Chemtron Biotech, Inc.
Jane Zhang
Vice President of Quality
9245 Brown Deer Road, Suite B
San Diego, California 92121

Re: K232736
Trade/Device Name: Chemtrue® Drug Screen Fentanyl/Tramadol Cup Test, Chemtrue® Drug Screen Fentanyl/Tramadol Dip Card Test, Chemtrue® Multi-Panel Drug Screen Cup Test, Chemtrue® Multi-Panel Drug Screen Dip Card Test.
Regulation Number: 21 CFR 862.3650
Regulation Name: Opiate test system
Regulatory Class: Class II
Product Code: DJG, DKZ, DIS, JXM, DIO, DJC, LDJ, LAF, DJR, DNK, LCM, JXN, LFG
Dated: November 16, 2023
Received: November 17, 2023

Dear 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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Joseph A. Kotarek -S

Digitally signed by Joseph A. Kotarek -S
Date: 2023.12.20 10:46:07 -05'00'

Joseph Kotarek
Branch Chief
Toxicology Branch
Division of Chemistry
and Toxicology Devices
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
k232736

Device Name
Device Name: Chemtrue® Drug Screen Multi-Panel Dip Card Tests

Indications for Use *(Describe)*

The Chemtrue® Multi-Panel Drug Screen Cup Tests are rapid lateral flow immunoassays for the qualitative detection of Amphetamine, Barbiturates, Benzodiazepines, Buprenorphine, Cocaine, Norfentanyl, Marijuana, Methamphetamine, Morphine, Opiates, Phencyclidine, Ecstasy, Methadone, Oxycodone, Propoxyphene , Tramadol and 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 Conc. (ng/mL)
Amphetamine	AMP	d-Amphetamine	300
Amphetamine	AMP	d-Amphetamine	500
Amphetamine	AMP	d-Amphetamine	1,000
Barbiturates	BAR	Secobarbital/Pentobarbital	200
Barbiturates	BAR	Secobarbital/Pentobarbital	300
Benzodiazepines	BZO	Oxazepam	200
Benzodiazepines	BZO	Oxazepam	300
Buprenorphine	BUP	Buprenorphine	10
Cocaine	COC	Benzoylecgonine	150
Cocaine	COC	Benzoylecgonine	300
Ecstasy	MDMA	d,l-Methylenedioxy methamphetamine	500
Norfentanyl	FYL	Norfentanyl	5
Methamphetamine	MET	d-Methamphetamine	300
Methamphetamine	MET	d-Methamphetamine	500
Methamphetamine	MET	d-Methamphetamine	1,000
Marijuana	THC	11-nor-Δ9-THC-9-COOH	50
Methadone	MTD	Methadone	300
Morphine	MOR	Morphine	300
Opiates	OPI	Morphine	2,000
Oxycodone	OXY	Oxycodone	100
Phencyclidine	PCP	Phencyclidine	25
Propoxyphene	PPX	Propoxyphene	300
Tricyclic Antidepressants	TCA	Nortriptyline	1,000
Tramadol	TML	Tramadol	100

The multi test panels can consist of any drug analytes listed above in any combination. Only one cut-off concentration will be included per analyte per device.

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, Propoxyphene and Tricyclic Antidepressants.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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

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

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Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
k232736

Device Name
Device Name: Chemtrue® Drug Screen Multi-Panel Cup Tests

Indications for Use *(Describe)*

The Chemtrue® Multi-Panel Drug Screen Cup Tests are rapid lateral flow immunoassays for the qualitative detection of Amphetamine, Barbiturates, Benzodiazepines, Buprenorphine, Cocaine, Norfentanyl, Marijuana, Methamphetamine, Morphine, Opiates, Phencyclidine, Ecstasy, Methadone, Oxycodone, Propoxyphene , Tramadol and 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 Conc. (ng/mL)
Amphetamine	AMP	d-Amphetamine	300
Amphetamine	AMP	d-Amphetamine	500
Amphetamine	AMP	d-Amphetamine	1,000
Barbiturates	BAR	Secobarbital/Pentobarbital	200
Barbiturates	BAR	Secobarbital/Pentobarbital	300
Benzodiazepines	BZO	Oxazepam	200
Benzodiazepines	BZO	Oxazepam	300
Buprenorphine	BUP	Buprenorphine	10
Cocaine	COC	Benzoylecgonine	150
Cocaine	COC	Benzoylecgonine	300
Ecstasy	MDMA	d,l-Methylenedioxy methamphetamine	500
Norfentanyl	FYL	Norfentanyl	5
Methamphetamine	MET	d-Methamphetamine	300
Methamphetamine	MET	d-Methamphetamine	500
Methamphetamine	MET	d-Methamphetamine	1,000
Marijuana	THC	11-nor-Δ9-THC-9-COOH	50
Methadone	MTD	Methadone	300
Morphine	MOR	Morphine	300
Opiates	OPI	Morphine	2,000
Oxycodone	OXY	Oxycodone	100
Phencyclidine	PCP	Phencyclidine	25
Propoxyphene	PPX	Propoxyphene	300
Tricyclic Antidepressants	TCA	Nortriptyline	1,000
Tramadol	TML	Tramadol	100

The multi test panels can consist of any drug analytes listed above in any combination. Only one cut-off concentration will be included per analyte per device.

