August 12, 2021

Assure Tech (Hangzhou) Co., Ltd.
% Joe Shia
Manager
LSI International
504 E Diamond Ave., Suite I
Gaithersburg, Maryland 20877

Re: K201630
Trade/Device Name: AssureTech DOA Dipstick Screen Panel Tests, AssureTech DOA Integrated Cup Tests
Regulation Number: 21 CFR 862.3650
Regulation Name: Opiate Test System
Regulatory Class: Class II
Product Code: DJG, DKZ, LDJ, DIO, LAF, JXM, DIS, LCM, DJR, LFG, JXN
Dated: September 29, 2020
Received: September 30, 2020

Dear Joe Shia:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Marianela Perez-Torres, Ph.D.
Deputy Director
Division of Chemistry
and Toxicology Devices
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

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

510(k) Number *(if known)*
k201630

Device Name
AssureTech DOA Dipstick Screen Panel Tests
AssureTech DOA Integrated Cup Tests

Indications for Use *(Describe)*
AssureTech DOA Dipstick Screen Panel Tests are competitive binding, lateral flow immunochromatographic assays for qualitative and simultaneous detection of 6-Monoacetylmorphine, Amphetamine, Oxazepam, Cocaine, Marijuana, Methamphetamine, Morphine, Oxycodone, Secobarbital, Buprenorphine, Methylenedioxy-methamphetamine, Phencyclidine, Methadone, EDDP, Nortriptyline and d-Propoxyphene in human urine at the cutoff concentrations of:

Drug(Identifier)	Cut-off level
6-Monoacetylmorphine	10 ng/mL
Amphetamine	500 ng/mL
Oxazepam	300 ng/mL
Cocaine	150 ng/mL
Marijuana	20 ng/mL
Methamphetamine	500 ng/mL
Morphine	300 ng/mL
Oxycodone	100 ng/mL
Secobarbital	300 ng/mL
Buprenorphine	10 ng/mL
Methylenedioxy-methamphetamine	500 ng/mL
Phencyclidine	25 ng/mL
Methadone	300 ng/mL
EDDP	300 ng/mL
Nortriptyline	1000 ng/mL
d-Propoxyphene	300 ng/mL

Configuration of the AssureTech DOA Dipstick Screen Panel Tests can consist of any combination of the above listed drug analytes.

The test may yield positive results for the prescription drugs Buprenorphine, Nortriptyline, Oxazepam, Secobarbital, Propoxyphene and Oxycodone when taken at or above prescribed doses. It is not intended to distinguish between prescription use or abuse of these drugs. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive. The test provides only preliminary test results. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. GC/MS or LC/MS is the preferred confirmatory method.
For in vitro diagnostic use only.

AssureTech DOA Integrated Cup Tests are competitive binding, lateral flow immunochromatographic assays for qualitative and simultaneous detection of 6-Monoacetylmorphine, Amphetamine, Oxazepam, Cocaine, Marijuana, Methamphetamine, Morphine, Oxycodone, Secobarbital, Buprenorphine, Methylenedioxy-methamphetamine, Phencyclidine, Methadone, EDDP, Nortriptyline and d-Propoxyphene in human urine at the cutoff concentrations of:

Drug(Identifier)	Cut-off level
6-Monoacetylmorphine	10 ng/mL
Amphetamine	500 ng/mL

Oxazepam	300 ng/mL
Cocaine	150 ng/mL
Marijuana	20 ng/mL
Methamphetamine	500 ng/mL
Morphine	300 ng/mL
Oxycodone	100 ng/mL
Secobarbital	300 ng/mL
Buprenorphine	10 ng/mL
Methylenedioxy-methamphetamine	500 ng/mL
Phencyclidine	25 ng/mL
Methadone	300 ng/mL
EDDP	300 ng/mL
Nortriptyline	1000 ng/mL
d-Propoxyphene	300 ng/mL

Configuration of the AssureTech DOA Integrated Cup Tests can consist of any combination of the above listed drug analytes.

