March 29, 2019

Advin Biotech, Inc.
Daniel Hsu
Senior QA/RA Manager
10340 Camino Santa Fe, Suite G
San Diego, CA 92121

Re: k182123
Trade/Device Name: ATTEST Drug Screen Cup
ATTEST Drug Screen Dip Card
Regulation Number: 21 CFR 862.3650
Regulation Name: Opiate test system
Regulatory Class: Class II
Product Code: DJG, DKZ, DIO, DJC
Dated: February 7, 2019
Received: February 12, 2019

Dear Daniel Hsu:

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)*
k182123

Device Name
ATTEST Drug Screen Cup
ATTEST Drug Screen Dip Card

Indications for Use *(Describe)*
The ATTEST Drug Screen Cup and the ATTEST Drug Screen Dip Card are rapid lateral flow immunoassays for the qualitative detection of 6-Acetylmorphine, d-Amphetamine, Benzoylecgonine, Buprenorphine, EDDP, d/l-Methadone, d-Methamphetamine, d/lMethylenedioxymethamphetamine, Morphine, Nortriptyline, Oxazepam, Oxycodone, Phencyclidine, d-Propoxyphene, Secobarbital and THC-COOH in human urine. The test cut-off concentrations and the compounds the tests are calibrated to are as follows:

Analyte	Calibrator	Cutoff (ng/mL)
6-Acetylmorphine	6-monoacetylmorphine	10
Amphetamine	d-Amphetamine	500
Amphetamine	d-Amphetamine	1,000
Barbiturates	Secobarbital/Pentobarbital	300
Benzodiazepines	Oxazepam	300
Buprenorphine	Buprenorphine	10
EDDP	2-ethylidene-1,5-dimethyl-3-3- diphenylpyrrolidine	300
Cocaine	Benzoylecgonine	150
Cocaine	Benzoylecgonine	300
Ecstasy	d,l-Methylenedioxymethamphetamine	500
Methamphetamine	d-Methamphetamine	500
Methamphetamine	d-Methamphetamine	1,000
Marijuana	11-nor-Δ^9-THC-9-COOH	50
Methadone	d/l-Methadone	300
Opiates	Morphine	300
Opiates	Morphine	2,000
Oxycodone	Oxycodone	100
Phencyclidine	Phencyclidine	25
Propoxyphene	Propoxyphene	300
Tricyclic Antidepressants	Nortriptyline	1,000

The single or multi-test panels can consist of the above listed analytes in any combination, up to a maximum of 16 analytes, with and without on-board adulteration/specimen validity tests (SVT) in the dip card format and in the cup format. The drug screen tests are intended for prescription use only.
The tests provide only a preliminary result. A more specific alternative chemical method should be used in order to obtain a confirmed presumptive positive result if the donor doesn't admit use or anytime required by testing procedures. Gas Chromatography / Mass Spectrometry (GC/MS), Liquid Chromatography / Mass Spectrometry (LC/MS) and their tandem mass-spectrometer versions are the preferred confirmatory methods. Careful consideration and judgment should be applied to any drugs of abuse screen test result, particularly when evaluating preliminary positive results.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

Date: March 28, 2019

Submitter: Advin Biotech, Inc.
10340 Camino Santa Fe, Suite G
San Diego, California 92121

Contact: Daniel Hsu
Telephone: 858-866-8382, ext. 100
Email: daniel.hsu@advinbio.com

A. 510(k) Number:
K182123

B. Purpose for Submission:
- **a.** Addition of Amphetamine 1000, Cocaine 300, Methamphetamine 1000 and 6-Acetylmorphine 10 to a previously cleared device (k122809)
- **b.** Update formulation of Opiate 300 assay from the same previously cleared device

C. Measurand:
6-Acetylmorphine, d-Amphetamine, Benzoylecgonine, d-Methamphetamine and Morphine

D. Type of Test:
Qualitative lateral-flow immunoassay

E. Applicant:
Advin Biotech, Inc.

F. Proprietary and Established Names:
- **a.** ATTEST Drug Screen Cup
- **b.** ATTEST Drug Screen Dip Card

G. Regulatory Information:

Assay	PRODUCT CODE	CLASSIFICATION	REGULATION NUMBER/DESCRIPTION	PANEL
6-AM	DJG	II	862.3650/Enzyme Immunoassay, Opiates	Toxicology
AMP	DKZ	II	862.3100/ Enzyme Immunoassay, Amphetamine	Toxicology
COC	DIO	II	862.3250/Enzyme Immunoassay, Cocaine and cocaine metabolites	Toxicology

