March 27, 2019

Hangzhou AllTest Biotech Co., Ltd
% Feng-Yu Lee, Principal Regulatory Consultant
IVDD Regulatory Consultant
29222 Rancho Viejo Rd., Suite 218
San Juan Capistrano, CA 92675

Re: K182738
Trade/Device Name: Single and Multi-Drug Rapid Test Panel With Adulteration (Urine)
Single and Multi-Drug Rapid Test Panel (Urine)
Single and Multi-Drug Rapid Test Cup With Adulteration (Urine)
Single and Multi-Drug Rapid Test Cup (Urine)
Single Drug Rapid Test Dipstick (Urine)
Single and Multi-Drug Home Rapid Test Panel (Urine)
Single and Multi-Drug Home Rapid Test Cup (Urine)
Single Drug Home Rapid Test Dipstick (Urine)
Regulation Number: 21 CFR 862.3100
Regulation Name: Amphetamine test system
Regulatory Class: Class II
Product Code: DKZ, NFT, DIS, PTH, JXM, NFV, DJG, NGL, DIO, NFY, DJR, PTG, DJC, NGG, LDJ, NFW, LAF, DNK, NGI, LCM, NGM, LFG, QAW
Dated: February 18, 2019
Received: February 19, 2019

Dear Feng-Yu Lee:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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 -S

for 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
k182738

Device Name
Single and Multi-Drug Rapid Test Cup With Adulteration (Urine)

Indications for Use *(Describe)*

The Single and Multi-Drug Rapid Test Cup With Adulteration (Urine) are rapid chromatographic immunoassay for the qualitative detection of single or multiple drugs and drug metabolites in urine at the following cut-off concentrations: Amphetamine 500ng/mL, Secobarbital 300ng/mL, Benzodiazepines 300ng/mL, Buprenorphine 10ng/mL, Cocaine 150ng/mL, Marijuana 50ng/mL, Methadone 300ng/mL, Methamphetamine 500ng/mL, Methylenedioxymethamphetamine 500ng/mL, Morphine 300ng/mL and 2,000ng/mL, Phencyclidine 25ng/mL, Nortriptyline 1,000ng/mL, Oxycodone 100ng/mL, and 2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine 300ng/mL.

This assay provides only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/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 indicated.

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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Food and Drug Administration

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Department of Health and Human Services
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Office of Chief Information Officer
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PRAStaff@fda.hhs.gov

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Indications for Use

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Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
k182738

Device Name
Single and Multi-Drug Rapid Test Panel With Adulteration (Urine)

Indications for Use *(Describe)*

The Single and Multi-Drug Rapid Test Panel With Adulteration (Urine) are rapid chromatographic immunoassay for the qualitative detection of single or multiple drugs and drug metabolites in urine at the following cut-off concentrations: Amphetamine 500ng/mL, Secobarbital 300ng/mL, Benzodiazepines 300ng/mL, Buprenorphine 10ng/mL, Cocaine 150ng/mL, Marijuana 50ng/mL, Methadone 300ng/mL, Methamphetamine 500ng/mL, Methylenedioxymethamphetamine 500ng/mL, Morphine 300ng/mL and 2,000ng/mL, Phencyclidine 25ng/mL, Nortriptyline 1,000ng/mL, Oxycodone 100ng/mL, and 2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine 300ng/mL.

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Indications for Use

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See PRA Statement below.

510(k) Number *(if known)*
k182738

Device Name
Single Drug Rapid Test Dipstick (Urine)

Indications for Use *(Describe)*

The Single Drug Rapid Test Dipstick (Urine) are rapid chromatographic immunoassay for the qualitative detection of individual drug and drug metabolite(s) in urine at the following cut-off concentrations:
Amphetamine 500ng/mL, Secobarbital 300ng/mL, Benzodiazepines 300ng/mL, Buprenorphine 10ng/mL, Cocaine 150ng/mL, Marijuana 50ng/mL, Methadone 300ng/mL, Methamphetamine 500ng/mL, Methylenedioxymethamphetamine 500ng/mL, Morphine 300ng/mL and 2,000ng/mL, Phencyclidine 25ng/mL, Nortriptyline 1,000ng/mL, Oxycodone 100ng/mL, and 2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine 300ng/mL.

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Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are indicated.