The test may yield positive results for the prescription drugs Buprenorphine, Nortriptyline, Oxazepam, Secobarbital, Propoxyphene and Oxycodone when taken at or above prescribed doses. It is not intended to distinguish between prescription use or abuse of these drugs. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive. The test provides only preliminary test results. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. GC/MS or LC/MS is the preferred confirmatory method.
For in vitro diagnostic use only.

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
K201630

1. Date: September 29, 2020

2. Submitter: Assure Tech. Co., Ltd.
Building 1, No.10, Xiyuansan Road, Westlake Economic Zone
Hangzhou, China, 310030

3. Contact person: Joe Shia
LSI International Inc.
504E Diamond Ave., Suite J
Gaithersburg, MD 20877
Telephone: 240-505-7880
Email: shiajl@yahoo.com

4. Device Name: AssureTech DOA Dipstick Screen Panel Tests
AssureTech DOA Integrated Cup Tests

Classification: Class 2

Product Code	Classification	Regulation Section	Panel
DJG Monoacetylmorphine	II	21 CFR § 862.3650, Morphine Test System	Toxicology (91)
DKZ Amphetamine	II	21 CFR § 862.3100, Amphetamine Test System	Toxicology (91)
LDJ Cannabinoids	II	21 CFR § 862.3870, Cannabinoids Test System	Toxicology (91)
DIO Cocaine	II	21 CFR § 862.3250, Cocaine and Cocaine Metabolites Test System	Toxicology (91)
LAF Methamphetamine	II	21 CFR § 862.3610, Methamphetamine Test System	Toxicology (91)
DJG Morphine	II	21 CFR § 862.3650, Morphine Test System	Toxicology (91)
JXM Oxazepam	II	21 CFR § 862.3170, Benzodiazepine Test System	Toxicology (91)
DJG Oxycodone	II	21 CFR § 862.3650, Opiate Test System	Toxicology (91)
DIS Secobarbital	II	21 CFR § 862.3150, Barbiturate Test System	Toxicology (91)
DJG Buprenorphine	II	21 CFR § 862.3650, Opiate Test System	Toxicology (91)
LAF Methylenedioxy-methamphetamine	II	21 CFR § 862.3610, Methamphetamine Test System	Toxicology (91)
LCM Phencyclidine	unclassified	Enzyme Immunoassay Phencyclidine	Toxicology (91)
DJR Methadone	II	21 CFR § 862.3620, Methadone Test System	Toxicology (91)

DJR 2-ethylidene-1, 5-dimethyl-3, 3-diphenylpyrrolidine (EDDP)	II	21 CFR § 862.3620, Methadone Test System	Toxicology (91)
LFG Nortriptyline	II	21 CFR, 862.3910 Tricyclic Antidepressant Drugs Test System	Toxicology (91)
JXN Propoxyphene	II	21 CFR, 862.3700 Propoxyphene Test System	Toxicology (91)

5. Predicate Devices: K181768 & K182123

   AssureTech Panel Dip Tests and AssureTech Quick Cup Tests (K181768)
   Advin Biotech ATTEST Drug Screen Cup and ATTEST Drug Screen Dip Card (K182123)

6. Indications for Use

   AssureTech DOA Dipstick Screen Panel Tests are competitive binding, lateral flow immunochromatographic assays for qualitative and simultaneous detection of 6-Monoacetylmorphine, Amphetamine, Oxazepam, Cocaine, Marijuana, Methamphetamine, Morphine, Oxycodone, Secobarbital, Buprenorphine, Methylenedioxy-methamphetamine, Phencyclidine, Methadone, EDDP, Nortriptyline and d-Propoxyphene in human urine at the cutoff concentrations of:

Drug (Identifier)	Cut-off level
6-Monoacetylmorphine	10 ng/mL
Amphetamine	500 ng/mL
Oxazepam	300 ng/mL
Cocaine	150 ng/mL
Marijuana	20 ng/mL
Methamphetamine	500 ng/mL
Morphine	300 ng/mL
Oxycodone	100 ng/mL
Secobarbital	300 ng/mL
Buprenorphine	10 ng/mL
Methylenedioxy-methamphetamine	500 ng/mL
Phencyclidine	25 ng/mL
Methadone	300 ng/mL
EDDP	300 ng/mL
Nortriptyline	1000 ng/mL
d-Propoxyphene	300 ng/mL

   Configuration of the AssureTech DOA Dipstick Screen Panel Tests can consist of any combination of the above listed drug analytes.

