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

October 5, 2015

ASSURE TECH. CO., LTD.
C/O JOE SHIA
MANAGER
504 E DIAMOND AVE., SUITE I
GAITHERSBURG MD 20877

Re: K152025
Trade/Device Name: Assuretech Buprenorphine Tests (Strip, Panel Dip, Quick Cup, Turn-key Split Cup), Assuretech Methadone Tests (Strip, Panel Dip, Quick Cup, Turn-key Split Cup)
Regulation Number: 21 CFR 862.3620
Regulation Name: Methadone test system
Regulatory Class: II
Product Code: DJR, DJG
Dated: July 17, 2015
Received: July 22, 2015

Dear Mr. 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

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
k152025

Device Name
AssureTech Buprenorphine Strip; AssureTech Methadone Strip
AssureTech Buprenorphine/Methadone Panel Dip
AssureTech Buprenorphine/Methadone Turn Key-Split Cup; AssureTech Buprenorphine/Methadone Quick Cup

Indications for Use *(Describe)*
The AssureTech Buprenorphine Strip test is an immunochromatographic assay for the qualitative determination of Buprenorphine in human urine at a Cut-Off concentration of 10ng/mL. This test is calibrated to Buprenorphine (calibrator).

The test may yield preliminary positive results when prescription drug Buprenorphine is ingested, even at or above therapeutic doses. There are no uniformly recognized drug levels for Buprenorphine in urine. The test provides only preliminary test results. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Gas Chromatography/Mass Spectrometry 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 test is intended for over-the-counter and for prescription use.

The AssureTech Methadone Strip test is an immunochromatographic assay for the qualitative determination of Methadone in human urine at a Cut-Off concentration of 300ng/mL. This test is calibrated to Methadone (calibrator).

The test provides only preliminary test results. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Gas Chromatography/Mass Spectrometry 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 test is intended for over-the-counter and for prescription use.

The AssureTech Buprenorphine/Methadone Panel Dip test is an immunochromatographic assay for the qualitative determination of Buprenorphine and Methadone in human urine at a Cut-Off concentration of 10ng/mL and 300 ng/mL, respectively. These tests are calibrated to Buprenorphine and Methadone (calibrators).

The test may yield preliminary positive results when prescription drug Buprenorphine is ingested, even at or above therapeutic doses. There are no uniformly recognized drug levels for Buprenorphine in urine. The test provides only preliminary test results. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Gas Chromatography/Mass Spectrometry 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.

The AssureTech Buprenorphine/Methadone Quick Cup test is an immunochromatographic assay for the qualitative determination of Buprenorphine and Methadone in human urine at a Cut-Off concentration of 10ng/mL and 300 ng/mL, respectively. These tests are calibrated to Buprenorphine and Methadone (calibrators).

The test may yield preliminary positive results when prescription drug Buprenorphine is ingested, even at or above therapeutic doses. There are no uniformly recognized drug levels for Buprenorphine in urine. The test provides only preliminary test results. A more specific alternative chemical method must be used in order to obtain a confirmed

analytical result. Gas Chromatography/Mass Spectrometry 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.

The AssureTech Buprenorphine/Methadone Turn Key-Split Cup test is an immunochromatographic assay for the qualitative determination of Buprenorphine and Methadone in human urine at a Cut-Off concentration of 10ng/mL and 300 ng/mL, respectively. These tests are calibrated to Buprenorphine and Methadone (calibrators).