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)

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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)*
k182738

Device Name
Single and Multi-Drug Home Rapid Test Cup (Urine)

Indications for Use *(Describe)*

The Single and Multi-Drug Home Rapid Test Cup (Urine) are rapid chromatographic immunoassay for the qualitative detection of single or multiple drugs and drug metabolites in urine at the following cut-off concentrations: Amphetamine 500ng/mL, Secobarbital 300ng/mL, Benzodiazepines 300ng/mL, Buprenorphine 10ng/mL, Cocaine 150ng/mL, Marijuana 50ng/mL, Methadone 300ng/mL, Methamphetamine 500ng/mL, Methylenedioxymethamphetamine 500ng/mL, Morphine 300ng/mL and 2,000ng/mL, Phencyclidine 25ng/mL, Nortriptyline 1,000ng/mL, Oxycodone 100ng/mL, and 2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine 300ng/mL.

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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)

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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)*
k182738

Device Name
Single and Multi-Drug Home Rapid Test Panel (Urine)

Indications for Use *(Describe)*

The Single and Multi-Drug Home Rapid Test Panel (Urine) are rapid chromatographic immunoassay for the qualitative detection of single or multiple drugs and drug metabolites in urine at the following cut-off concentrations: Amphetamine 500ng/mL, Secobarbital 300ng/mL, Benzodiazepines 300ng/mL, Buprenorphine 10ng/mL, Cocaine 150ng/mL, Marijuana 50ng/mL, Methadone 300ng/mL, Methamphetamine 500ng/mL, Methylenedioxymethamphetamine 500ng/mL, Morphine 300ng/mL and 2,000ng/mL, Phencyclidine 25ng/mL, Nortriptyline 1,000ng/mL, Oxycodone 100ng/mL, and 2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine 300ng/mL.

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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)

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Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
k182738

Device Name
Single Drug Home Rapid Test Dipstick (Urine)

Indications for Use *(Describe)*

The Single Drug Home Rapid Test Dipstick (Urine) are rapid chromatographic immunoassay for the qualitative detection of individual drug and drug metabolite(s) in urine at the following cut-off concentrations:
Amphetamine 500ng/mL, Secobarbital 300ng/mL, Benzodiazepines 300ng/mL, Buprenorphine 10ng/mL, Cocaine 150ng/mL, Marijuana 50ng/mL, Methadone 300ng/mL, Methamphetamine 500ng/mL, Methylenedioxymethamphetamine 500ng/mL, Morphine 300ng/mL and 2,000ng/mL, Phencyclidine 25ng/mL, Nortriptyline 1,000ng/mL, Oxycodone 100ng/mL, and 2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine 300ng/mL.

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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)

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510(K) SUMMARY

This summary of 5l0(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA l990 and 21 CFR §807.92.

The assigned 510(k) number is: k182738

1. Submitter's Identification:

Hangzhou AllTest Biotech Co., Ltd

#550, Yinhai Street

Hangzhou Economic & Technological Development Area,

Hangzhou 310018, P.R. China

c/o IVDD Regulatory Consultant

29122 Rancho Viejo Road, Suite 212

San Juan Capistrano, CA 92675

Contact Person: Feng-Yu Lee

Phone Number: 1-949-218-0929

Fax Number: 1-949-218-0928

Date Summary Prepared: March 27, 2019

2. **Name of the Device:**

For Prescription Use

Single and Multi-Drug Rapid Test Panel With Adulteration (Urine)

Single and Multi-Drug Rapid Test Panel (Urine)

Single and Multi-Drug Rapid Test Cup With Adulteration (Urine)

Single and Multi-Drug Rapid Test Cup (Urine)

Single Drug Rapid Test Dipstick (Urine)

For Over-the-Counter

Single and Multi-Drug Home Rapid Test Panel (Urine)

Single and Multi-Drug Home Rapid Test Cup (Urine)

Single Drug Home Rapid Test Dipstick (Urine)