   The test may yield positive results for the prescription drugs Buprenorphine, Nortriptyline, Oxazepam, Secobarbital, Propoxyphene and Oxycodone when taken at or above prescribed doses. It is not intended to distinguish between prescription use or abuse of these drugs. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive. The test provides only preliminary test results. A more specific alternative chemical method must be used in order to obtain a confirmed

analytical result. GC/MS or LC/MS is the preferred confirmatory method.
For in vitro diagnostic use only.

AssureTech DOA Integrated Cup Tests are competitive binding, lateral flow immunochromatographic assays for qualitative and simultaneous detection of 6-Monoacetylmorphine, Amphetamine, Oxazepam, Cocaine, Marijuana, Methamphetamine, Morphine, Oxycodone, Secobarbital, Buprenorphine, Methylenedioxy-methamphetamine, Phencyclidine, Methadone, EDDP, Nortriptyline and d-Propoxyphene in human urine at the cutoff concentrations of:

Drug (Identifier)	Cut-off level
6-Monoacetylmorphine	10 ng/mL
Amphetamine	500 ng/mL
Oxazepam	300 ng/mL
Cocaine	150 ng/mL
Marijuana	20 ng/mL
Methamphetamine	500 ng/mL
Morphine	300 ng/mL
Oxycodone	100 ng/mL
Secobarbital	300 ng/mL
Buprenorphine	10 ng/mL
Methylenedioxy-methamphetamine	500 ng/mL
Phencyclidine	25 ng/mL
Methadone	300 ng/mL
EDDP	300 ng/mL
Nortriptyline	1000 ng/mL
d-Propoxyphene	300 ng/mL

Configuration of the AssureTech DOA Integrated Cup Tests can consist of any combination of the above listed drug analytes.

The test may yield positive results for the prescription drugs Buprenorphine, Nortriptyline, Oxazepam, Secobarbital, Propoxyphene and Oxycodone when taken at or above prescribed doses. It is not intended to distinguish between prescription use or abuse of these drugs. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive. The test provides only preliminary test results. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. GC/MS or LC/MS is the preferred confirmatory method.
For in vitro diagnostic use only.

7. Device Description

The AssureTech DOA Dipstick Screen Panel Tests and AssureTech DOA Integrated Cup Tests are immunochromatographic assays that use a lateral flow system for the qualitative detection of 6-Monoacetylmorphine, Amphetamine, Oxazepam, Cocaine, Marijuana, Methamphetamine, Morphine, Oxycodone, Secobarbital, Buprenorphine, Methylenedioxy-methamphetamine, Phencyclidine, Methadone, EDDP, Nortriptyline and Propoxyphene (target analytes) in human urine. The products are single-use in vitro diagnostic devices, which come in the formats of DOA Dipstick Screen Panel Cards or Cups. Each test kit contains a Test Device (in one of the two formats), a package insert and a urine cup for sample collection. Each test device is sealed with a desiccant in an aluminum pouch.

8. Substantial Equivalence Information

A summary comparison of features of the AssureTech DOA Dipstick Screen Panel Tests and AssureTech DOA Integrated Cup Tests and the predicate devices is provided in following tables.