The test may yield preliminary positive results when prescription drug Buprenorphine is ingested, even at or above therapeutic doses. There are no uniformly recognized drug levels for Buprenorphine in urine. The test provides only preliminary test results. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Gas Chromatography/Mass Spectrometry 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: September 17, 2015

2. Submitter: Assure Tech. Co., Ltd.
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3. Contact person: Eric Lin
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4. Device Name: AssureTech Buprenorphine Strip
AssureTech Methadone Strip
AssureTech Buprenorphine/Methadone Panel Dip
AssureTech Buprenorphine/Methadone Quick Cup
AssureTech Buprenorphine/Methadone Turn Key-Split Cup

Classification:

Product Code	CFR	Panel
DJR	21 CFR, 862.3620 Methadone Test System	Toxicology
DJG	21 CFR, 862.3650 Opiate Test System	Toxicology

5. Predicate Devices: K142396

The Chemtrue® Multi-Panel Drug Screen Dip Card Tests

6. Intended Use

The AssureTech Buprenorphine Strip test is an immunochromatographic assay for the qualitative determination of Buprenorphine in human urine at a Cut-Off concentration of 10ng/mL. This test is calibrated to Buprenorphine (calibrator).

The test may yield preliminary positive results when prescription drug Buprenorphine is ingested, even at or above therapeutic doses. There are no uniformly recognized drug levels for Buprenorphine in urine. The test provides only preliminary test results. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Gas Chromatography/Mass Spectrometry 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 test is intended for over-the-counter and for prescription use.

The AssureTech Methadone Strip test is an immunochromatographic assay for the qualitative

determination of Methadone in human urine at a Cut-Off concentration of 300ng/mL. This test is calibrated to Methadone (calibrator).

The test provides only preliminary test results. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Gas Chromatography/Mass Spectrometry 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 test is intended for over-the-counter and for prescription use.

The AssureTech Buprenorphine/Methadone Panel Dip test is an immunochromatographic assay for the qualitative determination of Buprenorphine and Methadone in human urine at a Cut-Off concentration of 10ng/mL and 300 ng/mL, respectively. These tests are calibrated to Buprenorphine and Methadone (calibrators).

The test may yield preliminary positive results when prescription drug Buprenorphine is ingested, even at or above therapeutic doses. There are no uniformly recognized drug levels for Buprenorphine in urine. The test provides only preliminary test results. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Gas Chromatography/Mass Spectrometry 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.

The AssureTech Buprenorphine/Methadone Quick Cup test is an immunochromatographic assay for the qualitative determination of Buprenorphine and Methadone in human urine at a Cut-Off concentration of 10ng/mL and 300 ng/mL, respectively. These tests are calibrated to Buprenorphine and Methadone (calibrators).

The test may yield preliminary positive results when prescription drug Buprenorphine is ingested, even at or above therapeutic doses. There are no uniformly recognized drug levels for Buprenorphine in urine. The test provides only preliminary test results. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Gas Chromatography/Mass Spectrometry 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.

The AssureTech Buprenorphine/Methadone Turn Key-Split Cup test is an immunochromatographic assay for the qualitative determination of Buprenorphine and Methadone in human urine at a Cut-Off concentration of 10ng/mL and 300 ng/mL, respectively. These tests are calibrated to Buprenorphine and Methadone (calibrators).

The test may yield preliminary positive results when prescription drug Buprenorphine is

ingested, even at or above therapeutic doses. There are no uniformly recognized drug levels for Buprenorphine in urine. The test provides only preliminary test results. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Gas Chromatography/Mass Spectrometry 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.

7. Device Description

The AssureTech Buprenorphine Strip, AssureTech Methadone Strip, AssureTech Buprenorphine/Methadone Panel Dip, AssureTech Buprenorphine/Methadone Quick Cup and AssureTech Buprenorphine/Methadone Turn Key-Split Cup are immunochromatographic assays that use a lateral flow system for the qualitative detection of Buprenorphine and/or Methadone (target analytes) in human urine. The Quick Cup format does not contain a turn-key for device activation. The tests are 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.

8. Substantial Equivalence Information

A summary comparison of features of the AssureTech Buprenorphine Tests and AssureTech Methadone Tests and the predicate devices is provided in Table 1 & Table 2.