3. **Common or Usual Name: Drugs of Abuse Test**

Panel: Toxicology

Analyte	**Product Code** Professional / OTC	**Regulation Section**
Amphetamine	DKZ / NFT	21CFR 862.3100, Amphetamine Test System
Secobarbital	DIS / PTH	21 CFR 862.3150, Barbiturates Test System
Benzodiazepines	JXM / NFV	21 CFR 862.3170, Benzodiazepines Test System
Buprenorphine	DJG / NGL	21CFR 862.3650, Opiate Test System
Cocaine	DIO / NFY	21 CFR 862.3250, Cocaine and metabolites Test System
2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine	DJR / PTG	21 CFR 862.3620, Methadone Test System
Methylenedioxymethamphetamine	DJC / NGG	21 CFR 862.3610, Methamphetamine Test
Marijuana	LDJ / NFW	21 CFR 862.3870, Cannabinoids Test System
Methadone	DJR / PTG	21 CFR 862.3620, Methadone Test System
Methamphetamine	LAF / NGG	21 CFR 862.3610, Methamphetamine Test
Morphine (300 and 2000)	DNK / NGI	21 CFR 862.3640, Morphine Test System

Oxycodone	DJG / NGL	21 CFR 862.3650, Opiate Test System
Phencyclidine	LCM / NGM	Unclassified, Enzyme Immunoassay Phencyclidine
Nortriptyline	LFG / QAW	21 CFR 862.3910, Tricyclic Antidepressant Drugs Test System

4. Device Description:

The Candidate Drug Screen Tests are rapid lateral flow immunoassays in which drug-protein conjugates in the test device compete with drugs or drug metabolites that may be present in urine.

On each test strip, a drug-protein conjugate is added to the test band of the membrane known as the test region (T), and the anti-drug antibody-colloidal gold conjugate pads are placed at the forward end of the membrane. Anti-drug antibodies derived from sheep and/or mice are used on the candidate tests. If target drugs are present in the urine specimen below its cut-off concentration, the solution of the colored antibody-colloidal gold conjugates moves along with the sample solution by capillary action across the membrane to the immobilized drug-protein conjugate zone on the test band region. The colored antibody- gold conjugates then complexes with the drug-protein conjugates to form visible lines.

Therefore, the formation of the visible precipitant in the test band indicates a negative result. If the target drug level exceeds its cut-off concentration, the drug/metabolite antigen competes with drug protein conjugates on the test band region for the limited antibody on the colored drug antibody-colloidal gold conjugate pad. The drug will saturate the limited antibody binding sites and the colored antibody-colloidal gold conjugate cannot bind to the drug-protein conjugate at the test region of the test strip. Therefore, absence of the color band on the test region indicates a preliminary positive result. A band should form in the control region (C) of the devices regardless of the presence of drug in the sample to indicate that the test has been performed properly.

5. Intended Use:

(I) For Prescription Use

- Single and Multi-Drug Rapid Test Cup With Adulteration (Urine)

The Single and Multi-Drug Rapid Test Cup With Adulteration (Urine) are rapid chromatographic immunoassay for the qualitative detection of single or multiple drugs and drug metabolites in urine at the following cut-off concentrations: Amphetamine 500ng/mL,

Secobarbital 300ng/mL, Benzodiazepines 300ng/mL, Buprenorphine 10ng/mL, Cocaine 150ng/mL, Marijuana 50ng/mL, Methadone 300ng/mL, Methamphetamine 500ng/mL, Methylenedioxymethamphetamine 500ng/mL, Morphine 300ng/mL and 2,000ng/mL, Phencyclidine 25ng/mL, Nortriptyline 1,000ng/mL, Oxycodone 100ng/mL, and 2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine 300ng/mL.

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For Prescription Use.

- Single and Multi-Drug Rapid Test Panel With Adulteration (Urine)

The Single and Multi-Drug Rapid Test Panel With Adulteration (Urine) are rapid chromatographic immunoassay for the qualitative detection of single or multiple drugs and drug metabolites in urine at the following cut-off concentrations: Amphetamine 500ng/mL, Secobarbital 300ng/mL, Benzodiazepines 300ng/mL, Buprenorphine 10ng/mL, Cocaine 150ng/mL, Marijuana 50ng/mL, Methadone 300ng/mL, Methamphetamine 500ng/mL, Methylenedioxymethamphetamine 500ng/mL, Morphine 300ng/mL and 2,000ng/mL, Phencyclidine 25ng/mL, Nortriptyline 1,000ng/mL, Oxycodone 100ng/mL, and 2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine 300ng/mL.

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- Single Drug Rapid Test Dipstick (Urine)

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For Prescription Use.

