DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

October 9, 2014

CHEMTRON BIOTECH, INC.
JANE ZHANG
QA/RA DIRECTOR
9245 BROWN DEER ROAD, SUITE B
SAN DIEGO CA 92121

Re: K142396
Trade/Device Name: Chemtrue® BUP/TCA Single/Multi-Panel Drug Screen Dip Card/Cup/Cassette Tests;
Chemtrue® Multi-Panel Drug Screen Dip Card Tests;
Chemtrue® Multi-Panel Drug Screen Dip Card with OPI 2000 Tests
Regulation Number: 21 CFR 862.3650
Regulation Name: Opiate test system
Regulatory Class: II
Product Code: DJG, LFG
Dated: August 27, 2014
Received: August 28, 2014

Dear Ms. Jane Zhang:

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)*
k142396

Device Name
Chemtrue® BUP / TCA Single/Multi-Panel Drug Screen Dip Card / Cup / Cassette Tests
Chemtrue® Multi-Panel Drug Screen Dip Card Tests
Chemtrue® Multi-Panel Drug Screen Dip Card with OPI 2000 Tests

Indications for Use *(Describe)*
Chemtrue® BUP / TCA Single/Multi-Panel Drug Screen Dip Card / Cup / Cassette Tests:
The Chemtrue® BUP/TCA Single/Multi-Panel Drug Screen Dip Card /Cup/Cassette Tests are rapid lateral flow immunoassays for the qualitative detection of Buprenorphine (BUP) and/or Tricyclic Antidepressants (TCA) drugs in human urine. The test cut-off concentrations and the compounds the tests are calibrated to are as follows:

Analyte	Abbreviation	Calibrator	Cutoff Concentration (ng/mL)
Buprenorphine	BUP	Buprenorphine	10
Tricyclic Antidepressants	TCA	Nortriptyline	1000

The single and multi-panel tests are available in Dip Card, Cup and Cassette formats. The tests are intended for prescription and Over-The-Counter (OTC) use. The tests provide only a preliminary result. A more specific alternative chemical method must be used in order to obtain a confirmed assay result. Gas Chromatography / Mass Spectrometry (GC/MS) or Liquid Chromatography / Mass Spectrometry (LC/MS) are the preferred confirmatory methods. Clinical consideration and professional judgment should be applied to any drugs of abuse test result, particularly when preliminary positive results are indicated.
The tests are not intended to distinguish between prescription use or abuse of Buprenorphine and Tricyclic Antidepressants. There are no uniformly recognized cut-off concentration levels for Buprenorphine and Tricyclic Antidepressants in urine.

Chemtrue® Multi-Panel Drug Screen Dip Card Tests:
The Chemtrue® Multi-Panel Drug Screen Dip Card Tests are rapid lateral flow immunoassays for the qualitative detection of Buprenorphine, Amphetamine, Cocaine, Marijuana, Morphine, Methamphetamine, Phencyclidine, Benzodiazepines, Barbiturates, Ecstasy, Methadone, Oxycodone and Tricyclic Antidepressants drugs in human urine. The test cut-off concentrations and the compounds the tests are calibrated to are as follows:

Analyte	Abbreviation	Calibrator	Cutoff Concentration (ng/mL)
Buprenorphine	BUP	Buprenorphine	10
Tricyclic Antidepressants	TCA	Nortriptyline	1000
Amphetamine	AMP	d-Amphetamine	1000
Cocaine	COC	Benzoylecgonine	300
Methamphetamine	MAMP /MET	d-Methamphetamine	1000
Morphine	MOR	Morphine	300
Phencyclidine	PCP	Phencyclidine	25
Marijuana	THC	11-nor-Δ9-THC9-COOH	50
Benzodiazepines	BZO	Oxazepam	300
Barbiturates	BAR	Secobarbital/Pentobarbital	300
Ecstasy	MDMA	d,l-Methylenedioxymethamphetamine	500
Methadone	MTD	Methadone	300
Oxycodone	OXY	Oxycodone	100

The Chemtrue® Multi-Panel Drug Screen Dip Card Tests panel can consist of any combination of the above listed drug analytes. The tests are intended for prescription and Over-The-Counter (OTC) use.