MET	DJC	II	862.3610/Methamphetamine Test System	Toxicology
OPI	DJG	II	862.3650/Enzyme Immunoassay, Opiates	Toxicology

H. Intended Use

The ATTEST Drug Screen Cup and the ATTEST Drug Screen Dip Card are rapid lateral flow immunoassays for the qualitative detection of 6-Acetylmorphine, d-Amphetamine, Benzoylecgonine, Buprenorphine, EDDP, d/l-Methadone, d-Methamphetamine, d/l-Methylenedioxymethamphetamine, Morphine, Nortriptyline, Oxazepam, Oxycodone, Phencyclidine, d-Propoxyphene, Secobarbital and THC-COOH in human urine. The test cut-off concentrations and the compounds the tests are calibrated to are as follows:

Assay	Abbreviation	Calibrator	Cutoff Concentration (ng/mL)
6-Acetylmorphine	6AM	6-monoacetylmorphine	10
Amphetamine 500	AMP500	d-Amphetamine	500
Amphetamine 1000	AMP1000	d-Amphetamine	1,000
Barbiturates	BAR	Secobarbital/Pentobarbital	300
Benzodiazepines	BZO	Oxazepam	300
Buprenorphine	BUP	Buprenorphine	10
EDDP	EDDP	2-ethylidene-1,5-dimethyl-3-3-diphenylpyrrolidine	300
Cocaine 150	COC150	Benzoylecgonine	150
Cocaine 300	COC 300	Benzoylecgonine	300
Ecstasy	MDMA	d,l-Methylenedioxymethamphetamine	500
Methamphetamine 500	MET500	d-Methamphetamine	500
Methamphetamine 1000	MET1000	d-Methamphetamine	1,000
Marijuana	THC	11-nor-Δ^9-THC-9-COOH	50
Methadone	MTD	d/l-Methadone	300
Opiates 300	OPI300	Morphine	300
Opiates 2000	OPI2000	Morphine	2,000
Oxycodone	OXY	Oxycodone	100

Phencyclidine	PCP	Phencyclidine	25
Propoxyphene	PPX	Propoxyphene	300
Tricyclic Antidepressants	TCA	Nortriptyline	1,000

The single or multi-test panels can consist of the above listed analytes in any combination, up to a maximum of 16 analytes, with and without on-board adulteration/specimen validity tests (SVT) in the dip card format or in the cup format. Only one cutoff concentration per analyte will be included per device. The drug screen tests are intended for prescription use only.

The tests provide only a preliminary result. A more specific alternative chemical method should be used in order to obtain a confirmed presumptive positive result if the donor doesn't admit use or anytime required by testing procedures. Gas Chromatography / Mass Spectrometry (GC/MS), Liquid Chromatography / Mass Spectrometry (LC/MS) and their tandem mass-spectrometer versions are the preferred confirmatory methods. Careful consideration and judgment should be applied to any drugs of abuse screen test result, particularly when evaluating preliminary positive results.

The tests are not intended to differentiate between illicit and prescription use of benzodiazepines, barbiturates, buprenorphine, oxycodone, propoxyphene and tricyclic antidepressants. There are no uniformly recognized cutoff levels for these drugs in urine.

I. Device Descriptions:

For professional use, the devices consist of:

a. 10 or 25 test cups or dip cards with or without adulteration/specimen validity tests
b. Package insert
c. Procedure Card

J. Substantial Equivalence Information:

a. Predicate device names:
   i. Advin Multi-Drug Screen Test Cup
   ii. Advin Multi-Drug Screen Test Dipcard

b. Predicate 510(k) number(s):
   i. k122809

c. Comparisons with predicates:

Predicate Similarities and Differences Table for All Assays

Characteristic	Predicate (k122809)	Candidate Devices
Indications for use	Qualitative detection of drugs of abuse and/or their metabolites in human urine	Same

