54	4	56	4	56
20ng/ml	cutoff	60	34	26	36	24	32	28
25ng/ml	+25%cutoff	6	54	6	56	4	58	2
30ng/ml	+50%cutoff	60	60	0	60	0	60	0
35ng/ml	+75%cutoff	60	60	0	60	0	60	0
40ng/ml	+100%cutoff	60	60	0	60	0	60	0

Rapid Marijuana (THC) Test Dipcard 20:

Approximate concentration of sample	% of cutoff	Number of determinations per lot	Result					
			Lot 1		Lot 2		Lot 3	
			Positive	Negative	Positive	Negative	Positive	Negative
0ng/ml	Negative	60	0	60	0	60	0	60
5ng/ml	-75%cutoff	60	0	60	0	60	0	60
10ng/ml	-50%cutoff	60	0	60	0	60	0	60
15ng/ml	-25%cutoff	60	4	56	6	54	4	56
20ng/ml	cutoff	60	36	24	38	22	34	26
25ng/ml	+25%cutoff	60	56	4	56	4	58	2
30ng/ml	+50%cutoff	60	60	0	60	0	60	0
35ng/ml	+75%cutoff	60	60	0	60	0	60	0
40ng/ml	+100%cutoff	60	60	0	60	0	60	0

Rapid Marijuana (THC) Test Strip 50:

Approximate concentration of sample	% of cutoff	Number of determinations per lot	Result					
			Lot 1		Lot 2		Lot 3	
			Positive	Negative	Positive	Negative	Positive	Negative
0ng/ml	Negative	60	0	60	0	60	0	60
12.5ng/ml	-75%cutoff	60	0	60	0	60	0	60
25ng/ml	-50%cutoff	60	0	60	0	60	0	60
37.5ng/ml	-25%cutoff	60	4	56	6	54	2	58
50ng/ml	cutoff	60	36	24	38	22	34	26
62.5ng/ml	+25%cutoff	6	56	4	56	4	58	2
75ng/ml	+50%cutoff	60	60	0	60	0	60	0
87.5ng/ml	+75%cutoff	60	60	0	60	0	60	0
100ng/ml	+100%cutoff	60	60	0	60	0	60	0

Rapid Marijuana (THC) Test Dipcard 50:

Approximate concentration of sample	% of cutoff	Number of determinations per lot	Result					
			Lot 1		Lot 2		Lot 3	
			Positive	Negative	Positive	Negative	Positive	Negative
0ng/ml	Negative	60	0	60	0	60	0	60
12.5ng/ml	-75%cutoff	60	0	60	0	60	0	60
25ng/ml	-50%cutoff	60	0	60	0	60	0	60
37.5ng/ml	-25%cutoff	60	6	54	2	58	6	54
50ng/ml	cutoff	60	38	22	34	26	36	24

62.5ng/ml	+25%cutoff	60	58	2	56	4	54	6
75ng/ml	+50%cutoff	60	60	0	60	0	60	0
87.5ng/ml	+75%cutoff	60	60	0	60	0	60	0
100ng/ml	+100%cutoff	60	60	0	60	0	60	0

8.6 Accuracy

80 clinical urine specimens were analyzed by LC/MS and by 3 lots of Rapid Marijuana (THC) Test Strip and Rapid Marijuana (THC) Test Dipcard. Samples were divided by concentration into five categories: drug free, less than half the cutoff, near cutoff negative, near cutoff positive, and high positive. Results were as follows:

Rapid Marijuana (THC) Test Strip 20:

Operator	Co-Innovation Result	LC/MS Analysis					Total
		Neg.（drug free）	Neg.（< -50%cutoff）	Near cutoff neg.(-50%cutoff to cutoff)	Near cutoff pos. (cutoff to+50%cutoff)	Pos.（> +50%cutoff）	
Site1	Positive	0	0	1	8	31	80
	Negative	27	5	7	1	0	
Site2	Positive	0	0	1	8	31	80
	Negative	27	5	7	1	0	
Site3	Positive	0	0	1	8	31	80
	Negative	27	5	7	1	0	