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, Propoxyphene and Tricyclic Antidepressants.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
k232736

Device Name
Device Name: Chemtrue® Drug Screen Fentanyl / Tramadol Dip Card Tests

Indications for Use *(Describe)*

The Chemtrue® Drug Screen Fentanyl / Tramadol Dip Card Tests are rapid lateral flow immunoassays for the qualitative detection of Norfentanyl 5 and Tramadol 100 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)
Norfentanyl	FYL	Norfentanyl	5
Tramadol	TML	Tramadol	100

The Chemtrue® Drug Screen Fentanyl / Tramadol Dip Card Test detects and is calibrated against norfentanyl, the major metabolite of fentanyl in human urine. The test is available in Single and multi-panels.

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 test is not intended to differentiate between drugs of abuse and prescription use of Fentanyl/ Tramadol. The test is 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)

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
k232736

Device Name
Device Name: Chemtrue® Drug Screen Fentanyl / Tramadol Cup Tests

Indications for Use *(Describe)*

The Chemtrue® Drug Screen Fentanyl / Tramadol Cup Tests are rapid lateral flow immunoassays for the qualitative detection of Norfentanyl 5 and Tramadol 100 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)
Norfentanyl	FYL	Norfentanyl	5
Tramadol	TML	Tramadol	100

The Chemtrue® Drug Screen Fentanyl / Tramadol Cup Test detects and is calibrated against norfentanyl, the major metabolite of fentanyl in human urine. The test is available in Single and multi-panels.

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 test is not intended to differentiate between drugs of abuse and prescription use of Fentanyl/ Tramadol. The test is 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.

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, USA.
TEL: 858-450-0044;
FAX: 858-450-0046

Contact Person: Jane Zhang, Vice President of Quality
Official FDA Correspondent
9245 Brown Deer Road, Suite B
San Diego, CA 92121
Office: (858) 450-0044; FAX: (858) 450-0046
Email: jane@uschemtronbio.com

Date: September 06, 2023

B. DEVICE

Trade or Proprietary Name: Chemtrue® Drug Screen Fentanyl/Tramadol Cup Test,
Chemtrue® Drug Screen Fentanyl/Tramadol Dip Card Test,
Chemtrue® Multi-Panel Drug Screen Cup Test,
Chemtrue® Multi-Panel Drug Screen Dip Card Test.

Common Name: Single/Multi-Drugs of Abuse Screen Urine Tests

Regulatory Class: Class II

Regulatory Information:

Drug of Abuse	Product Code	Panel	Regulation Section
Fentanyl (FYL)	DJG	Toxicology 91	21CFR 862.3650, Opiate test system.
Tramadol (TML)	DJG	Toxicology 91	21 CFR 862.3650, Opiate test system

These devices also incorporate the assays previously cleared under 510(k) numbers k153192 and k142396, which consist of any combinations of the following drug tests:

Drug of Abuse	Product Code	Panel	Regulation Section
Amphetamine	DKZ	Toxicology 91	21CFR 862.3100, Amphetamine Test System
Barbiturates	DIS	Toxicology 91	21 CFR 862.3150, Barbiturates Test System
Benzodiazepines	JXM	Toxicology 91	21 CFR 862.3170, Benzodiazepines Test System
Buprenorphine (BUP)	DJG	Toxicology 91	21CFR 862.3650, Opiate Test System
Cocaine	DIO	Toxicology 91	21 CFR 862.3250, Cocaine and metabolites Test System
Ecstasy (MDMA)	DJC	Toxicology 91	21 CFR 862.3610, Methamphetamine Test System
Marijuana	LDJ	Toxicology 91	21 CFR 862.3870, Cannabinoids Test System
Methamphetamine	LAF	Toxicology 91	21 CFR 862.3610, Methamphetamine Test System
Methadone	DJR	Toxicology 91	21 CFR 862.3620, Methadone Test System
Morphine	DNK	Toxicology 91	21 CFR 862.3640, Morphine Test System
Opiates	DJG	Toxicology 91	21 CFR 862.3650, Opiate Test System
Oxycodone	DJG	Toxicology 91	21 CFR 862.3650, Opiate Test System

Phencyclidine	LCM	Toxicology 91	Unclassified, Enzyme immunoassay Phencyclidine
Propoxyphene	JXN	Toxicology 91	21 CFR 862.3700 Propoxyphene test system
Tricyclic Antidepressants (TCA)	LFG	Toxicology 91	21 CFR 862.3910, Tricyclic antidepressant drugs test system.