Table 1: Features Comparison of AssureTech Buprenorphine Strip and the Predicate Devices

Item	Device	Predicate - K142396
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	Buprenorphine	Same
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
Cut-Off Values	10 ng/mL	Same
Intended Use	For over-the-counter and prescription uses.	Same
Configurations	Strip	Dip Card

Table 2: Features Comparison of AssureTech Methadone Strip and the Predicate Devices

Item	Device	Predicate - K142396

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	Methadone	Same
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
Cut-Off Values	300 ng/mL	Same
Intended Use	For over-the-counter and prescription uses.	Same
Configurations	Strip	Dip Card

Table 3: Features Comparison of AssureTech Buprenorphine/Methadone Panel Dip and the Predicate Devices

Item	Device	Predicate - K142396
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	Buprenorphine and Methadone	Same
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
Cut-Off Values	10ng/mL for Buprenorphine and 300 ng/mL for Methadone	Same
Intended Use	For over-the-counter and prescription uses.	Same
Configurations	Panel Dip	Same

Table 4: Features Comparison of AssureTech Buprenorphine/Methadone Cup and the Predicate Devices

Item	Device	Predicate - K142396
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	Buprenorphine and Methadone	Same
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
Cut-Off Values	10ng/mL for Buprenorphine and 300 ng/mL for Methadone	Same
Intended Use	For over-the-counter and prescription uses.	Same
Configurations	Cup with or without turn-key	Dip Card

9. Test Principle

AssureTech Buprenorphine Strip, AssureTech Methadone Strip, AssureTech Buprenorphine/Methadone Panel Dip, AssureTech Buprenorphine/Methadone Quick Cup and AssureTech Buprenorphine/Methadone Turn Key-Split Cup are rapid tests for the qualitative detection of Buprenorphine and/or Methadone 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 GC/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 two runs per day for 25 days per device in a randomized order. The results obtained are summarized in the following tables.

Buprenorphine

AssureTech Buprenorphine Strip

Lot Number	-100% cut off	-75% cut off	-50% cut off	-25% cutoff	cut off	+25% cut off	+50% cut off	+75% cut off	+100% cut off

Lot 1	50-/0+	50-/0+	50-/0+	50-/0+	4-/46+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 2	50-/0+	50-/0+	50-/0+	50-/0+	1-/49+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 3	50-/0+	50-/0+	50-/0+	50-/0+	3-/47+	50+/0-	50+/0-	50+/0-	50+/0-

AssureTech Buprenorphine /Methadone Panel Dip

Lot Number	-100% cut off	-75% cut off	-50% cut off	-25% cutoff	cut off	+25% cut off	+50% cut off	+75% cut off	+100% cut off
Lot 1	50-/0+	50-/0+	50-/0+	50-/0+	3-/47+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 2	50-/0+	50-/0+	50-/0+	50-/0+	2-/48+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 3	50-/0+	50-/0+	50-/0+	50-/0+	2-/48+	50+/0-	50+/0-	50+/0-	50+/0-

AssureTech Buprenorphine/Methadone Turn-Key Split Cup

Lot Number	-100% cut off	-75% cut off	-50% cut off	-25% cutoff	cut off	+25% cut off	+50% cut off	+75% cut off	+100% cut off
Lot 1	50-/0+	50-/0+	50-/0+	50-/0+	4-/46+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 2	50-/0+	50-/0+	50-/0+	50-/0+	2-/48+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 3	50-/0+	50-/0+	50-/0+	50-/0+	2-/48+	50+/0-	50+/0-	50+/0-	50+/0-

AssureTech Buprenorphine/Methadone Quick Cup

Lot Number	-100% cut off	-75% cut off	-50% cut off	-25% cutoff	cut off	+25% cut off	+50% cut off	+75% cut off	+100% cut off
Lot 1	50-/0+	50-/0+	50-/0+	50-/0+	2-/48+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 2	50-/0+	50-/0+	50-/0+	50-/0+	2-/48+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 3	50-/0+	50-/0+	50-/0+	50-/0+	3-/47+	50+/0-	50+/0-	50+/0-	50+/0-

