DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

November 2, 2015

NANTONG EGENS BIOTECH CO., LTD.
C/O JOE SHIA
BUSINESS DIRECTOR
504 EAST DIAMOND AVE. SUITE I
GAITHERSBURG, MD 20877

Re: K152643
Trade/Device Name: EGENS Urine Test Marijuana (THC)
EGENS Urine Test MDMA
Regulation Number: 21 CFR 862.3870
Regulation Name: Cannabinoid test system
Regulatory Class: II
Product Code: LDJ, LAF
Dated: September 9, 2015
Received: September 15, 2015

Dear Mr. 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. 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 Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney H. Lias -S

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
k152643

Device Name
EGENS Urine Test Cup THC-MDMA
EGENS Urine Test DipCard THC-MDMA
EGENS Urine Test Cassette Marijuana

Indications for Use *(Describe)*
EGENS Urine Test Cup THC-MDMA is a rapid test for the qualitative detection of Cannabinoids and Methylenedioxymethamphetamine in human urine at a cutoff concentration of 50 ng/mL and 500 ng/mL, respectively. EGENS Urine Test Cup THC-MDMA 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 is the preferred confirmatory method. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive.

For in vitro diagnostic use only. The tests are intended for over-the-counter and for prescription use.

EGENS Urine Test DipCard THC-MDMA is a rapid test for the qualitative detection of Cannabinoids and Methylenedioxymethamphetamine in human urine at a cutoff concentration of 50 ng/mL and 500 ng/mL, respectively. EGENS Urine Test DipCard THC-MDMA 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 is the preferred confirmatory method. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive.

For in vitro diagnostic use only. The tests are intended for over-the-counter and for prescription use.

EGENS Urine Test Cassette Marijuana is a rapid test for the qualitative detection of Cannabinoids in human urine at a cutoff concentration of 50 ng/mL.
EGENS Urine Test Cassette Marijuana 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 is the preferred confirmatory method. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive.

For in vitro diagnostic use only. The tests are intended for over-the-counter and for prescription 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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510(k) SUMMARY

1. Date: October 26, 2015

   Submitter: NANTONG EGENS BIOTECHNOLOGY, LTD.
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2. Contact person: Yan Cao
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3. Device Name: EGENS Urine Test Marijuana (THC)
   EGENS Urine Test MDMA

   Classification: Class II

Product Code	**CFR #**	**Panel**
LDJ	21 CFR, 862.3870 Cannabinoids Test System	Toxicology
LAF	21 CFR, 862.3610 Methylenedioxymethamphetamine Test System	Toxicology

4. Predicate Devices: K142580
   Chemtrue Multi-Panel DOA DipCard Tests

5. Intended Use:
   EGENS Urine Test Marijuana (THC) is a rapid test for the qualitative detection of Cannabinoids in human urine at a cutoff concentration of 50 ng/mL. The tests are available in a Cassette format, a Cup format and a Dip Card format.

   EGENS Urine Test Marijuana (THC) 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 is the preferred confirmatory method. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive.

   For in vitro diagnostic use only. The tests are intended for over-the-counter and for prescription use..

EGENS Urine Test MDMA is a rapid test for the qualitative detection of Methylenedioxymethamphetamine in human urine at a cutoff concentration of 500 ng/mL. The tests are available in a Cup format and a Dip Card format.

EGENS Urine Test MDMA 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 is the preferred confirmatory method. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive.

For in vitro diagnostic use only. The tests are intended for over-the-counter and for prescription use.

6. Device Description:
   EGENS Urine Test MDMA uses immunochromatographic assays for Methylenedioxymethamphetamine. These tests are lateral flow systems for the qualitative detection of Methylenedioxymethamphetamine in human urine. EGENS Urine Test Marijuana (THC) uses immunochromatographic assays for Cannabinoids. These tests are lateral flow systems for the qualitative detection of Cannabinoids in human urine. Each test is the first step in a two-step process. The second step is to send the sample for laboratory testing if preliminary positive results are obtained.