<table>
<tr><td>Methodology</td><td colspan="3">Lateral flow immunochromatographic assay based on competitive binding</td><td>Same</td></tr>
<tr><td>Specimen</td><td colspan="3">Human urine</td><td>Same</td></tr>
<tr><td>Analytes, calibrators, cutoffs</td><td colspan="3"><table>
<tr><th>Assay</th><th>Calibrator</th><th>Cutoff (ng/mL)</th></tr>
<tr><td>Amphetamine</td><td>d-amphetamine</td><td>500</td></tr>
<tr><td>Barbiturates</td><td>Secobarbital</td><td>300</td></tr>
<tr><td>Benzodiazepine</td><td>Oxazepam</td><td>300</td></tr>
<tr><td>Buprenorphine</td><td>Buprenorphine</td><td>10</td></tr>
<tr><td>Cocaine</td><td>Benzoylecgonine</td><td>150</td></tr>
<tr><td>EDDP</td><td>2-ethylidene-1,5-dimethyl-3-3-diphenyl-pyrrolidine</td><td>300</td></tr>
<tr><td>Ecstasy</td><td>d/l-methylene-dioxy-meth-amphetamine</td><td>500</td></tr>
<tr><td>Methamphetamine</td><td>d-meth-amphetamine</td><td>500</td></tr>
<tr><td>Methadone</td><td>d/l-methadone</td><td>300</td></tr>
<tr><td>Morphine</td><td>Morphine</td><td>300</td></tr>
<tr><td>Opiates</td><td>Morphine</td><td>2,000</td></tr>
<tr><td>Oxycodone</td><td>Oxycodone</td><td>100</td></tr>
<tr><td>Phencyclidine</td><td>Phencyclidine</td><td>25</td></tr>
<tr><td>Propoxyphene</td><td>d-propoxyphene</td><td>300</td></tr>
<tr><td>Tricyclics</td><td>Nortriptyline</td><td>1,000</td></tr>
<tr><td>Marijuana</td><td>THC-COOH</td><td>50</td></tr>
</table></td><td>Same except the additions of:<table>
<tr><th>Assay</th><th>Calibrator</th><th>cutoff</th></tr>
<tr><td>6-AM</td><td>6-acetyl-morphine</td><td>10</td></tr>
<tr><td>Amphetamine</td><td>d-amphetamine</td><td>1,000</td></tr>
<tr><td>Cocaine</td><td>Benzoyl-ecgonine</td><td>300</td></tr>
<tr><td>Meth-amphetamine</td><td>d-meth-amphetamine</td><td>1,000</td></tr>
</table></td></tr>
<tr><td>Test formats</td><td colspan="3">Cup, Dip Card, Cassette</td><td>Cup and Dip Card only</td></tr>
</table>

K. Standard Referenced:

Cutoffs shown in the table below are harmonized with DHHS/SAMHSA screening cutoffs for drugs of abuse in urine (Federal Register Notice, Volume 82. No.13, January 23, 2017):

Assay Name	Abbreviation	Calibrator Drug	Cutoff level (ng/mL)
6-AM	6AM	6-monoacetylmorphine	10
Amphetamine	AMP	d-amphetamine	500
Cocaine	COC	Benzoylecgonine	150
Methamphetamine	MET	d-methamphetamine	500
MDMA	MDMA	d/l-methylenedioxymethamphetamine	500
Opiates 2000	OPI	Morphine (free)	2000
Oxycodone	OXY	Oxycodone	100
PCP	PCP	Phencyclidine	25
THC	THC	THC-COOH	50

L. **Test Principle:**

The ATTEST Drug Screen Cup and the ATTEST Drug Screen Dip Card are rapid lateral flow immunoassays in which drug-protein conjugates compete for limited antibody sites with drugs or drug metabolites that may be present in the urine. Each test strip consists of one or two drug-protein conjugates which are printed on nitrocellulose membrane in the test (T) regions. The anti-drug antibody-colloidal gold conjugates are dried onto a pad which is located beneath the nitrocellulose membrane bearing the test line(s). If target drugs are present in the urine specimen below the cut-off concentration of the assay, the solution of the colored antibody-colloidal gold conjugate that has been rehydrated by the urine sample migrates by capillary action across the membrane to the immobilized drug-protein conjugate zone on the test (T) region. The colored antibody-gold conjugate then binds with the drug-protein conjugate to form visible lines in the test (T) regions. The formation of a visible line in the test (T) region on any strip indicates a negative result, regardless of the intensity of the visible line.