Methadone

AssureTech Methadone Strip

Lot Number	-100% cut off	-75% cut off	-50% cut off	-25% cutoff	cut off	+25% cut off	+50% cut off	+75% cut off	+100% cut off
Lot 1	50-/0+	50-/0+	50-/0+	50-/0+	2-/48+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 2	50-/0+	50-/0+	50-/0+	50-/0+	3-/47+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 3	50-/0+	50-/0+	50-/0+	50-/0+	4-/46+	50+/0-	50+/0-	50+/0-	50+/0-

AssureTech Buprenorphine/Methadone Panel Dip

Lot Number	-100% cut off	-75% cut off	-50% cut off	-25% cutoff	cut off	+25% cut off	+50% cut off	+75% cut off	+100% cut off
Lot 1	50-/0+	50-/0+	50-/0+	50-/0+	2-/48+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 2	50-/0+	50-/0+	50-/0+	50-/0+	3-/47+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 3	50-/0+	50-/0+	50-/0+	50-/0+	2-/48+	50+/0-	50+/0-	50+/0-	50+/0-

AssureTech Buprenorphine/Methadone Turn-Key Split Cup

Lot Number	-100% cut off	-75% cut off	-50% cut off	-25% cutoff	cut off	+25% cut off	+50% cut off	+75% cut off	+100% cut off
Lot 1	50-/0+	50-/0+	50-/0+	50-/0+	1-/49+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 2	50-/0+	50-/0+	50-/0+	50-/0+	2-/48+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 3	50-/0+	50-/0+	50-/0+	50-/0+	3-/47+	50+/0-	50+/0-	50+/0-	50+/0-

AssureTech Buprenorphine/Methadone Quick Cup

Lot Number	-100% cut off	-75% cut off	-50% cut off	-25% cutoff	cut off	+25% cut off	+50% cut off	+75% cut off	+100% cut off
Lot 1	50-/0+	50-/0+	50-/0+	50-/0+	3-/47+	50+/0-	50+/0-	50+/0-	50+/0-

Lot 2	50-/0+	50-/0+	50-/0+	50-/0+	2-/48+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 3	50-/0+	50-/0+	50-/0+	50-/0+	2-/48+	50+/0-	50+/0-	50+/0-	50+/0-

b. Linearity

Not applicable.

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. Cut-off

A total of 150 samples equally distributed at concentrations of -50% Cut-Off; -25% Cut-Off; Cut-Off; +25% Cut-Off; +50% Cut-Off were tested using three different lots of each device by three different operators. Results were all positive at and above +25% Cut-off and all negative at and below -25% Cut-off for both Buprenorphine and Methadone.

The following cut-off values for the candidate devices have been verified.

Calibrator	**Cut-off (ng/mL)**
Buprenorphine	10
Methadone	300

e. 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 batches of each device. Compounds that showed no interference at a concentration of 100μg/mL are summarized in the following tables. There were no differences observed for different devices.

Buprenorphine:

Acetophenetidin	Ethyl-p-aminobenzoate	Phencyclidine
N-Acetylprocainamide	Fenoprofen	Phenelzine
Acetylsalicylic Acid	Furosemide	Phenobarbital
Aminopyrine	Gentisic acid	Phentermine
Amitriptyline	Hemoglobin	Phenylephrine-L
Amoxicillin	Hydralazine	Phenylethylamine
Amobarbital	(+/-)-4-Hydroxyamphetamine HCL	Phenylpropanolamine
D-Amphetamine	Hydrochlorothiazide	Prednisolone Acetate
L-Amphetamine	Hydrocodone	Prednisone
Amphetamine Sulfate	Hydrocortisone	Procaine(Novocaine)
Ampicinine(Ampicillin)	Hydroxyhippuric acid	Promazine
Apomorphine	p-Hydroxymethamphetamine	Promethazine
L-Ascorbic Acid	Ibuprofen	Propoxyphene,d-
Aspartame	Imipramine	Propranolol
Atropine	Isoxsuprine	Pseudoephedrine HCL
Benzilic acid	Isoproterenol-(+/-)	Quinidine
Benzphetamine	Ketamine	Quinine