Table 1: Features Comparison of AssureTech DOA Dipstick Screen Panel Tests and the Predicate Devices

Item	Device	Predicates - K181768 & K182123
Indication(s) for Use	For the qualitative determination of drugs of abuse in human urine.	Same (but the number of drugs detected is different)
Calibrator and Cut-Off Values	6-Monoacetylmorphine (6-MAM): 10 ng/mL Amphetamine (AMP): 500 ng/ml Oxazepam (BZO):300 ng/ml Cocaine (COC): 150 ng/ml Marijuana (THC):20 ng/ml Methamphetamine (MET): 500 ng/ml Morphine (MOR): 300ng/mL Oxycodone (OXY) : 100 ng/ml Secobarbital (BAR): 300 ng/ml Buprenorphine (BUP): 10 ng/ml Methylenedioxy-methamphetamine (MDMA): 500 ng/ml Phencyclidine (PCP): 25 ng/ml Methadone (MTD): 300 ng/ml 2-ethylidene-1, 5-dimethyl-3, 3-diphenylpyrrolidine (EDDP): 300 ng/ml Nortriptyline (TCA): 1000 ng/ml Propoxyphene (PPX): 300 ng/ml	Same as candidate device with exclusion of 6-Monoacetylmorphine (6-MAM) 10 ng/mL And Marijuana (THC) 50 ng/ml
Methodology	Competitive binding, lateral flow immunochromatographic assays based on the principle of antigen antibody immunochemistry.	Same
Type of Test	Qualitative	Same
Specimen Type	Human Urine	Same
Intended Use	For prescription	For over-the-counter For prescription
Configurations	Dip Card	Same

Table 2: Features Comparison of AssureTech DOA Integrated Cup Tests and the Predicate Devices

Item	Device	Predicates - K181768 & K182123

Indication(s) for Use	For the qualitative determination of drugs of abuse in human urine.	Same (but the number of drugs detected is different)
Calibrator and Cut-Off Values	6-Monoacetylmorphine (6-MAM): 10 ng/mL Amphetamine (AMP): 500 ng/ml Oxazepam (BZO):300 ng/ml Cocaine (COC): 150 ng/ml Marijuana (THC):20 ng/ml Methamphetamine (MET): 500 ng/ml Morphine (MOR): 300ng/mL or 2000 ng/ml Oxycodone (OXY) : 100 ng/ml Secobarbital (BAR): 300 ng/ml Buprenorphine (BUP): 10 ng/ml Methylenedioxy-methamphetamine (MDMA): 500 ng/ml Phencyclidine (PCP): 25 ng/ml Methadone (MTD): 300 ng/ml 2-ethylidene-1, 5-dimethyl-3, 3-diphenylpyrrolidine (EDDP): 300 ng/ml Nortriptyline (TCA): 1000 ng/ml Propoxyphene (PPX): 300 ng/ml	Same as candidate device with exclusion of 6-Monoacetylmorphine (6-MAM) 10 ng/mL And Marijuana (THC) 50 ng/ml
Methodology	Competitive binding, lateral flow immunochromatographic assays based on the principle of antigen antibody immunochemistry.	Same
Type of Test	Qualitative	Same
Specimen Type	Human Urine	Same
Intended Use	For prescription	For over-the-counter For prescription
Configurations	Cup	Same

9. Test Principle

The AssureTech DOA Dipstick Screen Panel Tests, and AssureTech DOA Integrated Cup Tests are rapid tests for the qualitative detection of 6-Monoacetylmorphine, Amphetamine, Oxazepam, Cocaine, Marijuana, Methamphetamine, Morphine, Oxycodone, Secobarbital, Buprenorphine, Methylenedioxy-methamphetamine, Phencyclidine, Methadone, EDDP, Nortriptyline and Propoxyphene 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 are below the 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.

10. Performance Characteristics

1. Analytical Performance

a. Precision

Precision studies were carried out for samples with concentrations of -100% cut off, -75% cut off, -50% cut off, -25% cut off, +25% cut off, +50% cut off, +75% cut off and +100% cut off. These samples were prepared by spiking drug in negative samples. Each drug concentration was confirmed by LC/MS. All sample aliquots were blindly labeled by the person who prepared the samples and didn't take part in the sample testing. For each concentration, tests were performed one run per lot per day for 10 days per device in a randomized order at each testing site. There were total three POC testing sites. The results obtained are summarized in the following tables.