C. PREDICATE DEVICES

k153192: Chemtrue® Multi-Panel Drug Screen Cup/Dip Card Tests

D. INDICATIONS FOR USE:

The Chemtrue® Drug Screen Fentanyl / Tramadol Dip Card Test is a rapid lateral flow immunoassay for the qualitative detection of Norfentanyl (FYL) 5 and Tramadol (TML) 100 drugs in human urine. It is an in vitro diagnostic device. The test cut-off concentrations and calibrators are listed below:

Analyte	Abbreviation	Calibrator	Cutoff Concentration (ng/mL)
Norfentanyl	FYL	Norfentanyl	5
Tramadol	TML	Tramadol	100

The Chemtrue® Drug Screen Fentanyl / Tramadol Dip Card Test detects and is calibrated against norfentanyl, the major metabolite of fentanyl in human urine. The test is available in Single and multi-panels.

The test provides 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 the drug test result, particularly when preliminary positive result is indicated.

The test is not intended to differentiate between drugs of abuse and prescription use of Fentanyl/ Tramadol. The test is for in vitro diagnostic use only.

The Chemtrue® Drug Screen Fentanyl / Tramadol Cup Test is a rapid lateral flow immunoassay for the qualitative detection of Norfentanyl (FYL) 5 and Tramadol (TML) 100 drugs in human urine. It is an in vitro diagnostic device. The test cut-off concentrations and calibrators are listed below:

Analyte	Abbreviation	Calibrator	Cutoff Concentration (ng/mL)
Norfentanyl	FYL	Norfentanyl	5
Tramadol	TML	Tramadol	100

The Chemtrue® Drug Screen Fentanyl / Tramadol Cup Test detects and is calibrated against norfentanyl, the major metabolite of fentanyl in human urine. The test is available in Single and multi-panels.

The test provides 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 the drug test result, particularly when preliminary positive result is indicated.

The test is not intended to differentiate between drugs of abuse and prescription use of Fentanyl/ Tramadol. The test is for in vitro diagnostic use only.

The Chemtrue® Multi-Panel Drug Screen Dip Card Test is a rapid lateral flow immunoassay for the qualitative detection of Amphetamine, Barbiturates, Benzodiazepines, Buprenorphine, Cocaine, Ecstasy, Norfentanyl, Marijuana, Methamphetamine, Methadone, Morphine, Opiates, Oxycodone, Phencyclidine, Propoxyphene, Tramadol and 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)
Amphetamine	AMP	d-Amphetamine	300
Amphetamine	AMP	d-Amphetamine	500
Amphetamine	AMP	d-Amphetamine	1,000
Barbiturates	BAR	Secobarbital/Pentobarbital	200
Barbiturates	BAR	Secobarbital/Pentobarbital	300
Benzodiazepines	BZO	Oxazepam	200
Benzodiazepines	BZO	Oxazepam	300
Buprenorphine	BUP	Buprenorphine	10
Cocaine	COC	Benzoylecgonine	150
Cocaine	COC	Benzoylecgonine	300
Ecstasy	MDMA	d,l-Methylenedioxy methamphetamin	500
Norfentanyl	FYL	Norfentanyl	5
Methamphetamine	MET	d-Methamphetamine	300
Methamphetamine	MET	d-Methamphetamine	500
Methamphetamine	MET	d-Methamphetamine	1,000
Marijuana	THC	11-nor-Δ9-THC-9-COOH	50
Methadone	MTD	Methadone	300
Morphine	MOR	Morphine	300
Opiates	OPI	Morphine	2,000
Oxycodone	OXY	Oxycodone	100
Phencyclidine	PCP	Phencyclidine	25
Propoxyphene	PPX	Propoxyphene	300
Tricyclic Antidepressants	TCA	Nortriptyline	1,000
Tramadol	TML	Tramadol	100

The multi test panels can consist of any drug analytes listed above in any combination. Only one cut-off concentration will be included per analyte per device.

The test provides 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, Propoxyphene and Tricyclic Antidepressants.