7. Substantial Equivalence Information

Item	**Candidate Device** EGENS Urine Test Marijuana (THC)	**Predicate – K142580**
Indication(s) for use	For the qualitative determination of Cannabinoids in human urine	Same
Methodology	Competitive binding, lateral flow immunochromatographic assays based on the principle of antigen antibody immunochemistry.	Same
Results	Qualitative	Same
Specimen Type	Human urine	Same
Cut Off Values	Cannabinoids: 50ng/ml	Same for Cannabinoids
Configurations	Cup, Cassette and Dipcard	Dipcard
Conditions for Use	Over-the-Counter & Prescription Use	Same

Item	**Candidate Device** EGENS Urine Test MDMA	**Predicate – K142580**

Indication(s) for use	For the qualitative determination of Methylenedioxymethamphetamine in human urine	Same
Methodology	Competitive binding, lateral flow immunochromatographic assays based on the principle of antigen antibody immunochemistry.	Same
Results	Qualitative	Same
Specimen Type	Human urine	Same
Cut Off Values	Methylenedioxymethamphetamine: 500ng/ml	Same for MDMA
Configurations	Cup and Dipcard	Dipcard
Conditions for Use	Over-the-Counter & Prescription Use	Same

8. Test Principle

   The EGENS Urine Test MDMA is a rapid test for the qualitative detection of Methylenedioxymethamphetamine in urine samples. The EGENS Urine Test Marijuana (THC) is a rapid test for the qualitative detection of Cannabinoids 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 below its 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.

9. 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. For each concentration, tests were performed two runs per day by three operators for 25 days. All sample aliquots were masked and randomized. The results obtained are summarized in the following tables:

A. For Marijuana (THC) DipCard

Result / THC	-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+	46-/4+	32+/18-	46+/4-	50+/0-	50+/0-	50+/0-
Lot 2	50-/0+	50-/0+	50-/0+	46-/4+	31+/19-	46+/4-	50+/0-	50+/0-	50+/0-
Lot 3	50-/0+	50-/0+	50-/0+	46-/4+	33+/17-	46+/4-	50+/0-	50+/0-	50+/0-

B. For Methylenedioxymethamphetamine (MDMA) DipCard

Result / MET	-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+	47-/3+	30+/20-	46+/4-	50+/0-	50+/0-	50+/0-
Lot 2	50-/0+	50-/0+	50-/0+	47-/3+	30+/20-	46+/4-	50+/0-	50+/0-	50+/0-
Lot 3	50-/0+	50-/0+	50-/0+	47-/3+	30+/20-	46+/4-	50+/0-	50+/0-	50+/0-

C. For Marijuana (THC) Cup

Result / THC	-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+	46-/4+	30+/20-	48+/2-	50+/0-	50+/0-	50+/0-
Lot 2	50-/0+	50-/0+	50-/0+	46-/4+	33+/17-	48+/2-	50+/0-	50+/0-	50+/0-
Lot 3	50-/0+	50-/0+	50-/0+	46-/4+	33+/17-	48+/2-	50+/0-	50+/0-	50+/0-

D. For Methylenedioxymethamphetamine (MDMA) Cup

Result / MET	-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+	47-/3+	31+/19-	47+/3-	50+/0-	50+/0-	50+/0-
Lot 2	50-/0+	50-/0+	50-/0+	47-/3+	31+/19-	47+/3-	50+/0-	50+/0-	50+/0-
Lot 3	50-/0+	50-/0+	50-/0+	47-/3+	31+/19-	47+/3-	50+/0-	50+/0-	50+/0-

E. For Marijuana (THC) Cassette

Result / THC	-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+	48-/2+	33+/17-	46+/4-	50+/0-	50+/0-	50+/0-
Lot 2	50-/0+	50-/0+	50-/0+	48-/2+	31+/19-	46+/4-	50+/0-	50+/0-	50+/0-
Lot 3	50-/0+	50-/0+	50-/0+	48-/2+	31+/19-	46+/4-	50+/0-	50+/0-	50+/0-

b. Linearity

Not applicable.

c. Stability

The EGENS Urine Test MDMA and the EGENS Urine Test Marijuana (THC) are stable at 4-30^{o}C for 24 months as determined by conducting accelerated and real-time stability testing.