The tests provide only a preliminary result. A more specific alternative chemical method must be used in order to obtain a

confirmed assay result. Gas Chromatography / Mass Spectrometry (GC/MS) or Liquid Chromatography / Mass Spectrometry (LC/MS) are the preferred confirmatory methods. Clinical consideration and professional judgment should be applied to any drugs of abuse test result, particularly when preliminary positive results are indicated.

The tests are not intended to differentiate between drugs of abuse and prescription use of Benzodiazepines, Barbiturates, Buprenorphine, Oxycodone and Tricyclic Antidepressants. There are no uniformly recognized cut-off concentration levels for these drugs in urine.

Chemtrue® Multi-Panel Drug Screen Dip Card with OPI 2000 Tests:
The Chemtrue® Multi-Panel Drug Screen Dip Card with OPI 2000 Tests are rapid lateral flow immunoassays for the qualitative detection of Buprenorphine, Amphetamine, Cocaine, Marijuana, Opiates 2000, Methamphetamine, Phencyclidine, Benzodiazepines, Barbiturates, Ecstasy, Methadone, Oxycodone and Tricyclic Antidepressants drugs in human urine. The test cut-off concentrations and the compounds the tests are calibrated to are as follows:

Analyte	Abbreviation	Calibrator	Cutoff Concentration (ng/mL)
Buprenorphine	BUP	Buprenorphine	10
Tricyclic Antidepressants	TCA	Nortriptyline	1000
Amphetamine	AMP	d-Amphetamine	1000
Cocaine	COC	Benzoylecgonine	300
Methamphetamine	MAMP /MET	d-Methamphetamine	1000
Opiates	OPI	Morphine	2000
Phencyclidine	PCP	Phencyclidine	25
Marijuana	THC	11-nor-Δ9-THC9-COOH	50
Benzodiazepines	BZO	Oxazepam	300
Barbiturates	BAR	Secobarbital/Pentobarbital	300
Ecstasy	MDMA	d,l-Methylenedioxymethamphetamine	500
Methadone	MTD	Methadone	300
Oxycodone	OXY	Oxycodone	100

The Chemtrue® Multi-Panel Drug Screen Dip Card with OPI 2000 Tests can consist of any combination of the above listed drug analytes. The tests are intended for prescription and Over-The-Counter (OTC) use.

The tests provide only a preliminary result. A more specific alternative chemical method must be used in order to obtain a confirmed assay result. Gas Chromatography / Mass Spectrometry (GC/MS) or Liquid Chromatography / Mass Spectrometry (LC/MS) are the preferred confirmatory methods. Clinical consideration and professional judgment should be applied to any drugs of abuse test result, particularly when preliminary positive results are indicated.

The tests are not intended to differentiate between drugs of abuse and prescription use of Benzodiazepines, Barbiturates, Buprenorphine, Oxycodone and Tricyclic Antidepressants. There are no uniformly recognized cut-off concentration levels for these drugs in urine.

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.

510(k) Summary

AS REQUIRED BY 21 CFR 807.92(c)

A. SUBMITTER: Chemtron Biotech, Inc. 9245 Brown Deer Road, Suite B, San Diego, CA 92121.

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Contact Person: Jane Zhang, Director of QA/RA

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Email: jane@uschemtronbio.com

Date Prepared: October 08, 2014

B. DEVICE

Device Name: Chemtrue® BUP/TCA Single/Multi-Panel Drug Screen Dip Card/Cup/Cassette Tests

Chemtrue® Multi-Panel Drug Screen Dip Card Tests

Chemtrue® Multi-Panel Drug Screen Dip Card with OPI 2000 Tests

Common Name: Multi-Drug Urine Test Panel

Regulatory Class: Class II

Regulatory Information:

Drug of Abuse	Product Code	Device Panel	Regulation Number
Buprenorphine (BUP)	DJG	Toxicology 91	21CFR 862.3650
Tricyclic Antidepressants (TCA)	LFG	Toxicology 91	21 CFR 862.3910

This 510(k) has been submitted for clearance of new BUP/TCA drugs of abuse cup devices and to incorporate BUP/TCA analytes to previously FDA cleared Chemtrue Single/Multi-Panel Drug Screen Dip Card/Cassette Tests (k102203, k111322, k121339, and k123080). These tests have been previously cleared for prescription use (k102203 and k111322) and over-the-counter use (k121339 and k123080) and already contain the following drugs of abuse analytes:

Drug of Abuse	Product Code	Panel	Regulation Section
Amphetamine	DKZ	Toxicology 91	21CFR 862.3100, Amphetamine Test System
Cocaine	DIO	Toxicology 91	21 CFR 862.3250, Cocaine and metabolites Test System
Methamphetamine	LAF	Toxicology 91	21 CFR 862.3610, Methamphetamine Test System
Opiates	DJG	Toxicology 91	21 CFR 862.3650, Opiate Test System
Phencyclidine	LCM	Toxicology 91	Unclassified, Enzyme immunoassay Phencyclidine
Marijuana	LDJ	Toxicology 91	21 CFR 862.3870, Cannabinoids Test System
Benzodiazepines	JXM	Toxicology 91	21 CFR 862.3170, Benzodiazepines Test System

Barbiturates	DIS	Toxicology 91	21 CFR 862.3150, Barbiturates Test System
Ecstasy (MDMA)	DJC	Toxicology 91	21 CFR 862.3610, Methamphetamine Test System
Methadone	DJR	Toxicology 91	21 CFR 862.3620, Methadone Test System
Oxycodone	DJG	Toxicology 91	21 CFR 862.3650, Opiate Test System
Morphine	DNK	Toxicology 91	21 CFR 862.3640, Morphine Test System

C. PREDICATE DEVICE:

510(k): k061718. Innovacon Spectrum II Test Card and Innovacon Spectrum II Test Card with Integrated Cups

D. INDICATONS FOR USE:

Device Name: Chemtrue® BUP / TCA Single/Multi-Panel Drug Screen Dip Card / Cup / Cassette Tests

Chemtrue® Multi-Panel Drug Screen Dip Card Tests

Chemtrue® Multi-Panel Drug Screen Dip Card with OPI 2000 Tests

Indications for Use:

Chemtrue® BUP / TCA Single/Multi-Panel Drug Screen Dip Card / Cup / Cassette Tests:

The Chemtrue® BUP/TCA Single/Multi-Panel Drug Screen Dip Card /Cup/Cassette Tests are rapid lateral flow immunoassays for the qualitative detection of Buprenorphine (BUP) and/or Tricyclic Antidepressants (TCA) drugs in human urine. The test cut-off concentrations and the compounds the tests are calibrated to are as follows:

Analyte	**Abbreviation**	**Calibrator**	**Cutoff Concentration**
Buprenorphine	BUP	Buprenorphine	10 ng/mL
Tricyclic Antidepressants	TCA	Nortriptyline	1000 ng/mL

The single and multi-panel tests are available in Dip Card, Cup and Cassette formats. The tests are intended for prescription and Over-The-Counter (OTC) use. The tests provide only a preliminary result. A more specific alternative chemical method must be used in order to obtain a confirmed assay result. Gas Chromatography / Mass Spectrometry (GC/MS) or Liquid Chromatography / Mass Spectrometry (LC/MS) are the preferred confirmatory methods. Clinical consideration and professional judgment should be applied to any drugs of abuse test result, particularly when preliminary positive results are indicated.

The tests are not intended to distinguish between prescription use or abuse of Buprenorphine and Tricyclic Antidepressants. There are no uniformly recognized cut-off concentration levels for Buprenorphine and Tricyclic Antidepressants in urine.

Chemtrue® Multi-Panel Drug Screen Dip Card Tests:

The Chemtrue® Multi-Panel Drug Screen Dip Card Tests are rapid lateral flow immunoassays for the qualitative detection of Buprenorphine, Amphetamine, Cocaine, Marijuana, Morphine, Methamphetamine, Phencyclidine, Benzodiazepines, Barbiturates,

Ecstasy, Methadone, Oxycodone and Tricyclic Antidepressants drugs in human urine. The test cut-off concentrations and the compounds the tests are calibrated to are as follows:

Analyte	Abbreviation	Calibrator	Cutoff Concentration (ng/mL)
Buprenorphine	BUP	Buprenorphine	10
Tricyclic Antidepressants	TCA	Nortriptyline	1000
Amphetamine	AMP	d-Amphetamine	1000
Cocaine	COC	Benzoylecgonine	300
Methamphetamine	MAMP /MET	d-Methamphetamine	1000
Morphine	MOR	Morphine	300
Phencyclidine	PCP	Phencyclidine	25
Marijuana	THC	11-nor-Δ^9-THC9-COOH	50
Benzodiazepines	BZO	Oxazepam	300
Barbiturates	BAR	Secobarbital/Pentobarbital	300
Ecstasy	MDMA	d,l-Methylenedioxymethamphetamine	500
Methadone	MTD	Methadone	300
Oxycodone	OXY	Oxycodone	100

The Chemtrue® Multi-Panel Drug Screen Dip Card Tests panel can consist of any combination of the above listed drug analytes. The tests are intended for prescription and Over-The-Counter (OTC) use.