Analysis of Discordant Results Rapid Marijuana (THC) Test Strip 20

Rapid Marijuana (THC) Test Strip 20			LC/MS Analysis	
Operator	Cutoff(ng/mL)	Test Result	Drug Concentration (ng/mL)	Drug in Urine
Site 1	20	Positive	15.8	(-)-11-nor-9-Carboxy-Δ^9-THC
	20	Negative	23.6	(-)-11-nor-9-Carboxy-Δ^9-THC
Site 2	20	Positive	15.8	(-)-11-nor-9-Carboxy-Δ^9-THC
	20	Negative	23.6	(-)-11-nor-9-Carboxy-Δ^9-THC
Site 3	20	Positive	15.8	(-)-11-nor-9-Carboxy-Δ^9-THC

	20	Negative	23.6	(-)-11-nor-9-Carboxy-Δ^9-THC

Rapid Marijuana (THC) Test Dipcard 20:

Operator	Co-Innovation Result	LC/MS Analysis					Total
		Neg.（drug free）	Neg.（< -50%cutoff）	Near cutoff neg.(-50%cutoff to cutoff)	Near cutoff pos. (cutoff to+50%cutoff)	Pos.（> +50%cutoff）	
Site1	Positive	0	0	1	8	31	80
	Negative	27	5	7	1	0	
Site2	Positive	0	0	1	8	31	80
	Negative	27	5	7	1	0	
Site3	Positive	0	0	1	8	31	80
	Negative	27	5	7	1	0	

Analysis of Discordant Results Rapid Marijuana (THC) Test Dipcard 20

Rapid Marijuana (THC) Test Dipcard 20			LC/MS Analysis	
Operator	Cutoff(ng/mL)	Test Result	Drug Concentration (ng/mL)	Drug in Urine
Site 1	20	Positive	15.8	(-)-11-nor-9-Carboxy-Δ^9-THC
	20	Negative	23.6	(-)-11-nor-9-Carboxy-Δ^9-THC
Site 2	20	Positive	15.8	(-)-11-nor-9-Carboxy-Δ^9-THC
	20	Negative	23.6	(-)-11-nor-9-Carboxy-Δ^9-THC
Site 3	20	Positive	15.8	(-)-11-nor-9-Carboxy-Δ^9-THC
	20	Negative	23.6	(-)-11-nor-9-Carboxy-Δ^9-THC

Rapid Marijuana (THC) Test Strip 50:

Operator	Co-Innovation Result	LC/MS Analysis					Total
		Neg.（drug free）	Neg.（< -50%cutoff）	Near cutoff neg.(-50%cutoff to cutoff)	Near cutoff pos. (cutoff to+50%cutoff)	Pos.（> +50%cutoff）	
Site1	Positive	0	0	1	9	30	80
	Negative	21	10	8	1	0	

Site2	Positive	0	0	1	9	30	80
	Negative	21	10	8	1	0	
Site3	Positive	0	0	1	9	30	80
	Negative	21	10	8	1	0	

Analysis of Discordant Results Rapid Marijuana (THC) Test Strip 50

Rapid Marijuana (THC) Test Strip 50			LC/MS Analysis	
Operator	Cutoff(ng/mL)	Test Result	Drug Concentration (ng/mL)	Drug in Urine
Site 1	50	Positive	41.6	(-)-11-nor-9-Carboxy-Δ^9-THC
	50	Negative	60.2	(-)-11-nor-9-Carboxy-Δ^9-THC
Site 2	50	Positive	41.6	(-)-11-nor-9-Carboxy-Δ^9-THC
	50	Negative	60.2	(-)-11-nor-9-Carboxy-Δ^9-THC
Site 3	50	Positive	41.6	(-)-11-nor-9-Carboxy-Δ^9-THC
	50	Negative	60.2	(-)-11-nor-9-Carboxy-Δ^9-THC

Rapid Marijuana (THC) Test Dipcard 50:

Operator	Co-Innovation Result	LC/MS Analysis					Total
		Neg.（drug free）	Neg.（< -50%cutoff）	Near cutoff neg.(-50%cutoff to cutoff)	Near cutoff pos. (cutoff to+50%cutoff)	Pos.（> +50%cutoff）	
Site1	Positive	0	0	1	9	30	80
	Negative	21	10	8	1	0	
Site2	Positive	0	0	1	9	30	80
	Negative	21	10	8	1	0	
Site3	Positive	0	0	1	9	30	80
	Negative	21	10	8	1	0	