Control materials are not provided with the device. The labeling provides information on how to obtain control materials.

d. Cut-off

Cut-off studies were conducted using a total of 125 Cannabinoids samples and 125 Methylenedioxymethamphetamine samples equally distributed at concentrations of -50%, -25%, at the cut-off, +25%, +50% of their respective cut-offs. These samples were tested using three different lots by three different operators. Results were all positive at +50% cut-off and all negative at -50% cut-off for both Cannabinoids and Methylenedioxymethamphetamine. The following cut-off values for the test devices have been verified.

Test	**Calibrator**	**Cut-off (ng/ml)**
Marijuana (THC）	Cannabinoids	50
Methylenedioxymethamphetamine (MDMA)	Methylenedioxymethamphetamine	500

e. Interference

Potential interfering substances found in human urine of physiological or pathological conditions were added to urine containing Cannabinoids. These urine samples were tested using three lots of the EGENS Urine Test Marijuana (THC) devices by three different operators. There were no differences observed for different formats of the device. Compounds that showed no interference at a concentration of 100μg/mL are summarized below:

Cannabinoids

4-Acetamidophenol	Diphenhydramine	Oxalic acid
Acetophenetidin	Doxylamine	Oxazepam
N-Acetvprocainamide	Ecaonine dydrochloride	Oxolinic acid
Acetvsalicvlic acid	Ecqonine methylester	Pentobarbital
Aminopvrine	Ephedrine	Perphenazine
Amityptvline	Fenoprofen	Phencyclidine
Amorbarbital	Furosemide	Phenelzine
Amoxicillin	Gentisic acid	Phenobarbital
Ampicillin	Hemoglobin	Phentermine
l-Ascorbic Acid	Hydrocortisone	L-Phenylephrine
Amphetamine	O-Hydroxyhippuric acid	(+/-)Phenylethylamine
Apormorphine	p-Hydroxy-methamphetamine	Phenylpropanotamine
Aspartame	3-Hydroxytyramine	Prednisone
Atropine	Ibuprofen	D.L-Propanolol
Benzillic acid	Imipramine	D-Propoxyphene
Benzoic acid	Iproniazid	D-Pseudoephedrine
Benzoylecaonine	(±)Isoproterenol	Quinine
Benzphetamine	Isoxsuprine	Ranitidine
Bilirubin	Ketamine	Salicylic acid
Caffeine	Ketoprofen	Secobarbital
Cannabidiol	Labetalol	Serotonin (5-Hydroxytyramine)
Chloralhvdrate	Loperamide	Sulfamethazine
Chloramphenicol	Maprotiline	Sulindac
Chlordiazepoxide	Meperidine	Temazepam
Chlorothiazide	Meprobamate	Tetrahydrocortisone,3 Acetate
(±)Chlorpheniramine	Methadone	Tetrahydrocortisone,(β-D glucuronide)
Chlorpromazine	Methoxyphenamine	Tetrahydrozoline
Chlorquine	3,4-Methylenedioxy-amphetamine	Thiamine
Cholesterol	Methylenedioxy- methamphetamine	Thioridazine
Clomipramine	Nalidixic acid	D.L-Tyrosine
Clonidine	Nalorphine	Tolbutamide
Cocaine hydrochloride	Naloxone	Triamterene
Cortisone	Naltrexone	Trifluoperazine
(-)cotinine	Naproxen	Trimethoprim
Creatinine	Niacinamide	Triyptamine
Dextromethlorphan	Nifedipine	D.L-Tryptophan

Diazepam	Norethindrone	Yyramine
Diclolrfenac	D-Norpropoxyphene	Uric acid
Diflunisal	Noscapine	Verapamil
Diaoxin	D.L-Octopamine	Zomepirac