The Chemtrue® Multi-Panel Drug Screen Cup Test is a rapid lateral flow immunoassay for the qualitative detection of Amphetamine, Barbiturates, Benzodiazepines, Buprenorphine, Cocaine, Ecstasy, Norfentanyl, Marijuana, Methamphetamine, Methadone, Morphine, Opiates, Oxycodone,

Phencyclidine, Propoxyphene, Tramadol and 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)
Amphetamine	AMP	d-Amphetamine	300
Amphetamine	AMP	d-Amphetamine	500
Amphetamine	AMP	d-Amphetamine	1,000
Barbiturates	BAR	Secobarbital/Pentobarbital	200
Barbiturates	BAR	Secobarbital/Pentobarbital	300
Benzodiazepines	BZO	Oxazepam	200
Benzodiazepines	BZO	Oxazepam	300
Buprenorphine	BUP	Buprenorphine	10
Cocaine	COC	Benzoylecgonine	150
Cocaine	COC	Benzoylecgonine	300
Ecstasy	MDMA	d,l-Methylenedioxy methamphetamine	500
Norfentanyl	FYL	Norfentanyl	5
Methamphetamine	MET	d-Methamphetamine	300
Methamphetamine	MET	d-Methamphetamine	500
Methamphetamine	MET	d-Methamphetamine	1,000
Marijuana	THC	11-nor-Δ9-THC-9-COOH	50
Methadone	MTD	Methadone	300
Morphine	MOR	Morphine	300
Opiates	OPI	Morphine	2,000
Oxycodone	OXY	Oxycodone	100
Phencyclidine	PCP	Phencyclidine	25
Propoxyphene	PPX	Propoxyphene	300
Tricyclic Antidepressants	TCA	Nortriptyline	1,000
Tramadol	TML	Tramadol	100

The multi test panels can consist of any drug analytes listed above in any combination. Only one cut-off concentration will be included per analyte per device.

The test provides 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, Propoxyphene and Tricyclic Antidepressants.

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 Dip Card or Cup formats, as indicated by the test name.

F. SUBSTANTIAL EQUIVALENCE INFORMATION:

Comparison with the predicate devices is outlined below:

Item	Device	Predicate - k153192
Indication(s) for Use	Same	Qualitative determination of drugs of abuse in human urine.
Specimen Type	Same	Human urine
Type of Test	Same	Qualitative test of *in vitro* diagnostic device
Methodology /Technological Characteristics	Same	Lateral flow, antibody and antigen competitive binding qualitative immunoassay.
Configurations	Same	Cup and Dip Card
Storage	Same	2 - 30˚C

Item	Differences						
	Candidate Device	Predicate - k153192					
Calibrator /Cut Off	Norfentanyl 5 ng/mL Tramadol 100 ng/mL	AMP at 300/500/ 1000 ng/mL	BAR at 200/ 300 ng/mL	BZO at 200/ 300 ng/mL	BUP at 10 ng/mL	COC at 150/300 ng/mL	MDMA at 500 ng/mL	MET at 300/500/ 1000 ng/mL
		MTD at 300 ng/mL	MOR at 300 ng/mL	OPI at 2000 ng/mL	OXY at 100 ng/mL	PCP at 25 ng/mL	PPX at 300 ng/mL	TCA at 1000 ng/mL
		THC at 50 ng/mL						

G. TEST PRINCIPLE

These devices 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 that are used on the Fentanyl and Tramadol Test devices are derived from mouse.

H. PERFORMANCE CHARACTERISTICS

Performance data of AMP300/500, BAR200, BZO200, COC150, MET300/500 and PPX were presented in the cleared 510(k) k153192 submission. AMP1000, BAR3000, BZO300, BUP10, COC300, MET1000, MOR, PCP, THC, MDMA, MTD, OPI2000, OXY and TCA analytes were previously cleared under k143599 and k142396. In this submission, Fentanyl (FYL) and Tramadol (TML) study data are summarized and presented below:

1. Precision/ Reproducibility Studies:

Precision/reproducibility studies were carried out for Norfentanyl and Tramadol spiked urine controls with LC/MS confirmed concentrations of 0%, -50%, -25%, 100%, +25% and +50% of the drug cut-off. All the aliquots were blindly coded by the research coordinator who prepared the samples and didn't perform the testing. These blind coded samples were used for FYL5 and TML100 tests in Cup and Dip Card formats in a randomized order. Five (5) replicates at each control level were tested with three (3) lots each device format of FYL and TML Drug Screen Cup/Dip Card Tests by each of the three operators. Each operator tested the blind-labeled samples according to proposed package inserts, record the test results and sign on the data collection form. The study was performed in five (5) consecutive days. The data is analyzed and summarized in the tables below:

Table 1a. **FYL Dip Card Test:** Cutoff: 5 ng/mL

Lot No.	0	-50% Cut off	-25% Cut off	Cut Off	+25% Cut off	+50% Cut off
Lot 1	10- / 0+	10- / 0+	10- / 0+	8+ / 2-	10+ / 0-	10+ / 0-
Lot 2	10- / 0+	10- / 0+	10- / 0+	9+ / 1-	10+ / 0-	10+ / 0-
Lot 3	10- / 0+	10- / 0+	10- /0+	8+ / 2-	10+ / 0-	10+ / 0-
SUM	**30- / 0+**	**30- / 0+**	**30- / 0+**	**25+ / 5-**	**30+ / 0-**	**30+ / 0-**

Table 1b. **TML Dip Card Test:** Cutoff: 100 ng/mL

Lot No.	0	-50% Cut off	-25% Cut off	Cut Off	+25% Cut off	+50% Cut off
Lot 1	10- / 0+	10- / 0+	10- / 0+	9+ / 1-	10+ / 0-	10+ / 0-
Lot 2	10- / 0+	10- / 0+	10- / 0+	7+ / 3-	10+ / 0-	10+ / 0-
Lot 3	10- / 0+	10- / 0+	10- /0+	9+ / 1-	10+ / 0-	10+ / 0-
SUM	**30- / 0+**	**30- / 0+**	**30- / 0+**	**25 +/ 5-**	**30+ / 0-**	**30+ / 0-**

Table 1c. **FYL Cup Test:** Cutoff: 5 ng/mL

Lot No.	0	-50% Cut off	-25% Cut off	Cut Off	+25% Cut off	+50% Cut off
Lot 1	10- / 0+	10- / 0+	10- / 0+	9+ / 1-	10 + / 0-	10 + / 0-
Lot 2	10- / 0+	10- / 0+	10- / 0+	9 +/ 1-	10 + / 0-	10 + / 0-
Lot 3	10- / 0+	10- / 0+	10- /0+	8+ / 2-	10 + / 0-	10 + / 0-
SUM	**30- / 0+**	**30- / 0+**	**30- / 0+**	**26+ / 4-**	**30+ / 0-**	**30+ / 0-**

Table 1d. **TML Cup Test:** Cutoff: 100 ng/mL

Lot No.	0	-50% Cut off	-25% Cut off	Cut Off	+25% Cut off	+50% Cut off

Lot 1	10- / 0+	10- / 0+	10- / 0+	9+ / 1-	10+ / 0-	10+ / 0-
Lot 2	10- / 0+	10- / 0+	10- / 0+	7+ / 3-	10+ / 0-	10+ / 0-
Lot 3	10- / 0+	10- / 0+	10- /0+	8+ / 2-	10+ / 0-	10+ / 0-
SUM	**30- / 0+**	**30- / 0+**	**30- / 0+**	**24+ / 6-**	**30+ / 0-**	**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:

   Norfentanyl 5 related compounds:

Substances	**Concentration** ng/mL	**% Cross Reactivity**
Norfentanyl	5	100
Fentanyl	10	100
4-Fluoro-isobutyryl Fentanyl	>20,000	<1
9-HydroxyRisperidone	10,000	<1
Acetyl Fentanyl	200	2.5
Acetyl Norfentanyl	200	2.5
(±)-β-Hydroxythiofentanyl Hcl	20	25
Acryl Fentanyl	30	16.7
Alfentanil	1,000	<1
Butyryl Fentanyl	15	33.3
Carfentanil Oxalate	>10,000	<1
Cis-d, I 3-Methylfentanyl	70	7.1
Despropionylfentanyl (4-ANPP)	>20,000	<1
Furanyl Fentanyl	80	6.25
Isobutyryl Fentanyl	5,000	<1
Labetalol Hydrochloride	>100,000	<1
MT-45	7,500	<1
Norcarfentail Oxalate	>20,000	<1
Ocfentanil	1,000	<1
Para-fluoro butyrl Fentanyl (P-FBF)	20	25
para-Fluorofentanyl	10	50
Remifentanil	>20,000	<1
Risperidone	10,000	<1
Sufentanil	3,000	<1
Thienyl Fentnayl	40	12.5
Trans-d, I 3-Methylfentanyl	30	16.7
Trazodone	>100,000	<1
U-47700	>100,000	<1
Valeryl Fentanyl	>100,000	<1

Note: The cross-reactivity of ω-1-Hydroxyfentanyl was not tested in this product and may be a source of false positive results.