The tests provide only a preliminary result. A more specific alternative chemical method must be used in order to obtain a confirmed assay result. Gas Chromatography / Mass Spectrometry (GC/MS) or Liquid Chromatography / Mass Spectrometry (LC/MS) are the preferred confirmatory methods. Clinical consideration and professional judgment should be applied to any drugs of abuse test result, particularly when preliminary positive results are indicated.

The tests are not intended to differentiate between drugs of abuse and prescription use of Benzodiazepines, Barbiturates, Buprenorphine, Oxycodone and Tricyclic Antidepressants. There are no uniformly recognized cut-off concentration levels for these drugs in urine.

Chemtrue® Multi-Panel Drug Screen Dip Card with OPI 2000 Tests:

The Chemtrue® Multi-Panel Drug Screen Dip Card with OPI 2000 Tests are rapid lateral flow immunoassays for the qualitative detection of Buprenorphine, Amphetamine, Cocaine, Marijuana, Opiates 2000, Methamphetamine, Phencyclidine, Benzodiazepines, Barbiturates, Ecstasy, Methadone, Oxycodone and Tricyclic Antidepressants drugs in human urine. The test cut-off concentrations and the compounds the tests are calibrated to are as follows:

Analyte	Abbreviation	Calibrator	Cutoff Concentration (ng/mL)
Buprenorphine	BUP	Buprenorphine	10
Tricyclic Antidepressants	TCA	Nortriptyline	1000
Amphetamine	AMP	d-Amphetamine	1000
Cocaine	COC	Benzoylecgonine	300

Methamphetamine	MAMP /MET	d-Methamphetamine	1000
Opiates	OPI	Morphine	2000
Phencyclidine	PCP	Phencyclidine	25
Marijuana	THC	11-nor-Δ^9-THC9-COOH	50
Benzodiazepines	BZO	Oxazepam	300
Barbiturates	BAR	Secobarbital/Pentobarbital	300
Ecstasy	MDMA	d,l-Methylenedioxymethamphetamine	500
Methadone	MTD	Methadone	300
Oxycodone	OXY	Oxycodone	100

The Chemtrue® Multi-Panel Drug Screen Dip Card with OPI 2000 Tests can consist of any combination of the above listed drug analytes. The tests are intended for prescription and Over-The-Counter (OTC) use.

The tests provide only a preliminary result. A more specific alternative chemical method must be used in order to obtain a confirmed assay result. Gas Chromatography / Mass Spectrometry (GC/MS) or Liquid Chromatography / Mass Spectrometry (LC/MS) are the preferred confirmatory methods. Clinical consideration and professional judgment should be applied to any drugs of abuse test result, particularly when preliminary positive results are indicated.

The tests are not intended to differentiate between drugs of abuse and prescription use of Benzodiazepines, Barbiturates, Buprenorphine, Oxycodone and Tricyclic Antidepressants. There are no uniformly recognized cut-off concentration levels for these drugs in urine.

E. DEVICE DESCRIPTION

The Chemtrue® Drug Screen Tests are colloidal gold based lateral flow immunoassays for the rapid, qualitative detection of drugs of abuse in human urine. The tests are single-use, in vitro diagnostic devices, which come in the formats of dip card, cup, or cassette, as indicated by the test name.