If the target drug level exceeds the cutoff concentration of the assay, the drug/metabolite antigen in the urine will bind to and saturate the limited antibody sites during the capillary migration up the strip. The saturated antibody sites will be unavailable to bind to the drug-protein conjugate on the membrane, so no visible lines will appear. Therefore, absence of a visible line in the test (T) region indicates a preliminary positive result. A separate antibody-antigen reaction forms control (C) lines which must appear on the strip to interpret the results. The lack of a visible control (C) line indicates an insufficient specimen volume or improper test technique and the test must be repeated.

M. **Performance Characteristics:**

a. <u>Analytical performance:</u>

i. *Precision/Reproducibility:*

The precision, reproducibility and sensitivity of the ATTEST Drug Screen Cup and the ATTEST Drug Screen Dip Card were evaluated at Advin Biotech and at three (3) external testing sites. Data obtained at all testing sites across the intended use populations indicate >99% correlation at +/-50% of each assay cutoff.

ii. *Linearity/Assay Reportable Range:*
Not applicable. Devices intended for qualitative determinations only.

iii. *Traceability, Stability, Expected Values (controls, calibrators, methods):*

1. Traceability: The assays shown in the table below are harmonized with the DHHS/SAMHSA screening cutoffs for drugs of abuse in urine (Federal Register Notice, Volume 82. No.13, January 23, 2017):

Assay Name	Abbreviation	Calibrator Drug	Cutoff level (ng/mL)
6-AM	6AM	6-monoacetylmorphine	10
Amphetamine	AMP	d-amphetamine	500
Cocaine	COC	Benzoylecgonine	150
Methamphetamine	MET	d-methamphetamine	500
MDMA	MDMA	d/l-methylenedioxymethamphetamine	500
Opiates 2000	OPI	Morphine (free)	2000
Oxycodone	OXY	Oxycodone	100
PCP	PCP	Phencyclidine	25
THC	THC	THC-COOH	50

2. Stability: Device stability has been or will be determined using accelerated stress testing and real-time studies. All accelerated studies have been completed. Real-time stability testing in room temperature conditions have been completed for Amphetamine 1000, Cocaine 300 and Methamphetamine 1000 assays. In real-time, room temperature conditions, devices in both formats are stable for 28 months when stored at room temperature in sealed foil. Real-time stability studies for the 6-AM assay and the reformulated OPI 300 assay are ongoing.
3. Controls: Devices have been evaluated with various 3rd party commercial controls. FDA-cleared controls manufactured by Biochemical Diagnostics, Inc. (a Kova International company) are recommended by Advin Biotech, Inc. for use in verifying the performance of the assays.

iv. *Detection Limit/sensitivity:*
Assays contained within the devices bear the cutoff levels shown in the table in section H above. Field studies demonstrate the sensitivity of the assays in the hands of intended professional users and are summarized in section M.a.i. above.

v. *Analytical Specificity:*
The specificity of each assay was determined through the testing of contrived solutions made by spiking certified standards of chemically-related or structurally-similar compounds into drug free urine. The relative cross-

reactivity (if any) represents the minimum concentration necessary to yield a result similar to the cutoff level of the respective assay.

Assay/Cutoff	Compound	Concentration (ng/mL)	Relative cross-reactivity (%)
6-AM 10	6-acetylmorphine	10	100
	Diacetylmorphine (heroin)	300	3.3
	Morphine	>100,000	<0.1
	Codeine	>100,000	<0.1
	Oxycodone	>100,000	<0.1
	Oxymorphone	>100,000	<0.1
AMP 500	d-Amphetamine	500	100
	l-Amphetamine	50,000	1
	MDA	8,000	6.5
	Phentermine	45,000	1.1
AMP 1000	d-Amphetamine	1,000	100
	l-Amphetamine	100,000	1
	MDA	15,000	6.7
	Phentermine	100,000	1.0
BAR 300	Secobarbital	300	100
	Amobarbital	2,500	12
	Aprobarbital	500	60
	Butabarbital	100	300
	Butalbital	300	100
	Cyclopentobarbital	500	60
	Pentobarbital	250	120
	Phenobarbital	300	100
BZO 300	Oxazepam	300	100
	Alprazolam	200	150
	α-Hydroxyalprazolam	1,900	15.8
	Bromazepam	1,000	30
	Clobazam	200	150
	Clonazepam	1,500	20
	7-Aminoclonazepam	>100,000	<0.3
	Clorazepate	750	40
	Desalkylflurazepam	1,200	25
	Diazepam	1,000	30
	Flunitrazepam	250	120
	Lorazepam	3,900	7.7
	Lorazepam glucuronide	5,000	6
	Nitrazepam	250	120
	Norchlordiazepoxide	500	60
	Nordiazepam	390	76.9
	Temazepam	150	200
	Triazolam	2,500	12
BUP 10	Buprenorphine	10	100
	Buprenorphine-3-β-glucuronide	3.5	286