DOA Dipstick Screen Panel

Result / Drug Conc. % of cutoff	**6-MAM**			**AMP**		
	Lot 1	Lot 2	Lot 3	Lot 1	Lot 2	Lot 3
-100%	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+
-75%	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+
-50%	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+
-25%	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+
cutoff	24+/6	23+/7-	25+/5-	23+/7-	23+/7-	27+/3-
+25%	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-
+50%	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-
+75%	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-
+100%	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-

Result / Drug Conc. % of cutoff	**BAR**		**BUP**			
	Lot 1	Lot 2	Lot 1	Lot 2	Lot 1	Lot 2
-100%	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+
-75%	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+
-50%	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+
-25%	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+
cutoff	27+/3-	27+/3-	27+/3-	27+/3-	27+/3-	27+/3-
+25%	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-
+50%	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-
+75%	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-
+100%	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-

Result / Drug Conc. % of cutoff	**BZO**			**COC**		
	Lot 1	Lot 2	Lot 3	Lot 1	Lot 2	Lot 3
-100%	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+
-75%	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+
-50%	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+
-25%	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+
cutoff	28+/2-	28+/2-	27+/3-	22+/8-	25+/5-	23+/7-

+25%	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-
+50%	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-
+75%	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-
+100%	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-

Result / Drug Conc. % of cutoff	**EDDP**			**MDMA**		
	Lot 1	Lot 2	Lot 3	Lot 1	Lot 2	Lot 3
-100%	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+
-75%	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+
-50%	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+
-25%	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+
cutoff	24+/6-	24+/6-	24+/6-	24+/6-	24+/6-	22+/8-
+25%	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-
+50%	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-
+75%	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-
+100%	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-

Result / Drug Conc. % of cutoff	**MET**			**MOR**		
	Lot 1	Lot 2	Lot 3	Lot 1	Lot 2	Lot 3
-100%	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+
-75%	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+
-50%	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+
-25%	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+
cutoff	25+/5	25+/5-	24+/6-	23+/7-	24+/6-	25+/5-
+25%	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-
+50%	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-
+75%	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-
+100%	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-

Result / Drug Conc. % of cutoff	**MTD**			**OXY**		
	Lot 1	Lot 2	Lot 3	Lot 1	Lot 2	Lot 3
-100%	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+
-75%	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+
-50%	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+
-25%	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+
cutoff	27+/3-	26+/4-	26+/4-	28+/2-	27+/3-	28+/2-
+25%	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-
+50%	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-
+75%	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-
+100%	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-

Result / Drug Conc. % of cutoff	**PCP**			**PPX**		
	Lot 1	Lot 2	Lot 3	Lot 1	Lot 2	Lot 3
-100%	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+
-75%	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+
-50%	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+
-25%	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+
cutoff	25+/5-	25+/5-	24+/6-	25+/5-	25+/5-	26+/4-

+25%	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-
+50%	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-
+75%	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-
+100%	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-

Result / Drug Conc. % of cutoff	**TCA**			**THC**		
	Lot 1	Lot 2	Lot 3	Lot 1	Lot 2	Lot 3
-100%	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+
-75%	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+
-50%	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+
-25%	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+
cutoff	23+/7-	23+/7-	24+/6-	24+/6-	22+/8-	22+/8-
+25%	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-
+50%	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-
+75%	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-
+100%	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-

DOA Integrated Cup

Result / Drug Conc. % of cutoff	**6-MAM**			**AMP**		
	Lot 1	Lot 2	Lot 3	Lot 1	Lot 2	Lot 3
-100%	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+
-75%	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+
-50%	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+
-25%	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+
cutoff	24+/6-	23+/7-	23+/7-	23+/7-	24+/6-	26+/4-
+25%	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-
+50%	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-
+75%	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-
+100%	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-