Bezoic Acid	Labetalol	Ranitidine(Zantac)
Bilirubin	Levorphanol	Salicylic Acid
Caffeine	Loperamide	Secobarbital
Chloramphenicol	Maprotiline	Serotonin
Chlordiazepoxide HCL	Meprobamate	Sulfamethazine
Chloroquine	Methadone	Sulindac
Chlorothiazide	Methoxyphenamine	Temazepam
Chlorpheniramine	(+/-)-Methylenedioxyamphetamine(MDA)	11-Nor-Δ9-Tetrahydrocannabinol
Chlorpromazine	Methylphenidate	Tetracycline
Cholesterol	Nalbuphine	Tetrahydrozoline
Clomipramine	Nalidixic acid	Thiamine
Clonidine hydrochloride	Naloxone hydrochloride	L-Thyroxine
Cortisone	Naltrexone hydrochloride	ThioridazineHydrochloride
Cotinine(-)	Naproxen	Triamterene
Creatinine	Niacinamide	Trifluprom azine Hydrochloride
Deoxyepinephrine	Nifedipine	Trimethoprim
Dextromethorphan	Norethindrone	Trimipramine
Diazepam	Norpropoxyphene	Tryptamine
Diflunisal	Noscapine	DL-Tryptophan
Digoxin	Oxazepam	Tyramine
Doxylamine	Oxymetazoline	D/L-Tyrosine
Ecgonine methylester	Papaverine	Uric Acid
R(-)-Epinephrine	Penicillin	Verapamil
Erythromycin	Pentobarbital	Zomepirac
Estrone-3-sulfate	Perphenazine	

Methadone

Acetophenetidin	Ethyl-p-aminobenzoate	Phenelzine
N-Acetylprocainamide	Fenoprofen	Phenobarbital
Acetylsalicylic Acid	Furosemide	Phentermine
Aminopyrine	Gentisic acid	Phenylephrine-L
Amitriptyline	Hemoglobin	Phenylethylamine
Amoxicillin	Hydralazine	Phenylpropanolamine
Amobarbital	(+/-)-4-Hydroxyamphetamine HCL	Prednisolone Acetate
D-Amphetamine	Hydrochlorothiazide	Prednisone
L-Amphetamine	Hydrocodone	Procaine(Novocaine)
Amphetamine Sulfate	Hydrocortisone	Promazine
Ampicinine(Ampicillin)	a -Hydroxyhippuric acid	Promethazine
Apomorphine	p-Hydroxymethamphetamine	Propoxyphene,d-
L-Ascorbic Acid	Ibuprofen	Propranolol
Aspartame	Imipramine	Pseudoephedrine HCL

Atropine	Isoxsuprine	Quinidine
Benzilic acid	Isoproterenol-(+/-)	Quinine
Benzphetamine	Ketamine	Ranitidine(Zantac)
Bezoic Acid	Labetalol	Salicylic Acid
Bilirubin	Levorphanol	Secobarbital
Caffeine	Loperamide	Serotonin
Chloramphenicol	Maprotiline	Sulfamethazine
Chlordiazepoxide HCL	Meprobamate	Sulindac
Chloroquine	Methoxyphenamine	Temazepam
Chlorothiazide	(+/-)-	11-Nor-Δ9-
Chlorpheniramine	Methylphenidate	Tetracycline
Chlorpromazine	Nalbuphine	Tetrahydrozoline
Cholesterol	Nalidixic acid	Thiamine
Clomipramine	Naloxone hydrochloride	L-Thyroxine
Clonidine hydrochloride	Naltrexone hydrochloride	ThioridazineHydrochloride
Cortisone	Naproxen	Triamterene
Cotinine(-)	Niacinamide	Triflupromazine
Creatinine	Nifedipine	Trimethoprim
Deoxyepinephrine	Norethindrone	Trimipramine
Dextromethorphan	Norpropoxyphene	Tryptamine
Diazepam	Noscapine	DL-Tryptophan
Diflunisal	Oxazepam	Tyramine
Digoxin	Oxymetazoline	D/L-Tyrosine
Doxylamine	Papaverine	Uric Acid
Ecgonine methylester	Penicillin	Verapamil
R(-)-Epinephrine	Pentobarbital	Zomepirac
Erythromycin	Perphenazine	
Estrone-3-sulfate	Phencyclidine	