F. SUBSTANTIAL EQUIVALENCE INFORMATION

Comparison with the predicate devices is outlined below:

Item	Candidate Devices	Predicate
Indication(s) for use	For qualitative detection of drugs of abuse in human urine	Same
Specimen Type	Human urine	Same
Methodology /Technological Characteristics	Lateral flow, competitive binding immunoassay based on the principle of antigen and antibody immunochemistry.	Same
Results	Qualitative	Same
Cut Off	Buprenorphine 10 ng/mL Tricyclic Antidepressants 1000 ng/mL Amphetamine 1000 ng/mL Cocaine 300 ng/mL	Same, except the predicate also has a 300 ng/mL cut off

	Methamphetamine 1000 ng/mL Morphine 300 ng/mL Opiates 2000 ng/mL PCP 25 ng/mL THC 50 ng/mL Benzodiazepines 300 ng/mL Barbiturates 300 ng/mL Ecstasy (MDMA) 500 ng/mL Methadone 300 ng/mL Oxycodone 100 ng/mL	and a 500 ng/mL cut off, for Amphetamine and Methamphetamine, respectively.
Configurations	Dip Card, Cup (for BUP/TCA tests only) and Cassette	Test Card and test card with integrated cup
Intended Use	Prescription and OTC Use	Prescription Use only

G. TEST PRINCIPLE

The Chemtrue® Drug Screen Tests are rapid lateral flow immunoassays in which chemically modified drugs (drug-protein conjugates) compete with drugs that may be present in urine. On each test strip, a drug-protein conjugate is striped on the test band of the membrane - known as the test region (T) and the anti-drug antibody-colloidal gold conjugate pads are placed at the forward end of the membrane. If target drugs are present in the urine specimen below its cut-off concentration, the solution of the colored antibody-colloidal gold conjugates moves along with the sample solution by capillary action across the membrane to the immobilized drug-protein conjugate zone on the test band region. The colored antibody-gold conjugates then complexes with the drug-protein conjugates to form visible lines. Therefore, the formation of the visible precipitant in the test band indicates a negative result. If the target drug level exceeds its cut-off concentration, the drug/metabolite antigen competes with drug-protein conjugates on the test band region for the limited antibody on the colored drug antibody-colloidal gold conjugate pad. The drug will saturate the limited antibody binding sites and the colored antibody-colloidal gold conjugate cannot bind to the drug-protein conjugate at the test region of the test strip. Therefore, absence of the color band on the test region indicates a preliminary positive result.

A band should form in the control region (C) of the devices regardless of the presence of drug in the sample to indicate that the test has been performed properly.

Monoclonal anti-drug antibodies are used on the BUP/AMP/COC/MET/MOR/OPI/ PCP/THC/BAR/MDMA/MTD/OXY Test devices which are derived from mouse. The polyclonal anti-drug antibodies are used on TCA/BZO Test devices which are derived from sheep/mouse.

H. PERFORMANCE CHARACTERISTICS

Performance data is only provided for BUP and TCA, as the new analytes. All other drugs of abuse analytes of the candidate devices (AMP, COC, MAMP, OPI, MOR, PCP, THC, BZO, BAR, MDMA, MTD, and OXY) were previously cleared under k102203, k111322, k121339, and k123080. Test strips, sample matrix, test format, and cut-off concentrations for the other drugs of abuse analytes are identical to those cleared under k102203, k111322, k121339, and k123080. See k102203, k111322, k121339, and k123080 for additional precision, specificity, interference, method comparison, and lay-user study information.

1. Reproducibility (Precision) Studies:

The precision study was conducted by three (3) Operators with three (3) lots of each device format in replicates of 10 devices/lot at each concentration level of Negative, 50%, 75%, cut-off, 125% and 150% of the cutoff. The study was conducted over a six (6) day period using GC/MS confirmed drug spiked samples. The samples were blind coded according to a random table and randomly distributed to three operators by the project Manager. The data is analyzed and summarized in the tables below:

Table 1a. **BUP Dip Card Test:** Cutoff: 10 ng/mL

Concentration Level	n	**TOTAL**	
		+	**-**
Negative	30	**0**	**30**
50% of cutoff	30	**0**	**30**
75% of cutoff	30	**0**	**30**
Cutoff	30	**10**	**20**
125% of cutoff	30	**30**	**0**
150% of cutoff	30	**30**	**0**

Table 1b. **TCA Dip Card Test:** Cutoff: 1000 ng/mL

Concentration Level	n	**TOTAL**	
		+	**-**
Negative	30	**0**	**30**
50% of cutoff	30	**0**	**30**
75% of cutoff	30	**0**	**30**
Cutoff	30	**1**	**29**
125% of cutoff	30	**30**	**0**
150% of cutoff	30	**30**	**0**

Table 1c. **BUP Cup Test:** Cutoff: 10 ng/mL

Concentration Level	n	**TOTAL**	
		+	**-**
Negative	30	**0**	**30**
50% of cutoff	30	**0**	**30**