(II) For Over-the-Counter

- Single and Multi-Drug Home Rapid Test Cup (Urine)

The Single and Multi-Drug Home Rapid Test Cup (Urine) are rapid chromatographic immunoassay for the qualitative detection of single or multiple drugs and drug metabolites in urine at the following cut-off concentrations: Amphetamine 500ng/mL, Secobarbital 300ng/mL, Benzodiazepines 300ng/mL, Buprenorphine 10ng/mL, Cocaine 150ng/mL, Marijuana 50ng/mL, Methadone 300ng/mL, Methamphetamine 500ng/mL, Methylenedioxymethamphetamine 500ng/mL, Morphine 300ng/mL and 2,000ng/mL, Phencyclidine 25ng/mL, Nortriptyline 1,000ng/mL, Oxycodone 100ng/mL, and 2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine 300ng/mL.

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For Over-The-Counter use.

- Single and Multi-Drug Home Rapid Test Panel (Urine)

The Single and Multi-Drug Home Rapid Test Panel (Urine) are rapid chromatographic immunoassay for the qualitative detection of single or multiple drugs and drug metabolites in urine at the following cut-off concentrations: Amphetamine 500ng/mL, Secobarbital 300ng/mL, Benzodiazepines 300ng/mL, Buprenorphine 10ng/mL, Cocaine 150ng/mL, Marijuana 50ng/mL, Methadone 300ng/mL, Methamphetamine 500ng/mL, Methylenedioxymethamphetamine 500ng/mL, Morphine 300ng/mL and 2,000ng/mL, Phencyclidine 25ng/mL, Nortriptyline 1,000ng/mL, Oxycodone 100ng/mL, and 2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine 300ng/mL.

This assay provides only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/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 indicated.

For Over-The-Counter use.

- Single Drug Home Rapid Test Dipstick (Urine)

The Single Drug Home Drug Rapid Test Dipstick (Urine) are rapid chromatographic immunoassay for the qualitative detection of individual drug and drug metabolite(s) in urine at the following cut-off concentrations: Amphetamine 500ng/mL, Secobarbital 300ng/mL, Benzodiazepines 300ng/mL, Buprenorphine 10ng/mL, Cocaine 150ng/mL, Marijuana 50ng/mL, Methadone 300ng/mL, Methamphetamine 500ng/mL, Methylenedioxymethamphetamine 500ng/mL, Morphine 300ng/mL and 2,000ng/mL, Phencyclidine 25ng/mL, Nortriptyline 1,000ng/mL, Oxycodone 100ng/mL, and 2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine 300ng/mL.

This assay provides only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/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 indicated.

For Over-The-Counter use.

6. Predicate Device Information:

The subject devices are substantially equivalent to the following 510(k) cleared device noted below.

Device Company: GUANGZHOU WONDFO BIOTECH CO., LTD.; and

510(K) Number: k173303

Device Name:

INSTANT-VIEW plus Multi-Drug of Abuse Urine Test - Simple Cup (OTC Use)

INSTANT-VIEW plus Multi-Drug Urine Test - Simple Cup (Prescription Use)

7. Comparison to Predicate Devices (Substantial Equivalence Comparison):

Similarities and Differences		
Item	Candidate Device(s)	Predicate Device(s)
Intended Use	Same	For the qualitative detection of drugs of abuse in human
Results	Same	Qualitative

Methodology	Same	Lateral flow, competitive binding immunoassay based on the principle of antigen and antibody
Intended Users	Same	Prescription and over the counter users
Cutoff Levels (ng/mL)	Amphetamine – 500 Secobarbital – 300 Benzodiazepines – 300 Buprenorphine – 10 Cocaine – 150 Marijuana – 50 Methadone – 300 Methamphetamine – 500 Methylenedioxymethamphetamine – 500 Morphine – 300 and 2000 Phencyclidine – 25 Nortriptyline - 1,000 Oxycodone – 100 2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine – 300	Amphetamine – 500 Barbiturates – 300 Benzodiazepines – 300 Buprenorphine – 10 Cocaine – 150 EDDP – 300 Ecstasy (MDMA) – 500 Marijuana – 50 Methadone – 300 Methamphetamine – 500 Morphine – 300 Opiates – 2000 Oxycodone – 100 Phencyclidine – 25 Tricyclic Antidepressants – 1000
Format	Cup, Panel / Dipstick	Cup, Panel / Dip Card, Cassette, and Dipstick

8. Conclusions from Verification and Validation Activities:

The results of all verification and validation activities demonstrate that the candidate device is substantially equivalent to the cleared predicate devices.