f. Specificity

To test specificity, drug metabolites and other components that are likely to interfere in urine samples were tested using three batches of each device. The lowest concentration that caused a positive result for each compound are listed below. There were no differences observed for different devices.

Buprenorphine (Cut-off=10 ng/mL)	**Result**	**% Cross-Reactivity**
Buprenorphine	Positive at 10 ng/mL	100%
Buprenorphine -3-D-	Positive at 10 ng/mL	100%
Norbuprenorphine	Positive at 50 ng/mL	20%
Norbuprenorphine-3-D-	Positive at 100 ng/mL	10%
Morphine	Negative at 100,000	<0.01%

Oxymorphone	Negative at 100,000	<0.01%
Hydromorphone	Negative at 100,000	<0.01%

Methadone (Cut-off=300 ng/mL)	**Result**	**% Cross-Reactivity**
Methadone	Positive at 300 ng/mL	100%
Doxylamine	Positive at 5000 ng/mL	6%
LAAM HCl	Positive at 10000 ng/mL	3%
Alpha Methadol	Positive at 2000 ng/mL	15%
EDDP	Negative at 100,000	<0.3%
EMDP	Negative at 100,000	<0.3%

g. 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 Buprenorphine Tests and the AssureTech Methadone Tests were performed in-house with three laboratory assistants for each device. Operators ran 80 (40 negative and 40 positive) unaltered clinical samples. The samples were blind labeled and compared to GC/MS results. The results are presented in the tables below:

Buprenorphine

Strip		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	2	14	25
	Negative	10	20	8	1	0
Viewer B	Positive	0	0	1	14	25
	Negative	10	20	9	1	0
Viewer C	Positive	0	0	1	15	25
	Negative	10	20	9	0	0

Discordant Results of Buprenorphine Strip

Viewer	**Sample Number**	**GC/MS Result**	**Strip Viewer Results**
Viewer A	11178	9.8	Positive
Viewer A	20805	9.6	Positive
Viewer B	20805	9.6	Positive
Viewer C	20805	9.6	Positive

Viewer A	31718	10.9	Negative
Viewer B	18342	10.6	Negative

Panel Dip		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	2	14	25
	Negative	10	20	8	1	0
Viewer B	Positive	0	0	2	14	25
	Negative	10	20	8	1	0
Viewer C	Positive	0	0	2	14	25
	Negative	10	20	8	1	0

Discordant Results of Buprenorphine Panel Dip

Viewer	Sample Number	GC/MS Result	Panel Dip Viewer Results
Viewer A	11178	9.8	Positive
Viewer A	20805	9.6	Positive
Viewer B	11178	9.8	Positive
Viewer B	20805	9.6	Positive
Viewer C	11178	9.8	Positive
Viewer C	20805	9.6	Positive
Viewer A	18342	10.6	Negative
Viewer B	31718	10.9	Negative
Viewer C	31718	10.9	Negative

Turn-Key Split Cup		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	1	20	9	1	0
Viewer B	Positive	0	0	1	14	25
	Negative	1	20	9	1	0
Viewer C	Positive	0	0	1	13	25
	Negative	1	20	9	2	0

Discordant Results of Buprenorphine Turn-Key Split Cup

Viewer	Sample Number	GC/MS Result	Turn-Key Split Cup
Viewer A	20805	9.6	Positive
Viewer B	11178	9.8	Positive