75% of cutoff	30	**1**	**29**
Cutoff	30	**5**	**25**
125% of cutoff	30	**30**	**0**
150% of cutoff	30	**30**	**0**

Table 1d. **TCA Cup Test:** Cutoff: 1000 ng/mL

Concentration Level	n	**TOTAL**	
		+	**-**
Negative	30	**0**	**30**
50% of cutoff	30	**0**	**30**
75% of cutoff	30	**0**	**30**
Cutoff	30	**1**	**29**
125% of cutoff	30	**30**	**0**
150% of cutoff	30	**30**	**0**

Table 1e. **BUP Cassette Test:** Cutoff: 10 ng/mL

Concentration Level	n	**TOTAL**	
		+	**-**
Negative	30	**0**	**30**
50% of cutoff	30	**0**	**30**
75% of cutoff	30	**0**	**30**
Cutoff	30	**9**	**21**
125% of cutoff	30	**29**	**1**
150% of cutoff	30	**30**	**0**

Table 1f. **TCA Cassette Test:** Cutoff: 1000 ng/mL

Concentration Level	n	**TOTAL**	
		+	**-**
Negative	30	**0**	**30**
50% of cutoff	30	**0**	**30**
75% of cutoff	30	**2**	**28**
Cutoff	30	**18**	**12**
125% of cutoff	30	**29**	**1**
150% of cutoff	30	**30**	**0**

2. Specificity Study: These studies were conducted by adding various drugs, drug metabolites, and other structurally-similar compounds likely to be present in the actual urine specimen.

   The following structurally-related compounds were tested for cross-reactivity and found to be positive if the levels were greater than the following listed concentrations:

Table 2a. **Buprenorphine (BUP):**

Substances	**Concentration** (ng/mL)	**% Cross Reactivity**
Buprenorphine	10	100
Norbuprenorphine	10	100

Table 2b. **Tricyclic Antidepressants (TCA):**

Substances	**Concentration** (ng/mL)	**% Cross Reactivity**
Nortriptyline	1000	100
Amitriptyline	1000	100
Desipramine	300	333
Doxepin HCl	2,000	50
Imipramine	50	2000
Protriptyline	4750	21.1
Trimipramine	2,000	50

3. Interference:

Over one hundred of potential interferents were tested and found not to cross-react when tested at concentrations of 100 µg/mL at ±25% of the drug (BUP and TCA) cut-off concentrations.

Table 3. The following compounds do not interfere with the tests:

Acetaminophen	Estrone	Oxolinic Acid
Acetanilide	Ethanol	Oxymetazoline HCl
6-Acetylmorphine	β-Estradiol	Oxymorphone
N-Acetylprocainamide	Fenoprofen	Papaverine HCl
4-Aminoantipyrine	Glucose	Penicillin G
Ampicillin	L-Glutamine	Pentazocine
(±) Amphetamine	Hydrochlorothiazide	Phenacetin
R(-)Amphetamine	Hemoglobin Human	Phenalzine Sulfate
S(+)Amphetamine	Hydralazine	Pheniramine Maleate
R (-) Apomorphine HCl	Hydrocodone	R- Phenylephrine
Aspirin	Hydrocortisone	Prednisolone
L-Ascorbic Acid	Hydromorphone	Prednisone
Atropine	3-Hydroxytyramine hydrobromide	Protryptiline
Benzocaine	Imipramine	(+) Quinidine
Benzoic Acid	Isoprenaline HCl	(-) Quinine
Benzoylecgonine	Ketamine	Ranitidine
Bilirubin	Labetolol HCl	Riboflavin
Bromopheniramine Maleate	Loperamide HCl	Salicylic Acid
Buprenorphine	(+/-) Methadone	Serotonin HCl
Cannabidiol	Methoxyphenamine	Sodium Chloride