	Norbuprenorphine	7.5	133
	Norbuprenorphine glucuronide	35	28
COC 150	Benzoylecgonine	150	100
	Cocaethylene	50,000	0.3
	Cocaine	5,000	3
	Ecgonine	50,000	0.3
COC 300	Benzoylecgonine	300	100
	Cocaethylene	100,000	0.3
	Cocaine	10,000	3
	Ecgonine	100,000	0.3
EDDP 300	2-Ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine	300	100
	d/l-Methadone	>100,000	<0.3
MET 500	d-Methamphetamine	500	100
	l-Methamphetamine	15,000	3.3
	d-Amphetamine	50,000	1
	l-Amphetamine	50,000	1
	1R, 2S(1)-Ephedrine	100,000	<0.5
	MDEA	30,000	1.7
	MDMA	3,500	14.3
	Mephentermine	75,000	0.7
MET 1000	d-Methamphetamine	1,000	100
	l-Methamphetamine	30,000	3.3
	d-Amphetamine	100,000	1
	l-Amphetamine	100,000	1
	1R, 2S(1)-Ephedrine	>100,000	<0.5
	MDEA	60,000	1.7
	MDMA	8,000	12.5
	Mephentermine	100,000	1
MDMA 500	(+/-)-methylenedioxymethamphetamine (MDMA)	500	100
	(+/-)-methylenedioxyamphetamine (MDA)	3,900	12.8
	(+/-)-methylenedioxyethylamphetamine (MDEA)	500	100
MTD 300	d/l-Methadone	300	100
	EDDP	>100,000	<0.3
OPI 300	Morphine	300	100
	6-Acetylmorphine (6-AM)	400	75
	Codeine	100	300
	Codeine-6-β-glucuronide	150	200
	Ethylmorphine	150	200
	Diacetylmorphine (heroin)	900	33.3
	Hydrocodone	500	60
	Hydromorphone	600	50
	Levorphanol	10,000	3
	Morphine-3-glucuronide	450	66.7

	Norcodeine	30,000	1
	Oxycodone	70,000	<0.5
	Thebaine	20,000	1.5
OPI 2000	Morphine	2,000	100
	6-Acetylmorphine (6-AM)	700	286
	Codeine	1,800	111
	Codeine-6-β-glucuronide	1,250	160
	Ethylmorphine	1,500	133
	Diacetylmorphine (heroin)	11,000	18.2
	Hydrocodone	5,000	40
	Hydromorphone	5,000	40
	Levorphanol	>100,000	<2
	Morphine-3-glucuronide	2,600	77
	Norcodeine	>100,000	<2
	Oxycodone	70,000	3
	Thebaine	95,000	2.1
OXY 100	Oxycodone	100	100
	Codeine	50,000	0.2
	Ethylmorphine	50,000	0.2
	Hydrocodone	5,000	2
	Hydromorphone	25,000	0.4
	Oxymorphone	12,500	0.8
PCP 25	Phencyclidine	25	100
	4-OH-Phencyclidine	1,500	1.7
PPX 300	d-Propoxyphene	300	100
	Norpropoxyphene	300	100
TCA 1000	Nortriptyline	1,000	100
	Amitriptyline	4,000	25
	Clomipramine	2,000	50
	Desipramine	500	200
	Doxepine	1,000	100
	Imipramine	1,000	100
	Promethazine	1,000	100
	Trimipramine	5,000	20
THC 50	11-nor-Δ^9-THC-COOH	50	100
	(+/-)-11-Hydroxy-Δ^9-THC	5,000	1
	Δ^8-THC	20,000	0.3
	Δ^9-THC	20,000	0.3
	Cannabinol	>100,000	<0.1
	Cannabidiol (CBD)	>100,000	<0.1

The potential interference (whether positive or negative) from compounds chemically dissimilar to target drugs, known endogenous agents, urine pH and specific gravity variances was also determined. Testing of compounds and endogenous agents was performed by spiking the substances into pooled urine containing target drugs at near-cutoff concentrations. Unless otherwise indicated, substances were tested for potential interference at concentrations of 100 µg/mL.