Viewer C	11178	9.8	Positive
Viewer A	31718	10.9	Negative
Viewer B	18342	10.6	Negative
Viewer C	18342	10.6	Negative
Viewer C	31718	10.9	Negative

Quick Cup		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	10	20	9	1	0
Viewer B	Positive	0	0	1	15	25
	Negative	10	20	9	0	0
Viewer C	Positive	0	0	2	14	25
	Negative	10	20	8	1	0

Discordant Results of Buprenorphine Quick Cup

Viewer	Sample Number	GC/MS Result	Quick Cup Viewer Results
Viewer A	20805	9.6	Positive
Viewer B	11178	9.8	Positive
Viewer C	11178	9.8	Positive
Viewer C	20805	9.6	Positive
Viewer A	31718	10.9	Negative
Viewer C	18342	10.6	Negative

Methadone (MTD)

Strip		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	2	14	25
	Negative	10	20	8	1	0
Viewer B	Positive	0	0	1	14	25
	Negative	10	20	9	1	0
Viewer C	Positive	0	0	1	14	25
	Negative	10	20	9	1	0

Discordant Results of MTD Strip

Viewer	Sample Number	GC/MS Result	Strip Viewer Results
Viewer A	36406	293	Positive

Viewer A	15168	291	Positive
Viewer B	15168	291	Positive
Viewer C	15168	291	Positive
Viewer A	82949	305	Negative
Viewer B	82949	305	Negative
Viewer C	82949	305	Negative

Panel Dip		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	2	15	25
	Negative	10	20	8	0	0
Viewer B	Positive	0	0	1	14	25
	Negative	10	20	9	1	0
Viewer C	Positive	0	0	1	15	25
	Negative	10	20	9	0	0

Discordant Results of MTD Panel Dip

Viewer	Sample Number	GC/MS Result	Panel Dip Viewer Results
Viewer A	36406	293	Positive
Viewer A	15168	291	Positive
Viewer B	15168	291	Positive
Viewer C	15168	291	Positive
Viewer B	82949	305	Negative

Turn-Key Split Cup		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	1	20	9	1	0
Viewer B	Positive	0	0	1	15	25
	Negative	1	20	9	0	0
Viewer C	Positive	0	0	1	14	25
	Negative	1	20	9	1	0

Discordant Results of MTD Turn-Key Split Cup

Viewer	Sample Number	GC/MS Result	Split Cup Viewer Results
Viewer A	15168	291	Positive
Viewer B	15168	291	Positive

Viewer C	36406	293	Positive
Viewer A	82949	305	Negative
Viewer C	82949	305	Negative

Quick Cup		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	10	20	9	1	0
Viewer B	Positive	0	0	2	14	25
	Negative	10	20	8	1	0
Viewer C	Positive	0	0	1	15	25
	Negative	10	20	9	0	0

Discordant Results of MTD Quick Cup

Viewer	Sample Number	GC/MS Result	Quick Cup Viewer Results
Viewer A	36406	293	Positive
Viewer B	36406	293	Positive
Viewer B	15168	291	Positive
Viewer C	36406	293	Positive
Viewer A	82949	305	Negative
Viewer B	82949	305	Negative

Lay-user study

A lay user study was performed at three intended user sites with 1113 lay persons. The lay users had diverse educational and professional backgrounds and ranged in age from 18 to > 50 years. Urine samples were prepared at the following concentrations; negative, +/-75%, +/-50%, +/-25% of the cutoff by spiking drug(s) into drug free-pooled urine specimens. The concentrations of the samples were confirmed by GC/MS. Each sample was aliquoted into individual containers and blind-labeled. Each participant was provided with the package insert, 1 blind labeled sample and a device. Each device was tested.