Chloramphenicol	Morphine	Sulfamethazine
Chlorothiazide	Naloxone	Temazepam
Cholesterol	Nalidixic Acid	Tetracycline
Cholic Acid	Naproxen	Tetrahydrozoline HCl
Cortisone	Niacinamide	Δ^9-Tetrahydrocannabinol
(-)-Cotinine	Nicotinamide	Thiamine HCl
11-Deoxycorticosterone	Nifedipine	Trifluoperazine HCl
Desalkyl Flurazepam	Norcodeine	Trimethoprim
Diazepam	Nordiazepam	Tryptamine
Diclofenac Sodium Salt	19-Norethindrone	Tyramine
Diflunisal	Normorphine	DL-Tyrosine
2,5 Dihydroxybenzoic(Gentisic)Acid	Norsertraline	L-Tryptophan
Dopamine	Noscapine HCl	Uric Acid
Doxepin HCl	Nortriptyline	Verapamil HCl
Duloxetine HCl	(+/-) Octapamine	Zomepirac sodium salt
EDDP Percholate	Oxazepam	

4. Effect of Urine pH and Specific Gravity Studies: The testing results demonstrate that the urine pH ranges from 3.0 to 8.5 at ±25% and ±50% drug (BUP and TCA) cut-off concentrations do not affect the test performance. The specific gravity (SG) ranges of 1.002, 1.010, 1.015, 1.020, 1.025 and 1.030 at ±25% and ±50% drug (BUP and TCA) cut-off concentrations do not affect the test results.

5. Stability Study: To establish and support the shelf life and expiration date, stability studies were conducted under accelerated temperature (at 60^{o}C and 40^{o}C), and real time (25^{o}C±2^{o}C) with three (3) lots of each device format. The stability study results support two (2) years shelf-life of the products at (2 to 30^{o}C). The real time stability study is still on-going.

6. Method Comparison Studies:
   Chemtrue® BUP/TCA Single /Multi-Panel Tests were compared to the GC/MS Reference Method. The accuracy of the Chemtrue® Test devices were evaluated against the confirmed GC/MS values in this blind-labeled clinical specimen correlation study (a total of 174 clinical specimens). Three operators performed the testing. Each operator tested one device format with one unique set of blind coded samples. Each blind labeled sample was randomly distributed to each operator by the Clinical Research Cooperator. The results are summarized in the tables below:

Table 6a. Summary from method comparison (Accuracy) study of Chemtrue® Drug Screen Dip Card Test results versus GC/MS

Chemtrue®	**(-)**	**(+)**	**% Agreement**

Drug Screen Dip Card	No drug present	GC/MS Negative (≤ 50% of the cutoff)	Near cutoff negative (75% of the C/O to cutoff)	Near cutoff positive (Cutoff to 125% of the C/O)	GC/MS Positive (≥150% of the cutoff)	**with GC/MS values**
BUP (+)	0	0	2	6	25	100%
(-)	40	7	5	0	0	96.3%
TCA (+)	0	0	0	8	26	100%
(-)	40	6	9	0	0	100%

Table 6b. Summary of a method comparison (Accuracy) study of Chemtrue® Drug Screen Cup Test results versus the GC/MS

Chemtrue® Drug Screen Cup	**(-)**			**(+)**		**% Agreement with GC/MS values**
	No drug present	GC/MS Negative (≤ 50% of the cutoff)	Near cutoff negative (75% of the C/O to cutoff)	Near cutoff positive (Cutoff to 125% of the C/O)	GC/MS Positive (≥150% of the cutoff)	
BUP (+)	0	0	2	6	25	100%
(-)	40	7	5	0	0	96.3%
TCA (+)	0	0	0	8	26	100%
(-)	40	6	9	0	0	100%

Table 6c. Summary of a method comparison (Accuracy) study of Chemtrue® Drug Screen Cassette Test results versus the GC/MS

Chemtrue® Drug Screen Cassette	**(-)**			**(+)**		**% Agreement with GC/MS values**
	No drug present	GC/MS Negative (≤ 50% of the cutoff)	Near cutoff negative (75% of the C/O to cutoff)	Near cutoff positive (Cutoff to 125% of the C/O)	GC/MS Positive (≥150% of the cutoff)	
BUP (+)	0	0	2	6	25	100%
(-)	40	7	5	0	0	96.3%
TCA (+)	0	0	0	8	26	100%
(-)	40	6	9	0	0	100%

Table 6d. DISCORDANT RESULTS: There are two (2) discordant results for each format:

Cutoff Value (ng/mL)	Analyte assay (POS/NEG)	Drug/Metabolite GC/MS value (ng/mL)	
		Drug Analyte	GC/MS Value (ng/mL)
Buprenorphine 10	+	Buprenorphine	9.5
Buprenorphine 10	+	Buprenorphine	9.8