Potential interfering substances found in human urine of physiological or pathological conditions were added to urine containing Methylenedioxymethamphetamine. These urine samples were tested using three lots of the EGENS Urine Test MDMA devices by three different operators. There were no differences observed for different formats of the device. Compounds that showed no interference at a concentration of 100µg/mL are summarized below:

Methylenedioxymethamphetamine

4-Acetamidophenol	Diphenhydramine	Oxalic acid
Acetophenetidin	Doxylamine	Oxazepam
N-Acetvprocainamide	Ecaonine dydrochloride	Oxolinic acid
Acetvsalicvlic acid	Ecqonine methylester	Pentobarbital
Aminopvrine	(-)-Ψ-Ephedrine	Perphenazine
Amityptvline	Fenoprofen	Phencyclidine
Amorbarbital	Furosemide	Phenelzine
Amoxicillin	Gentisic acid	Phenobarbital
Ampicillin	Hemoglobin	Phentermine
l-Ascorbic Acid	Hydrocortisone	L-Phenylephrine
Amphetamine	O-Hydroxyhippuric acid	Phenylethylamine
Apormorphine	p-Hydroxy-methamphetamine	Phenylpropanotamine
Aspartame	3-Hydroxytyramine	Prednisone
Atropine	Ibuprofen	D.L-Propanolol
Benzillic acid	Imipramine	D-Propoxyphene
Benzoic acid	Iproniazid	D-Pseudoephedrine
Benzoylecaonine	(±)Isoproterenol	Quinine
Benzphetamine	Isoxsuprine	Ranitidine
Bilirubin	Ketamine	Salicylic acid
Caffeine	Ketoprofen	Secobarbital
Cannabidiol	Labetalol	Serotonin (5-Hydroxytyramine)
Chloralhvdrate	Loperamide	Sulfamethazine
Chloramphenicol	Maprotiline	Sulindac
Chlordiazepoxide	Meperidine	Temazepam
Chlorothiazide	Meprobamate	Tetrahydrocortisone,3 Acetate
(±)Chlorpheniramine	Methadone	Tetrahydrocortisone,(β-D glucuronide)
Chlorpromazine	Methoxyphenamine	Tetrahydrozoline

Chlorquine	3,4-Methylenedioxy-amphetamine	Thiamine
Cholesterol	3,4-Methylenedioxy-methamphetamine	Thioridazine
Clomipramine	Nalidixic acid	D.L-Tyrosine
Clonidine	Nalorphine	Tolbutamide
Cocaine hydrochloride	Naloxone	Triamterene
Cortisone	Naltrexone	Trifluoperazine
(-)cotinine	Naproxen	Trimethoprim
Creatinine	Niacinamide	Triyptamine
Dextromethlorphan	Nifedipine	D.L-Tryptophan
Diazepam	Norethindrone	Yyramine
Diclolrfenac	D-Norpropoxyphene	Uric acid
Diflunisal	Noscapine	Verapamil
Diaoxin	D.L-Octopamine	Zomepirac

f. Specificity

To test the specificity, drug metabolites and other components that are likely to be present in urine samples were tested. The target drug Cannabinoids, its drug metabolites and the related compounds were tested using three lots of the EGENS Urine Test Marijuana (THC) for each format of the devices by three different operators. The target drug Methylenedioxymethamphetamine, its drug metabolites and the related compounds were tested using three lots of the EGENS Urine Test MDMA for each format of the devices by three different operators. These drug metabolites and components were tested at different concentrations. The obtained lowest detectable concentration was used to calculate the cross-reactivity. Results are shown in the following tables. There were no differences observed for different formats for each of the drug devices.