Result / Drug Conc. % of cutoff	**BAR**			**BUP**		
	Lot 1	Lot 2	Lot 1	Lot 2	Lot 1	Lot 2
-100%	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+
-75%	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+
-50%	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+
-25%	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+
cutoff	28+/2-	26+/4-	28+/2-	28+/2-	27+/3-	27+/3-
+25%	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-
+50%	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-
+75%	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-
+100%	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-

Result / Drug Conc. % of cutoff	**BZO**			**COC**		
	Lot 1	Lot 2	Lot 3	Lot 1	Lot 2	Lot 3
-100%	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+
-75%	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+
-50%	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+

-25%	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+
cutoff	28+/2-	28+/2-	29+/1-	23+/7-	26+/4-	24+/6-
+25%	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-
+50%	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-
+75%	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-
+100%	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-

Result / Drug Conc. % of cutoff	**EDDP**			**MDMA**		
	Lot 1	Lot 2	Lot 3	Lot 1	Lot 2	Lot 3
-100%	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+
-75%	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+
-50%	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+
-25%	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+
cutoff	24+/6-	24+/6-	25+/5-	23+/7-	22+/8-	22+/8-
+25%	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-
+50%	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-
+75%	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-
+100%	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-

Result / Drug Conc. % of cutoff	**MET**			**MOR**		
	Lot 1	Lot 2	Lot 3	Lot 1	Lot 2	Lot 3
-100%	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+
-75%	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+
-50%	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+
-25%	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+
cutoff	23+/7-	27+/3-	23+/7-	22+/8-	24+/6-	23+/7-
+25%	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-
+50%	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-
+75%	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-
+100%	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-

Result / Drug Conc. % of cutoff	**MTD**			**OXY**		
	Lot 1	Lot 2	Lot 3	Lot 1	Lot 2	Lot 3
-100%	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+
-75%	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+
-50%	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+
-25%	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+
cutoff	26+/4-	27+/3-	27+/3-	27+/3-	28+/2-	28+/2-
+25%	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-
+50%	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-
+75%	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-
+100%	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-

Result / Drug Conc. % of cutoff	**PCP**			**PPX**		
	Lot 1	Lot 2	Lot 3	Lot 1	Lot 2	Lot 3
-100%	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+
-75%	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+
-50%	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+

-25%	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+
cutoff	25+/5-	25+/5-	24+/6-	25+/5-	27+/3-	25+/5-
+25%	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-
+50%	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-
+75%	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-
+100%	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-

Result / Drug Conc. % of cutoff	**TCA**			**THC**		
	Lot 1	Lot 2	Lot 3	Lot 1	Lot 2	Lot 3
-100%	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+
-75%	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+
-50%	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+
-25%	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+	30-/0+
cutoff	24+/6-	25+/5-	23+/7-	23+/7-	24+/6-	24+/6-
+25%	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-
+50%	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-
+75%	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-
+100%	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-	30+/0-

c. Stability

The devices are stable at 4-30 °C for 24 months based on the accelerated stability study at 45 °C and real time stability determination at both 4 °C and 30 °C.

d. Interference

Potential interfering substances found in human urine of physiological or pathological conditions were added to drug-free urine and target drugs urine with concentrations at 25% below and 25% above Cut-Off levels. These urine samples were tested using three lots of each device. Compounds that showed no interference at a concentration of 100µg/mL (albumin was tested at 100 mg/dL and ethanol at 1%) are summarized in the following table. There were no differences observed for different devices.