7. OTC Lay-user Studies:

A total of 300 people participated in an OTC lay-user study at three (3) intended user sites with LC/MS confirmed urine samples at the following concentrations: negative, 50%, 75%, 125%, 150% and 200% of the cutoff by spiking drugs into drug-free urine pool. Each sample was aliquotted into an individual blind-labeled container. Each lay-user was provided with a package insert, up to two blind labeled samples and test device(s). The results are summarized below:

Table 7a. Chemtrue® BUP/TCA Drug Screen Dip Card Test *vs* LC/MS Value Analysis

Drug Analyte	Cut Off (ng/mL)	Results	Drug Concentrations (Per LC/MS Values)					
			No Drug present	50% of the cutoff	75% of the cutoff	125% of the cutoff	150% of the cutoff	200% of the cutoff
BUP	10	# of positive	0	0	0	30	30	30
		# of Negative	30	30	30	0	0	0
		Total	30	30	30	30	30	30
		Agreement	100%	100%	100%	100%	100%	100%

Table 7b. Chemtrue® BUP/TCA Drug Screen Dip Card Test *vs* LC/MS Value Analysis

Drug Analyte	Cut Off (ng/mL)	Results	Drug Concentrations (Per LC/MS Values)					
			No Drug present	50% of the cutoff	75% of the cutoff	125% of the cutoff	150% of the cutoff	200% of the cutoff
TCA	1000	# of positive	0	0	1	30	30	30
		# of Negative	30	30	29	0	0	0
		Total	30	30	30	30	30	30
		Agreement	100%	100%	96.7%	100%	100%	100%

Table 7c. Chemtrue® BUP/TCA Drug Screen Cup Test *vs* LC/MS Value Analysis

Drug Analyte	Cut Off (ng/mL)	Results	Drug Concentrations (Per LC/MS Values)					
			No Drug present	50% of the cutoff	75% of the cutoff	125% of the cutoff	150% of the cutoff	200% of the cutoff
BUP	10	# of positive	0	0	0	30	30	30
		# of Negative	30	30	30	0	0	0
		Total	30	30	30	30	30	30
		Agreement	100%	100%	100%	100%	100%	100%

Table 7d. Chemtrue® BUP/TCA Drug Screen Cup Test *vs* LC/MS Value Analysis

Drug Analyte	Cut Off (ng/mL)	Results	Drug Concentrations (Per LC/MS Values)					
			No Drug present	50% of the cutoff	75% of the cutoff	125% of the cutoff	150% of the cutoff	200% of the cutoff
TCA	1000	# of positive	0	0	0	30	30	30
		# of Negative	30	30	30	0	0	0
		Total	30	30	30	30	30	30
		Agreement	100%	100%	100%	100%	100%	100%

Table 7e. Chemtrue® BUP/TCA Drug Screen Cassette Test *vs* LC/MS Value Analysis

Drug Analyte	Cut Off (ng/mL)	Results	Drug Concentrations (Per LC/MS Values)					
			No Drug present	50% of the cutoff	75% of the cutoff	125% of the cutoff	150% of the cutoff	200% of the cutoff
BUP	10	# of positive	0	0	0	30	30	30
		# of Negative	30	30	30	0	0	0
		Total	30	30	30	30	30	30
		Agreement	100%	100%	100%	100%	100%	100%

Table 7f. Chemtrue® BUP/TCA Drug Screen Cassette Test *vs* LC/MS Value Analysis

Drug Analyte	Cut Off (ng/mL)	Results	Drug Concentrations (Per LC/MS Values)					
			No Drug present	50% of the cutoff	75% of the cutoff	125% of the cutoff	150% of the cutoff	200% of the cutoff

TCA	1000	# of positive	0	0	0	30	30	30
		# of Negative	30	30	30	0	0	0
		Total	30	30	30	30	30	30
		Agreement	100%	100%	100%	100%	100%	100%

Lay-users were also given surveys on the ease of understanding the package insert instructions. 99% of the lay users indicated that the device instructions can be easily followed. A Flesch-Kincaid reading analysis was performed on the package insert and the score revealed a reading grade level of less than 7.

I. CONCLUSION:

Based on the test principle and performance characteristics of the proposed device, it is concluded that the candidate devices are substantially equivalent to the predicate device.