Tramadol 100 related compounds:

Substances	Concentration ng/mL	% Cross Reactivity
Tramadol	100	100
n-Desmethyl Tramadol	400	25
o-Desmethyl Tramadol	1,000	10
Venlafaxine	>100,000	<1
o-Desmethyl Venlafaxine	>10,000	<1

3. Interference:

Following potential interferents were tested with one lot each of the test device format. It was confirmed not to cross-react, when tested at concentrations of 100 µg/mL at ±25% of the drug cut-off concentrations:

Endogenous Compounds:

Albumin	Creatinine	r-Globulin	Octopamine
Acetone	Dopamine	Hemoglobin	Riboflavin
Ascorbic Acid	Ethanol	Human serum Albumin	Sodium Chloride
Atropine	Galactose	B-Hydroxybutyric Acid(F)	Uric Acid
Bilirubin	Glucose	Oxalic Acid	Urea
Cholesterol			

Structurally unrelated compounds:

Amlodipine besylate	I-Erythromycin	Norethindrone
7-Aminonitrazepam	Estradiol	Noscapine
Amoxicillin	Estrone	Octopamine
Ampicillin	Fenfluramine	Papaverine
Apomorphine	Fenofibrate	Penicillin-G
Aspirin	Fluphenazine(F)	Pentazocine
Aspartame	Fotemustine	Perphenazine
Baclofen	Furosemide	Phenelzine
Benzocaine6	Gemfibrozil	Phenylethylamine
Benzylpiperiazine	Guaiacolglyceryl ether	Phentermine
Benzoic Acid	Gentisic acid	Prednisone
4-Bromo-2,5,Dimethoxyphenethylamine	Hexobarbital	Promazine
Carisoprodol	Hydralazine	Promethazine
Clomipramine	Hydrocortisone	Propoxyphene
Cetirizine	3-Hydroxytyramine	Propranolol
Chloramphenicol	β-Hydroxybutyric Acid	Pyridoxine
Chlordiazepoxide	Ibuprofen	Pyrilamine
Chlorpheniramine	d,l-Isoproterenol	Pyrogallol
Chlorpromazine	Ketamine	Norpropoxyphene
Clofibrate	Lamotrigine	Quinidine
Clonidine	Lisinopril	Quinine
Cortisone	Loratidine	Quinolinic Acid
I-Cotinine	Maprotiline	Ranitidine
Creatine Hydrate	Meprobamate	Salicylic Acid
Cyclobenzaprine	Metoprolol	Sodium Azide
Cyclodextrin-r	Methapyrilene	Sulfamethazine
Cyproheptadine	Methylphenidate	Sulindac
Demoxepam	Nalidixic Acid	Tetracycline

Deoxycorticosterone	Naloxone	Tetrahydrozoline
Dextromethorphan	Naltrexone	Thiamine
Diclofenac	Naproxen	Thioridazine
Diflunisal	Niacinamide	Trifluoromethylphenyl-piperazine
Dimethyl-aminoantipyrine	N-desmethylapentadol	Trifluoperazine
Diphenhydramine	Nicotinic Acid	Tryptamine
Diphenylhydantoin	Nifedipine	Tyramine
		Zolpidem

The following compounds showed no interference at the concentrations below:

Compound	**Conc. (**ng/mL)	**Compound**	**Conc. (**ng/mL)
Acetylsalicylic Acid	500,000	Metformin	25,000
7-Aminoflunitrazepam	25,000	Norpseudoephedrine	25,000
Bupropion	25,000	Oxazepam Glucuronide	25,000
Caffeine	500,000	Sufentanil Citrate	25,000
Carbamazepine	25,000	11-nor-9 carboxy THC	50,000
Lorazepam Glucuronide	50,000	L-thyroxine	25,000
LSD	50,000	Zolpidem Tartrate	50,000

In addition, further testing with the following opioids compounds /drugs at a concentration of 100 ug/mL in ±25% of the cutoff drug urine controls confirm that no interference or cross-reactivity was observed with the Chemtrue® Drug Screen FYL/TML Tests.

6-Acetylmorphine	Hydromorphone	Norcodeine
Amphetamine	Levorphanol	Norketamine
Buprenorphine	Methadone	Normorphine
Codeine	Morphine	Noroxycodone
Dihydrocodeine	Morphine-3-glucuronide	Oxycodone
EDDP	Naloxone	Oxymorphone
Fluoxetine	norbuprenorphine	Pentazocine (Talwin)
Heroin	Morphine	Tramadol
Hydrocodone	Morphine-3-glucuronide	

The following opioids compounds /drugs do not interfere or cross-react at a concentration of 10 ug/mL in ±25% of the cutoff drug urine controls:

Meperidine	Normeperidine	Risperidone

Usability Interference Study: In addition to the cross-reactivity and interference studies presented above in this submission, the drug tests were tested with each of the drug analytes at 150% and 50% of the drug cut-off urine samples. The results confirmed that the no interference or cross-reactivity among these drug tests.