The following substances demonstrated no positive or negative interference on the assays encompassed in this submission:

Acetaminophen	Acetone	Acetylsalicylic acid (aspirin)
Albumin	Ampicillin	Ascorbic acid
Aspartame	Atropine	Benzocaine
Bilirubin	Caffeine	Chloroquine
Chlorpheniramine	Creatine	Dexbrompheniramine
Dextromethorphan	Dimethylaminoantipyrine	Diphenhydramine
Dimenhydrinate	Dopamine	Isoproterenol
Ephedrine	Erythromycin	Ethanol
Furosemide	Gabapentin	Glucose
Guaiacol glyceryl ether	Hemoglobin	Ibuprofen
Isoproterenol	Ketamine	Lidocaine
Methylephedrine	Naproxen	Niacinamide
Nicotine	Norephedrine	Oxalic acid
Pantoprazole	Penicillin-G	Pheniramine
Phenothiazine	l-Phenylephrine	B-Phenylethylamine
Pregablin	Procaine	Quinidine
Ranitidine	Riboflavin	Sertraline
Sodium chloride	Sulindac	Theophylline
Tyramine		

In addition to the spiked testing described above, in light of industry-known interferences presumably arising from the metabolites of these drugs in human urine, Advin Biotech has evaluated its assays for potential false positive results using clinical urine specimens from donors taking self-reported prescription-level or OTC high-dose levels of each of the following drugs and found no false positive results:

a. Rantidine (Zantac®)-donors taking high-doses per OTC instructions for use
b. Sertraline (Zoloft®)-donor taking prescription dose (steady-state level)
c. Naproxen (Aleve®)-donor taking high-dose per OTC instructions for use
d. Pantoprazole (Protonix®)-donor taking high-dose per OTC instructions for use
e. Gabapentin (Neurontin®)-donor taking high prescription doses of 900mg/day
f. Pregabalin (Lyrica®)-donor taking prescription dose
g. Atomoxetine (Strattera®)-donor taking prescription dose

To evaluate the potential effect of variances in urine pH on the assays, pooled urine specimens containing target drugs at near-cutoff concentrations were pH adjusted from 4.0 to 9.0 in increments of 1.0 and tested in duplicate.

To evaluate the potential effect of variances of urine specific gravity on the assays, pooled urine specimens containing target drugs at near-cutoff concentrations were diluted using deionized water or concentrated using sodium chloride to achieve specific gravity results of 1.003, 1.010, 1.015, 1.020, 1.025 and 1.030. Each solution was tested in duplicate.

The results demonstrated that pH levels of 4 to 9 and specific gravity levels of 1.003 to 1.030 do not affect the results of the assays. To mitigate the risk of specimen tampering,

adulteration or substitution, the ATTEST Drug Screen Cup and the ATTEST Drug Screen Dip Card can be constructed with specimen validity tests (SVT).

b. Method Comparison/Accuracy Studies

Advin Biotech performed a method comparison study of the ATTEST Drug Screen Cup and the ATTEST Drug Screen Dip Card using clinical urine specimens previously quantitated for the target drugs of abuse by gold-standard methods (GC/MS, LC/MS or equivalent). The results are shown in the table below. Data for previously-cleared assays (k122809) are taken from that submission and presented in combination with the new assays below:

The ATTEST Drug Screen Cup format

Drug Test/Cutoff (ng/mL)	Result	Drug-free	Drug quantitation by gold-standard method relative to assay cutoff level					
			-50% C/O to <-25% C/O	-25% C/O to C/O	C/O to +25% C/O	>+25% C/O to +50% C/O	>+50% C/O	Agreement
6-AM/10	Neg	40	4	1	0	0	0	100%
	Pos	0	0	0	1	4	35	100%
AMP/500	Neg	40	3	0	0	0	0	97.7%
	Pos	0	0	1	2	2	45	100%
AMP/1000	Neg	40	3	3	0	0	0	100%
	Pos	0	0	0	3	3	40	100%
BAR/300	Neg	40	1	1	0	0	0	95.2%
	Pos	0	0	2	5	2	36	100%
BUP/10	Neg	40	1	1	0	0	0	95.5%
	Pos	0	0	2	8	0	32	100%
BZO/300	Neg	40	0	1	0	0	0	93.2%
	Pos	0	0	3	1	6	34	100%
COC/150	Neg	40	0	3	0	0	0	97.70%
	Pos	0	0	1	4	1	53	100%
COC/300	Neg	40	3	2	0	0	0	100%
	Pos	0	0	0	2	3	35	100%
EDDP/300	Neg	40	0	1	0	0	0	93.2%
	Pos	0	0	3	5	2	33	100%
MDMA/500	Neg	40	1	1	0	0	0	95.5%
	Pos	0	0	2	5	1	34	100%
MET/500	Neg	40	1	0	0	0	0	93.2%
	Pos	0	0	3	1	3	51	100%
MET/1000	Neg	40	3	3	0	0	0	100%
	Pos	0	0	0	2	3	40	100%
MTD/300	Neg	40	0	2	0	0	0	95.5%
	Pos	0	0	2	4	0	37	100%
OPI/300	Neg	40	2	1	0	0	0	97.72%
	Pos	0	0	1	3	1	46	100%
OPI/2000	Neg	40	1	0	0	0	0	93.2%
	Pos	0	0	2	4	3	40	100%
OXY/100	Neg	40	1	0	0	0	0	93.2%
	Pos	0	0	3	7	1	33	100%
PCP/25	Neg	40	0	3	0	0	0	97.7%
	Pos	0	0	1	3	8	33	100%
PPX/300	Neg	40	0	1	0	0	0	95.3%
	Pos	0	0	2	5	2	33	100%
TCA/1000	Neg	40	0	2	0	0	0	95.5%
	Pos	0	0	2	5	7	28	100%
THC/50	Neg	40	1	2	0	0	0	97.7%
	Pos	0	0	1	4	7	44	100%

Summary of Discordant Results, ATTEST Cup format

Drug Test/ Cutoff (ng/ml)	ATTEST Cup Result	Result w/ GC/MS or LC/MS	
		Drug Concentration (ng/ml)	Analyte
AMP/500	Positive	477	Amphetamine
BAR/300	Positive	265	Barbital
	Positive	286	Barbital
BUP/10	Positive	8	Buprenorphine
	Positive	9	Buprenorphine
BZO/300	Positive	244	Oxazepam
	Positive	252	Oxazepam
	Positive	295	Oxazepam
COC/150	Positive	146	Benzoylecgonine
EDDP/300	Positive	250	EDDP
	Positive	263	EDDP
	Positive	275	EDDP
MDMA/500	Positive	368	MDMA
	Positive	381	MDMA
MET/500	Positive	394	Methamphetamine
	Positive	461	Methamphetamine
	Positive	478	Methamphetamine
OPI/300	Positive	289	Morphine
MTD/300	Positive	266	Methadone
	Positive	273	Methadone
OPI/2000	Positive	1,898	Morphine
	Positive	1,990	Morphine
OXY/100	Positive	88	Oxycodone
	Positive	98	Oxycodone
	Positive	99	Oxycodone
PCP/25	Positive	22.9	Phencyclidine
PPX/300	Positive	242	Norpropoxyphene
	Positive	285	Norpropoxyphene
TCA/1000	Positive	786	Nortriptyline
	Positive	859	Nortriptyline
THC/50	Positive	49	11-nor-Δ^9-THC-9-COOH