THC (Cut-off=50 ng/mL)	**Result**	**% Cross-Reactivity**
11-Nor-Δ^9-Tetrahydrocannabinol-9-COOH	Positive at 50 ng/mL	100%
11-Hydroxy-Δ^9-Tetrahydrocannabinol	Positive at 5000 ng/mL	1%
11-Nor-Δ^8-Tetrahydrocannabinol-9-COOH	Positive at 50 ng/mL	100%
Cannabinol	Positive at 20000 ng/mL	0.3%
Δ^8-Tetrahydrocannabinol	Positive at 10000 ng/mL	0.5%

Δ^9-Tetrahydrocannabinol	Positive at 10000 ng/mL	0.5%
Cannabidiol	Positive at 20000 ng/mL	0.3%
11-Nor-Δ^9-THC-carboxy glucuronide	Positive at 2500 ng/mL	2%
(-)-11-nor-9-carboxy-Δ 9-THC	Positive at 2500 ng/mL	2%

MDMA (Cut-off=500 ng/mL)	**Result**	**% Cross-Reactivity**
D,L-3,4-Methylenedioxymethamphetamine (MDMA)	Positive at 500 ng/mL	100%
3,4- Methylenedioxymethamphetamine HCl (MDA)	Positive at 3,000 ng/mL	16.7%
3,4-Methylenedioxymethy-amphetamine(MDEA)	Positive at 1,000 ng/mL	50%
d-methamphetamine	> 50,000ng/mL	<1%
d-amphetamine	> 50,000ng/mL	<1%
l-amphetamine	> 50,000ng/mL	<1%
l-methamphetamine	> 50,000ng/mL	<1%

g. Effect of Specific Gravity and Urine pH

Twelve urine samples of normal, high, and low specific gravity ranges (1.000 to 1.035) were collected and spiked with Cannabinoids at 25% below and 25% above the THC cut-off level. These samples were tested using three lots of each of the EGENS Urine Test Marijuana (THC) devices (DipCard, Cup, and Cassette) by three different operators.

Twelve urine samples of normal, high, and low specific gravity ranges (1.000 to 1.035) were collected and spiked with Methylenedioxymethamphetamine at 25% below and 25% above the MDMA cut-off level. These samples were tested using three lots of each of the EGENS Urine Test MDMA devices (DipCard and Cup) by three different operators.

The pH of an aliquot negative urine pool was adjusted to pH ranges of 4.00 to 9.00 in 1 pH unit increments and spiked with Cannabinoids at 25% below and 25% above the THC cut-off level. These samples were tested using three lots of each of the EGENS Urine Test Marijuana (THC) devices (DipCard, Cup, and Cassette) by three different operators.

The pH of an aliquot negative urine pool was adjusted to pH ranges of 4.00 to 9.00 in 1 pH unit increments and spiked with Methylenedioxymethamphetamine at 25% below and 25% above the MDMA cut-off level. These samples were tested using three lots of each of the EGENS Urine Test MDMA devices (DipCard and Cup) by three different operators.

The device performance was found to not be affected by varying specific gravity and pH. There were no differences observed for different formats.

2. Comparison Studies

The method comparison for the EGENS Urine Test Marijuana (THC) were performed in-house with three laboratory assistants for each format of the device. Operators ran 80 (40 negative and 40 positive) unaltered clinical samples. The samples were masked and randomized. The obtained test results were compared to GC/MS results. The results are presented in the table below:

Cannabinoids DipCard

Group / Operators		**Negative**	**Low Negative by GC/MS (less than -50%)**	**Near Cutoff Negative by GC/MS (Between -50% and cutoff)**	**Near Cutoff Positive by GC/MS (Between the cutoff and +50%)**	**High Positive by GC/MS (greater than +50%)**
Viewer A	Positive	0	0	1	14	25
	Negative	14	12	13	1	0
Viewer B	Positive	0	0	1	14	25
	Negative	14	12	13	1	0
Viewer C	Positive	0	0	1	14	25
	Negative	14	12	13	1	0

Discordant table:

Viewer	Sample number	GC/MS result	Chemical Entity by GC/MS	Viewer result
Viewer A	A1422	48	11-Nor-Δ^9-Tetrahydrocannabinol-9-COOH	positive
Viewer A	A1440	52		negative
Viewer B	A1452	49		positive
Viewer B	A1440	52		negative
Viewer C	A1452	49		positive
Viewer C	A1418	52		negative