Analysis of Discordant Results Rapid Marijuana (THC) Test Dipcard 50

Rapid Marijuana (THC) Test Dipcard 50			LC/MS Analysis	
Operator	Cutoff(ng/mL)	Test Result	Drug Concentration (ng/mL)	Drug in Urine

Site 1	50	Positive	41.6	(-)-11-nor-9-Carboxy-Δ^9-THC
	50	Negative	60.2	(-)-11-nor-9-Carboxy-Δ^9-THC
Site 2	50	Positive	41.6	(-)-11-nor-9-Carboxy-Δ^9-THC
	50	Negative	60.2	(-)-11-nor-9-Carboxy-Δ^9-THC
Site 3	50	Positive	41.6	(-)-11-nor-9-Carboxy-Δ^9-THC
	50	Negative	60.2	(-)-11-nor-9-Carboxy-Δ^9-THC

8.7 Home Use Consumer Study

180 lay users from age 18 to 65 years participated in the study. Urine samples were prepared at the following concentrations: 0, +/- 50% cutoff, +/- 25% cutoff and +100% cutoff by spiking target drug (-)-11-nor-9-Carboxy-Δ^9-THC into drug free urine specimens. Each sample contain different drugs and the different concentrations. The concentrations of target drugs were confirmed with LC/MS. Each participant performed only 1 test on provided specimen with one format of Rapid Marijuana (THC) Test (Strip, Dipcard) using the English package insert as guide to perform the test. They were asked to fill out an English questionnaire after finishing the test. Results were as follows:

Rapid Marijuana (THC) Test Strip 20:

Approximate concentration of sample	% of cutoff	Number of determinations per lot	Layer user Results		Agreement (%)
			Positive	Negative	
0ng/ml	Negative	30	0	30	100%
10ng/ml	-50%cutoff	30	0	30	100%
15ng/ml	-25%cutoff	30	2	28	93%
25ng/ml	+25%cutoff	30	27	3	90%
30ng/ml	+50%cutoff	30	30	0	100%
40ng/ml	+100%cutoff	30	30	0	100%

Rapid Marijuana (THC) Test Dipcard 20:

Approximate concentration of sample	% of cutoff	Number of determinations per lot	Layer user Results		Agreement (%)
			Positive	Negative	
0ng/ml	Negative	30	0	30	100%
10ng/ml	-50%cutoff	30	0	30	100%
15ng/ml	-25%cutoff	30	3	27	90%
25ng/ml	+25%cutoff	30	28	2	93%
30ng/ml	+50%cutoff	30	30	0	100%
40ng/ml	+100%cutoff	30	30	0	100%

Rapid Marijuana (THC) Test Strip 50:

Approximate concentration of sample	% of cutoff	Number of determinations per lot	Layer user Results		Agreement (%)
			Positive	Negative	
0ng/ml	Negative	30	0	30	100%
25ng/ml	-50%cutoff	30	0	30	100%
37.5ng/ml	-25%cutoff	30	1	29	97%
62.5ng/ml	+25%cutoff	30	28	2	93%
75ng/ml	+50%cutoff	30	30	0	100%
100ng/ml	+100%cutoff	30	30	0	100%

Rapid Marijuana (THC) Test Dipcard 50:

Approximate concentration of sample	% of cutoff	Number of determinations per lot	Layer user Results		Agreement (%)
			Positive	Negative	
0ng/ml	Negative	30	0	30	100%
25ng/ml	-50%cutoff	30	0	30	100%
37.5ng/ml	-25%cutoff	30	2	28	93%
62.5ng/ml	+25%cutoff	30	28	2	93%
75ng/ml	+50%cutoff	30	30	0	100%
100ng/ml	+100%cutoff	30	30	0	100%

180 questionnaires were distributed collected. The results show that the test is easy to be used and the instruction insert is clear.

Evaluation of the readability of the labeling
The entire package insert readability was assessed. We choose 30 chain sentences from Instructions Insert at OTC user read. The numbers of polysyllabic words are 10 words. According to SMOG Conversion Table of Appendix B the SMOG Readability Formula of "Labeling of Home-Use In Vitro Testing Products: Approved Guideline: GP-14A5", the reading level belong to 6 degree.

9. Conclusion:

The data collected in the performance and accuracy studies demonstrate that the Rapid Marijuana (THC) Test are substantially equivalent to the predicate device.

--- End of this section ---