The ATTEST Drug Screen Dip Card format

Drug Test/Cutoff (ng/mL)	Result	Drug-free	Drug quantitation by gold-standard method relative to assay cutoff level					
			-50% C/O to <-25% C/O	-25% C/O to C/O	C/O to +25% C/O	>+25% C/O to +50% C/O	>+50% C/O	Agreement
6-AM/10	Neg	40	4	1	0	0	0	100%
	Pos	0	0	0	1	4	35	100%
AMP/500	Neg	40	3	0	0	0	0	97.7%
	Pos	0	0	1	2	2	45	100%
AMP/1000	Neg	40	3	3	0	0	0	100%
	Pos	0	0	0	3	3	40	100%
BAR/300	Neg	40	1	1	0	0	0	95.2%
	Pos	0	0	2	5	2	36	100%
BUP/10	Neg	40	1	1	0	0	0	95.5%
	Pos	0	0	2	8	0	32	100%
BZO/300	Neg	40	0	1	0	0	0	93.2%
	Pos	0	0	3	1	6	34	100%
COC/150	Neg	40	0	3	0	0	0	97.70%
	Pos	0	0	1	4	1	53	100%
COC/300	Neg	40	3	2	0	0	0	100%
	Pos	0	0	0	2	3	35	100%
EDDP/300	Neg	40	0	1	0	0	0	93.2%
	Pos	0	0	3	5	2	33	100%
MDMA/500	Neg	40	1	1	0	0	0	95.5%
	Pos	0	0	2	5	1	34	100%
MET/500	Neg	40	1	0	0	0	0	93.2%
	Pos	0	0	3	1	3	51	100%
MET/1000	Neg	40	3	3	0	0	0	100%
	Pos	0	0	0	2	3	40	100%
MTD/300	Neg	40	0	2	0	0	0	95.5%
	Pos	0	0	2	4	0	37	100%
OPI/300	Neg	40	2	1	0	0	0	97.72%
	Pos	0	0	1	3	1	46	100%
OPI/2000	Neg	40	1	0	0	0	0	93.2%
	Pos	0	0	2	4	3	40	100%
OXY/100	Neg	40	1	0	0	0	0	93.2%
	Pos	0	0	3	7	1	33	100%
PCP/25	Neg	40	0	3	0	0	0	97.7%
	Pos	0	0	1	3	8	33	100%
PPX/300	Neg	40	0	1	0	0	0	95.3%
	Pos	0	0	2	5	2	33	100%
TCA/1000	Neg	40	0	2	0	0	0	95.5%
	Pos	0	0	2	5	7	28	100%
THC/50	Neg	40	1	2	0	0	0	97.7%
	Pos	0	0	1	4	7	44	100%

Summary of Discordant Results, ATTEST Dip Card format

Drug Test/ Cutoff (ng/ml)	ATTEST Dip Card Result	Result w/ GC/MS or LC/MS	
		Drug Concentration (ng/ml)	Analyte
AMP/500	Positive	477	Amphetamine
BAR/300	Positive	265	Barbital
	Positive	286	Barbital
BUP/10	Positive	8	Buprenorphine
	Positive	9	Buprenorphine
BZO/300	Positive	244	Oxazepam
	Positive	252	Oxazepam
	Positive	295	Oxazepam
COC/150	Positive	146	Benzoylecgonine
EDDP/300	Positive	250	EDDP
	Positive	263	EDDP
	Positive	275	EDDP
MDMA/500	Positive	368	MDMA
	Positive	381	MDMA
MET/500	Positive	394	Methamphetamine
	Positive	461	Methamphetamine
	Positive	478	Methamphetamine
MTD/300	Positive	266	Methadone
	Positive	273	Methadone
OPI/300	Positive	289	Morphine
OPI/2000	Positive	1,898	Morphine
	Positive	1,990	Morphine
OXY/100	Positive	88	Oxycodone
	Positive	98	Oxycodone
	Positive	99	Oxycodone
PCP/25	Positive	22.9	Phencyclidine
PPX/300	Positive	242	Norpropoxyphene
	Positive	285	Norpropoxyphene
TCA/1000	Positive	786	Nortriptyline
	Positive	859	Nortriptyline
THC/50	Positive	49	11-nor-Δ^9-THC-9-COOH

c. Clinical Studies

i. Clinical sensitivity: refer to accuracy table shown in section M.b. above

ii. Clinical specificity: refer to accuracy table show in section M.b. above

iii. Other clinical supportive data (when i and ii are not applicable): N/A

d. Read Time

To evaluate the reading time flexibility, the ATTEST Drug Screen Cup and the ATTEST Drug Screen Dip Card and were tested with drug standards at the concentration of 0, -50% and +50% cutoff level. The result was read and recorded at 4, 5, 10, 30, 60 and 75 minutes. Each solution was tested in duplicate. Data showed that the test results were stable for up to 75 minutes.

N. Proposed Labeling

The proposed labeling is deemed sufficient based on the outcomes of all intended user studies and meets the requirements of 21 CFR 809.10.

O. Conclusions

The data submitted in this premarket notification is complete and supports a substantial equivalence determination.