Cannabinoids Cup

Group / Operators		Negative	Low Negative by GC/MS (less than -50%)	Near Cutoff Negative by GC/MS (Between -50% and cutoff)	Near Cutoff Positive by GC/MS (Between the cutoff and +50%)	High Positive by GC/MS (greater than +50%)
Viewer A	Positive	0	0	0	13	25
	Negative	14	12	14	2	0
Viewer B	Positive	0	0	1	14	25
	Negative	14	12	13	1	0
Viewer C	Positive	0	0	1	14	25
	Negative	14	12	13	1	0

Discordant table:

Viewer	Sample number	GC/MS result	Chemical Entity by GC/MS	Viewer result
Viewer A	A1401	53	11-Nor-Δ^9-Tetrahydrocannabinol-9-COOH	negative
Viewer A	A1418	52		negative
Viewer B	A1422	48		positive
Viewer B	A1461	52		negative
Viewer C	A1452	49		positive
Viewer C	A1440	52		negative

Cannabinoids Cassette

Group / Operators		Negative	Low Negative by GC/MS (less than -50%)	Near Cutoff Negative by GC/MS (Between -50% and cutoff)	Near Cutoff Positive by GC/MS (Between the cutoff and +50%)	High Positive by GC/MS (greater than +50%)
Viewer A	Positive	0	0	1	13	25
	Negative	14	12	13	2	0
Viewer B	Positive	0	0	1	13	25
	Negative	14	12	13	2	0
Viewer C	Positive	0	0	1	14	25
	Negative	14	12	13	1	0

Discordant table:

Viewer	Sample number	GC/MS result	Chemical Entity by GC/MS	Viewer result
Viewer A	A1452	49	11-Nor-Δ^9-Tetrahydrocannabinol-9-COOH	positive
Viewer A	A1418	52		negative

Viewer A	A1461	52		negative
Viewer B	A1422	48		positive
Viewer B	A1440	52		negative
Viewer B	A1461	52		negative
Viewer C	A1422	48		positive
Viewer C	A1418	52		negative

The method comparison for the EGENS Urine Test MDMA were performed in-house with three laboratory assistants for each format of the device. Operators ran 80 (40 negative and 40 positive) unaltered clinical samples. The samples were masked and randomized. The obtained test results were compared to GC/MS results. The results are presented in the table below:

Methylenedioxymethamphetamine DipCard

Group / Operators		**Negative**	**Low Negative by GC/MS (less than -50%)**	**Near Cutoff Negative by GC/MS (Between -50% and cutoff)**	**Near Cutoff Positive by GC/MS (Between the cutoff and +50%)**	**High Positive by GC/MS (greater than +50%)**
Viewer A	Positive	0	0	0	10	26
	Negative	10	18	12	4	0
Viewer B	Positive	0	0	0	9	26
	Negative	10	18	12	5	0
Viewer C	Positive	0	0	0	10	26
	Negative	10	18	12	4	0

Discordant table:

Viewer	Sample number	GC/MS result	Chemical Entity by GC/MS	viewer results
Viewer A	A0918	505	D,L-3,4-Methylenedioxymethamphetamine	negative
Viewer A	A0937	510		negative
Viewer A	A0953	513		negative
Viewer A	A0979	506		negative
Viewer B	A0916	520		negative
Viewer B	A0918	505		negative
Viewer B	A0937	510		negative
Viewer B	A0953	513		negative
Viewer B	A0979	506		negative
Viewer C	A0918	505		negative
Viewer C	A0937	510		negative
Viewer C	A0953	513		negative
Viewer C	A0979	506		negative