Acetaminophen	β-Estradiol	Oxalic acid
Acetophenetidin	Erythromycin	Oxolinic acid
N-Acetylprocainamide	Ethanol (1%)	Oxymetazoline
Acetylsalicylic acid	Fenoprofen	Papaverine
Albumin (100 mg/dL)	Furosemide	Penicillin G
Aminopyrine	Gentisic acid	Perphenazine
Amoxicillin	Hemoglobin	Phenelzine
Ampicillin	Hydralazine	Prednisone
Apomorphine	Hydrochlorothiazide	(±)-Propranolol
Ascorbic acid	Hydrocortisone	Pseudoephedrine
Aspartame	O-Hydroxyhippuric acid	Quinine
Atropine	3-Hydroxytyramine	Ranitidine
Benzilic acid	Ibuprofen	Salicylic acid
Benzoic acid	Isoproterenol	Serotonin (5- Hydroxytyramine)
Bilirubin	Isoxsuprine	Sulfamethazine
Chloral hydrate	Ketamine	Sulindac
Chloramphenicol	Ketoprofen	Tetrahydrocortisone 3-(β-Dglucuronide)
Chlorothiazide	Labetalol	Tetrahydrocortisone 3-acetate
Chlorpromazine	Loperamide	Tetrahydrozoline

Cholesterol	Meperidine	Thiamine
Clonidine	Meprobamate	Thioridazine
Cortisone	Methoxyphenamine	Triamterene
(-)-Cotinine	Nalidixic acid	Trifluoperazine
Creatinine	Naloxone	Trimethoprim
Deoxycorticosterone	Naltrexone	DL-Tryptophan
Dextromethorphan	Naproxen	Tyramine
Diclofenac	Niacinamide	DL-Tyrosine
Diflunisal	Nifedipine	Uric acid
Digoxin	Norethindrone	Verapamil
Diphenhydramine	Noscapine	Zomepirac
Ecgonine methyl ester	(±)-Octopamine	

e. Specificity

To test specificity, drug metabolites and other components that are likely to interfere in urine samples were tested using three lots of each device. The lowest concentration that caused a positive result for each compound are listed below for 6-Monoacetylmorphine (6-MAM) and Marijuana (THC20). The rest data were reported in the k181768. There were no differences observed for different devices.

6-acetylmorphine (Cut-off=10 ng/mL)	**Result Positive at (ng/mL)**	**% Cross-Reactivity**
6-acetylmorphine	10	100%
Acetylcodeine	>10000	<0.1%
Buprenorphine	>10000	<0.1%
Codeine	>10000	<0.1%
Diacetylmorphine	1000	1%
Dihydrocodeine	>10000	<0.1%
Ethylmorphine	>10000	<0.1%
Hydrocodone	>10000	<0.1%
Hydromorphone	5000	0.2%
Morphine	10000	0.1%
Morphine-3-glucuronide	>10000	<0.1%
Nalorphine	5000	0.2%
Thebaine	>20000	<0.05%
Dextromethorphan	>100,000	<0.01%
Heroin	100,000	0.01%
Imipramine	>100,000	<0.01%
LAAM (Levacetylmethadol)	>100,000	<0.01%
Levorphanol	>100,000	<0.01%
Meperidine	>100,000	<0.01%
Methadone	>100,000	<0.01%
Mitragynine (kratom)	>20,000	<0.05%
Morphine 6-D-glucuronide	>100,000	<0.01%
Naloxone	>100,000	<0.01%
Naltrexone	>100,000	<0.01%
Naproxen	>100,000	<0.01%
Norbuprenorphine	>10,000	<0.1%
Norbuprenorphine glucuronide	>100,000	<0.01%
Norcodeine	>100,000	<0.01%
Norhydrocodone	>100,000	<0.01%
Normorphine	>100,000	<0.01%
Noroxycodone	>100,000	<0.01%
Noroxymorphone	>100,000	<0.01%
Norpropoxyphene	>100,000	<0.01%
Oxycodone	>100,000	<0.01%

Oxymorphone	>100,000	<0.01%
Oxymorphone-3β-D-glucuronide	>100,000	<0.01%
Tapentadol HCl	>100,000	<0.01%
Tramadol	>100,000	<0.01%

Marijuana (Cut-off=20 ng/mL)	**Result Positive at (ng/mL)**	**% Cross-Reactivity**
11-nor-D^9-THC-9 COOH	20	100%
11-nor-D^8-THC-9 COOH	20	100%
Δ^8-Tetrahydrocannabinol	>10000	<0.25%
Δ^9-Tetrahydrocannabinol	>10000	<0.25%
Cannabinol	>10000	<0.25%

f. Effect of Urine Specific Gravity and Urine pH

To investigate the effect of urine specific gravity and urine pH, urine samples, with 1.000 to 1.035 specific gravity or urine samples with pH 4 to 9 were spiked with target drugs at 25% below and 25% above Cut-Off levels. These samples were tested using three lots of each device. Results were all positive for samples at and above +25% Cut-Off and all negative for samples at and below -25% Cut-Off. There were no differences observed for different devices.