Table 3-3. Usability Interference Study Result Summary:

Targeted Drug Test/ Cutoff (ng/mL)	**Chemtrue® Drug Screen FYL/TML Test Results** with AMP/BAR/BZO/BUP/COC/ MDMA/MET/MOR300/MTD/OPI2000 (In separate device)/ OXY/PCP/ PPX/TCA/THC Test Strips	
	50% of the Targeted Drug Cutoff (**PAC**: All the results must be **-**)	**150% of the Targeted Drug Cutoff** (**PAC**: Only the targeted drug tests should be **+;** The other test strips must be **-**)

	# of "**+**" Results from the **targeted drug test strips**	# of "**-**" Results from the **targeted drug test strips**	Number of "**-**" results from **the other test strips**	# of "**+**" Results from the **targeted drug test strips**	# of "**-**" Results from **the other test strips**
FYL 5 Calibrator Norfentanyl 5	0	12	180	12	180
TML 100 calibrator Tramadol	0	12	180	12	180
AMP 300/500/1000 d-Amphetamine	0	36	270	36	270
BAR 300 Calibrator Pentobarbital	0	12	180	12	180
Calibrator Secobarbital	0	12	180	12	180
BAR200 3 clinical samples test data	N/A	0	0	12	180
BZO300: Calibrator Oxazepam	0	12	180	12	180
BZO200: 2 clinical samples test data	N/A	0	0	8	120
TCA 1000 Calibrator Nortripytline	0	12	180	12	180
4 clinical samples test data	N/A	0	0	16	240
COC150/300 Calibrator Benzoylecgonine	0	24	360	12	180
BUP 10 Calibrator Buprenophine	0	12	180	12	180
MDMA500 Calibrator d,l-Methylenedioxymethamphetamine	0	12	180	12	180
MTD 300 Calibrator Methadone	0	12	180	12	180
MOR300/**OPI**2000 Calibrator Morphine	0	12	180	12	180
PPX 300 Calibrator Propoxyphene	0	12	180	12	180
MET300/500/1000 d-Methamphetamine	0	36	270	36	270
OXY100 Calibrator Oxycodone	0	12	180	12	180
PCP 25 Calibrator Phencyclidine	0	12	180	12	180
THC50 Calibrator 11-nor-Δ^9-THC9-COOH	0	12	180	12	180
SUBTOTAL	**0**	**246**	**3,420**	**288**	**3,780**
TOTAL	**3,672**			**4,068**	

CONCLUSION: The usability interference study results demonstrate that no interference or cross reactivity among the 17 drug tests of the Chemtrue® Drug Screen Tests, when testing 50% of the drug cut off. No false positive result was presented. When testing with 150% of the drug cut off urine samples, only the targeted drug tests presented positive results, including the class-drug clinical samples, such as BAR, BZO and TCA that contain multiple drugs in the drug class. No false negative or false positive results were observed.

4. Effect of Urine pH and Specific Gravity Studies: The testing results demonstrate that the urine pH ranges from 2.0 to 9.0 at ±25% of the drug cut-off concentrations do not affect the test performance. The specific gravity (SG) ranges of 1.010, 1.015, 1.020, 1.025 and 1.030 at ±25% of the drug 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 60ºC, 50ºC and 40ºC), and real time (2ºC to 30ºC) with three (3) lots of each device format. The stability study results support two (2) years shelf life of the products at (2ºC to 30ºC). The real time stability study is still on going.

To validate robustness of the Chemtrue® Drug Screen FYL/TML Test devices, studies were conducted after the devices (Cup and Dip Card Tests) were exposed to various lighting, humidity and temperature conditions. The results support the robustness of the Chemtrue® Devices.

6. Method Comparison (Accuracy) Studies:

Chemtrue® Drug Screen FYL/TML Tests were compared to the LC/MS Reference Method. The accuracy of the Chemtrue® Test devices were evaluated against one hundred and seventy-six (176) clinical urine specimens. Each specimen was confirmed with LC/MS assay with the value assignment. Ninety-three (93) Fentanyl clinical urine specimens and eighty-three (83) Tramadol urine specimens in blind-code label were tested in this correlation study against the LC/MS reference method. Four (4) operators performed the tests. One drug analyst with one set of blind code in one device format - Dip Card / Cup were tested by one operator. Each blind-labeled sample was randomly distributed to each operator for each device format by the Clinical Research Cooperator. The results are summarized in the tables below:

Table 6a. Method comparison study summary: Chemtrue® Drug Screen Dip Card Test results *vs* LC/MS