Methylenedioxymethamphetamine Cup

Group / Operators		Negative	Low Negative by GC/MS (less than -50%)	Near Cutoff Negative by GC/MS (Between -50% and cutoff)	Near Cutoff Positive by GC/MS (Between the cutoff and +50%)	High Positive by GC/MS (greater than +50%)
Viewer A	Positive	0	0	0	10	26
	Negative	10	18	12	4	0
Viewer B	Positive	0	0	0	10	26
	Negative	10	18	12	4	0
Viewer C	Positive	0	0	0	10	26
	Negative	10	18	12	4	0

Discordant table:

Viewer	Sample number	GC/MS result	Chemical Entity by GC/MS	viewer results
Viewer A	A0918	505	D,L-3,4-Methylenedioxymethamphetamine	negative
Viewer A	A0937	510		negative
Viewer A	A0953	513		negative
Viewer A	A0979	506		negative
Viewer B	A0918	505		negative
Viewer B	A0937	510		negative
Viewer B	A0953	513		negative
Viewer B	A0979	506		negative
Viewer C	A0918	505		negative
Viewer C	A0937	510		negative
Viewer C	A0953	513		negative
Viewer C	A0979	506		negative

Lay-user study

A lay user study was performed at three intended user sites with 700 lay persons, of which, 100 tested for drug-free samples only, 360 for Cannabinoids samples only, and 240 for Methylenedioxymethamphetamine samples only. They had diverse educational and professional backgrounds and ranged in age from 21 to >50 years. Urine samples were prepared at the following concentrations; -100%, +/-75%, +/-50%, +/-25% of the cut-off by spiking each drug into drug free-pooled urine specimens. The concentrations of the samples were confirmed by GC/MS. Each sample was aliquoted into individual containers, blind-labeled and randomized. Each participant was provided with the package insert, 1 blind labeled sample and a device. The results are summarized below:

EGENS Marijuana Cassette format			OTC user		%Agreement
Drug	Concentration	Number of samples	Negative	Positive	With GC/MS

Drug -free	-100%	20	20	0	100%
Cannabinoids	-75%	20	20	0	100%
	-50%	20	20	0	100%
	-25%	20	18	2	90%
	+25%	20	3	17	85%
	+50%	20	0	20	100%
	+75%	20	0	20	100%

EGENS Marijuana DipCard format			OTC user		%Agreement
Drug	Concentration	Number of samples	Negative	Positive	With GC/MS
Drug -free	-100%	20	20	0	100%
Cannabinoids	-75%	20	20	0	100%
	-50%	20	20	0	100%
	-25%	20	18	2	90%
	+25%	20	3	17	85%
	+50%	20	0	20	100%
	+75%	20	0	20	100%

EGENS Marijuana Cup format			OTC user		%Agreement
Drug	Concentration	Number of samples	Negative	Positive	With GC/MS
Drug -free	-100%	20	20	0	100%
Cannabinoids	-75%	20	20	0	100%
	-50%	20	20	0	100%
	-25%	20	18	2	90%
	+25%	20	4	16	80%
	+50%	20	0	20	100%
	+75%	20	0	20	100%

EGENS MDMA DipCard format			OTC user		%Agreement
Drug	Concentration	Number of samples	Negative	Positive	With GC/MS
Drug -free	-100%	20	20	0	100%
MDMA	-75%	20	20	0	100%
	-50%	20	20	0	100%
	-25%	20	18	2	90%
	+25%	20	4	16	80%
	+50%	20	0	20	100%
	+75%	20	0	20	100%

EGENS MDMA Cup format		Number of samples	OTC user		%Agreement With GC/MS
Drug	Concentration		Negative	Positive	
Drug -free	-100%	20	20	0	100%
MDMA	-75%	20	20	0	100%
	-50%	20	20	0	100%
	-25%	20	17	3	85%
	+25%	20	3	17	85%
	+50%	20	0	20	100%
	+75%	20	0	20	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 the package insert and the score revealed a reading grade level of less than 7.

3. Clinical Studies

   Not applicable.

10. Conclusion

Based on the test principle and performance characteristics of the device, it's concluded that EGENS Urine Test Marijuana (THC) and EGENS Urine Test MDMA devices are substantially equivalent to the predicate.