2. Comparison Studies

Method comparison studies for the AssureTech DOA Dipstick Screen Panel Tests and the AssureTech DOA Integrated Cup Tests were performed at three POC sites for each device. Operators ran 80 (40 negative and 40 positive) unaltered clinical samples for each drug. The samples were blind labeled and compared to LC/MS results. The results are presented in the tables below for 6-Monoacetylmorphine (6-MAM) and Marijuana (THC20). The rest data were reported in the k181768.

6-MAM

Panel Dip		Negative	Low Negative by LC/MS (less than -50%)	Near Cutoff Negative by LC/MS (Between -50% and cutoff)	Near Cutoff Positive by LC/MS (Between the cutoff and +50%)	High Positive by LC/MS (greater than +50%)
Viewer A	Positive	0	0	0	15	25
	Negative	10	20	10	0	0
Viewer B	Positive	0	0	0	15	25
	Negative	10	20	10	0	0
Viewer C	Positive	0	0	0	15	25
	Negative	10	20	10	0	0

DOA Integrated Cup		Negative	Low Negative by LC/MS (less than -50%)	Near Cutoff Negative by LC/MS (Between -50% and cutoff)	Near Cutoff Positive by LC/MS (Between the cutoff and +50%)	High Positive by LC/MS (greater than +50%)

Viewer A	Positive	0	0	0	15	25
	Negative	10	20	10	0	0
Viewer B	Positive	0	0	0	15	25
	Negative	10	20	10	0	0
Viewer C	Positive	0	0	0	15	25
	Negative	10	20	10	0	0

THC20

Panel Dip		Negative	Low Negative by LC/MS (less than -50%)	Near Cutoff Negative by LC/MS (Between -50% and cutoff)	Near Cutoff Positive by LC/MS (Between the cutoff and +50%)	High Positive by LC/MS (greater than +50%)
Viewer A	Positive	0	0	0	14	25
	Negative	10	20	10	1	0
Viewer B	Positive	0	0	1	15	25
	Negative	10	20	9	0	0
Viewer C	Positive	0	0	1	15	25
	Negative	10	20	9	0	0

Discordant Results

Viewer	Sample Number	LC/MS Result	Dip Card Viewer Results
Viewer B	TH79	19.09	Positive
Viewer C	TH79	19.09	Positive
Viewer A	TH10	20.55	Negative

DOA Integrated Cup		Negative	Low Negative by LC/MS (less than -50%)	Near Cutoff Negative by LC/MS (Between -50% and cutoff)	Near Cutoff Positive by LC/MS (Between the cutoff and +50%)	High Positive by LC/MS (greater than +50%)
Viewer A	Positive	0	0	0	14	25
	Negative	10	20	10	1	0
Viewer B	Positive	0	0	0	15	25
	Negative	10	20	10	0	0
Viewer C	Positive	0	0	1	15	25
	Negative	10	20	9	0	0

Discordant Results

Viewer	Sample Number	LC/MS Result	Dip Card Viewer Results
Viewer C	TH79	19.09	Positive
Viewer A	TH10	20.55	Negative

3. Clinical Studies

Not applicable.

11. Conclusion

Based on the test principle and acceptable performance characteristics including precision, cut-off, interference, specificity, and method comparison studies of the devices, it's concluded that the AssureTech DOA Dipstick Screen Panel Tests and AssureTech DOA Integrated Cup Tests are substantially equivalent to the predicate.