Comparison between GC/MS and Lay Person Results for Buprenorphine Strip

% of Cutoff	Number of samples	Buprenorphine Concentration by GC/MS (ng/mL)	Lay person results		The percentage of correct results (%)
			No. of Positive	No. of Negative	
-100%Cutoff	21	0	0	21	100
-75%Cutoff	21	2.2	0	21	100
-50% Cutoff	21	5.5	0	21	100
-25% Cutoff	21	7.6	1	20	95
+25% Cutoff	21	12.6	21	0	100
+50% Cutoff	21	16.2	21	0	100

+75% Cutoff	21	17.8	21	0	100

Comparison between GC/MS and Lay Person Results for MTD Strip

% of Cutoff	Number of samples	Methadone Concentration by GC/MS (ng/mL)	Lay person results		The percentage of correct results (%)
			No. of Positive	No. of Negative	
-100%Cutoff	21	0	0	21	100
-75%Cutoff	21	69	0	21	100
-50% Cutoff	21	162	0	21	100
-25% Cutoff	21	251	1	20	95
+25% Cutoff	21	389	20	1	95
+50% Cutoff	21	463	21	0	100
+75% Cutoff	21	510	21	0	100

Comparison between GC/MS and Lay Person Results for BUP/MTD Panel DipCard

% Cutoff	No of samples	Concentration by GC/MS(ng/mL)		Lay person results		Correct Results (%)	
		Buprenorphine	Methadone	BUP	MTD	BUP	MTD
-100%	21	0	0	0+/21-	0+/21-	100	100
-75%	21	2.2	69	0+/21-	0+/21-	100	100
-50%	21	5.5	162	0+/21-	0+/21-	100	100
-25%	21	7.6	251	1+/20-	2+/19-	95	90
+25%	21	12.6	389	20+/1-	20+/1-	95	95
+50%	21	16.2	463	21+/0-	21+/0-	100	100
+75%	21	17.8	510	21+/0-	21+/0-	100	100

Comparison between GC/MS and Lay Person Results for BUP/MTD Turn-Key Split Cup

% Cutoff	No of samples	Concentration by GC/MS(ng/mL)		Lay person results		Correct Results (%)	
		Buprenorphine	Methadone	BUP	MTD	BUP	MTD
-100%	21	0	0	0+/21-	0+/21-	100	100
-75%	21	2.2	69	0+/21-	0+/21-	100	100
-50%	21	5.5	162	0+/21-	0+/21-	100	100
-25%	21	7.6	251	2+/19-	0+/21-	90	100
+25%	21	12.6	389	20+/1-	20+/1-	95	95
+50%	21	16.2	463	21+/0-	21+/0-	100	100
+75%	21	17.8	510	21+/0-	21+/0-	100	100

Comparison between GC/MS and Lay Person Results for BUP/MTD Quick Cup

% Cutoff	No of samples	Concentration by GC/MS(ng/mL)		Lay person results		Correct Results (%)	
		Buprenorphine	Methadone	BUP	MTD	BUP	MTD
-100%	21	0	0	0+/21-	0+/21-	100	100
-75%	21	2.2	69	0+/21-	0+/21-	100	100

-50%	21	5.5	162	0+/21-	0+/21-	100	100
-25%	21	7.6	251	0+/21-	1+/20-	100	95
+25%	21	12.6	389	20+/1-	21+/0-	95	100
+50%	21	16.2	463	21+/0-	21+/0-	100	100
+75%	21	17.8	510	21+/0-	21+/0-	100	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 each package insert and the scores revealed a reading Grade Level of 7.

3. Clinical Studies

Not applicable.

11. Conclusion

Based on the test principle and acceptable performance characteristics including precision, cut-off, interference, specificity, method comparison, and lay-user studies of the devices, it's concluded that the AssureTech Buprenorphine Strip, AssureTech Methadone Strip, AssureTech Buprenorphine/Methadone Panel Dip, AssureTech Buprenorphine/Methadone Quick Cup and AssureTech Buprenorphine/Methadone Turn Key-Split Cup are substantially equivalent to the predicate.