Chemtrue® Drug Screen Dip Card		**Concentration By LC/MS** (ng/mL)					**% Agreement**
		(-)			**(+)**		
		No drug present	Negative		Near cutoff positive (Cutoff to 150% of the C/O)	LC/MS Positive (>150% of the cutoff)	
			< 50% of the C/O	50% of the C/O to cutoff			
FYL 5	**(+)**	0	1	3	6	26	100%
	(-)	22	29	6	0	0	93.4%
TML100	**(+)**	0	0	0	8	23	100%
	(-)	20	20	12	0	0	100%

Table 6b. Method comparison study summary - Chemtrue® Drug Screen Cup Test results *vs* LC/MS

Chemtrue® Drug Screen Cup		**Concentration By LC/MS** (ng/mL)					**% Agreement**
		(-)			**(+)**		
		No drug present	Negative		Near cutoff positive (Cutoff to 150% of the C/O)	Positive (>150% of the C/O)	
			< 50% of the C/O	50% of the C/O to cutoff			
FYL 5	**(+)**	0	1	2	6	26	100%
	(-)	22	29	7	0	0	95%
TML100	**(+)**	0	0	0	8	23	100%
	(-)	20	20	12	0	0	100%

DISCORDANT RESULTS:

Cutoff Value (ng/mL)	Analyte assay (POS/NEG)	Drug Analyte	LC/MS Value (ng/mL)
Norfentanyl **5** Cup Test	+	Norfentanyl	3.38
	+	Norfentanyl	2.03*
	+	Norfentanyl	4.94
Norfentanyl **5** Dip Card Test	+	Norfentanyl	3.38
	+	Norfentanyl	2.03*

	+	Norfentanyl	3.97
	+	Norfentanyl	4.94

Five (5) discordant results were at or near the norfentanyl drug cutoff level of 5 ng/mL. One sample (it was tested with one Cup and one Dip Card device to present two test data) with a norfentanyl concentration of 2.03 ng/mL and Fentanyl concentration of 15.43 ng/ml returned a positive result. Further analysis indicated that the cross-reactive level of Fentanyl is 10 ng/ml. So the positive result could have been caused by the high concentration of Fentanyl in the urine sample.

7. OTC Lay-user Accuracy Studies:

One hundred and forty (140) intended lay-users participated in the evaluation for each of the device format (Dip Card and Cup) for OTC accuracy and usability study from three (3) intended user sites (Shopping Mall, School and Hotel) with LC/MS confirmed urine samples. The sample concentrations are consisted of no drug present (0), 50%, 75%, 125% and 150% of the cutoff by spiking drugs into drug-free urine pool. Each sample was aliquot into an individual blind-labeled container. Each lay-user was provided with a package insert in English only and two (2) random blind-coded samples with one each of the device format. The results are summarized in tables below:

Table 7a. OTC Accuracy study summary between Chemtrue® Dip Card Tests and the LC/MS values

Chemtrue® Drug Screen Dip Card Test		**Concentrations By LC-MS/MS** (ng/mL)					**% Agreement**
		(-)			**(+)**		
		No Drug Present	Negative (50% of the C/O)	Near cutoff Negative (75% of the C/O)	Near cutoff Positive (125% of the C/O)	Positive (150% of the C/O)	
FYL 5	**(+)**	0	0	0	24	23	100%
	(-)	93	23	23	0	0	100%
TML 100	**(+)**	0	0	0	23	23	100%
	(-)	93	24	24	0	0	100%

Table 7b. OTC Accuracy study summary between Chemtrue® Cup Tests and the LC/MS values

Chemtrue® Drug Screen Cup Test		**Concentrations By LC/MS** (ng/mL)					**% Agreement**
		(-)			**(+)**		
		No Drug Present	Negative (50% of the C/O)	Near cutoff Negative (75% of the C/O)	Near cutoff Positive (125% of the C/O)	Positive (150% of the C/O)	
FYL 5	**(+)**	0	0	0	22	23	100%
	(-)	93	25	24	0	0	100%
TML 100	**(+)**	0	0	0	24	23	100%
	(-)	93	24	23	0	0	100%

The results demonstrate that the agreement between the Chemtrue® Drug Screen FYL/TML test devices and LC/MS assayed values is 100%.

These lay-users were also given surveys on the ease of understanding the package insert instructions. The results demonstrate that over 92% of the lay users can easily follow the instructions to perform the test and interpret the results. A Flesch-Kincaid reading analysis supports a 7th grade reading level.

I. CONCLUSION:

Based on the test principle and performance characteristics of the device, it is concluded that the Chemtrue® Drug Screen FYL/TML Test devices are substantially equivalent to the predicate.