510(k) Summary

NOV 29 2012

AS REQUIRED BY 21 CFR 807.92(c)

The Assigned 510(k) number is k123080

Date of Summary: September 28th, 2012

Common Name: Drugs of Abuse Screening Tests

Classification Name: Immunoassay for the detection of drugs of abuse

Trade/Proprietary Name:

Chemtron Biotech, Inc.'s Chemtrue® Single / Multi-Panel Drug Screen Dip Card / Cassette Tests, contain 1 to 6 of the following DOA test(s) in each device:

1. Benzodiazepines (BZO) test strip
2. Barbiturates (BAR) test strip
3. Ecstasy (MDMA/XTC) test strip
4. Methadone (MTD) test strip
5. Opiates /Morphine (OPI/MOR/MOP) cut-off: 2000ng/mL test strip
6. Oxycodone (OXY) test strip

Owner:

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Substantial Equivalency

The Chemtrue® Single/Multi-Panel Drug Screen Test is substantially equivalent to other tests currently on the market.

Predicate Device Name	Predicate Device 510(k)#
Chemtrue® Single/Multi-Panel Drug Screen Dip Card/Cassette Tests	K111322

Intended Use

The Chemtrue® test device is intended for the qualitative detection of drugs of abuse, for Over-the-Counter (OTC) and *in vitro* diagnostic use.

The assay provides only a preliminary analytical test result. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Gas Chromatography / Mass Spectrometry (GC/MS) or Liquid Chromatography / Mass Spectrometry (LC/MS) are the preferred confirmatory methods.

The BAR,BZO and OXY assay will yield preliminary positive results when BAR, BZO, and OXY is ingested at or above therapeutic doses. There are no uniformly recognized drug levels for Barbiturate, Benzodiazepine and Oxycodone in urine. The Chemtrue® Single/Multi-Panel Drug Screen Cassette and Dip Card Tests shows the drug was or was not present at the cutoff level. This assay provides only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method for most drugs (HPLC is the preferred confirmatory method for tri-cyclic antidepressants). Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are indicated.

Technological Characteristics and Science Principles

The Drugs of Abuse (DOA) Screen Panels are one-step lateral flow immunoassays in which chemically labeled drugs (drug-protein conjugates) compete for limited antibody binding sites with drugs that may be present in urine. The test device consists of up to six test strips placed in separate panels of a plastic holder. 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 drug antibody-colloidal gold conjugate pads are placed at one end of the membrane (opposite in morphine). In the absence of drugs in the urine, the solution of the colored antibody-colloidal gold conjugates move along with the sample solution upward chromatographically by capillary action across the membrane to the immobilized drug-protein conjugate zones 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 occurs when the test urine is negative for the drug. If any drug is present in the urine, the drug/metabolite antigen competes with the drug-protein conjugates on the test band region for the limited antibody on the colored drug antibody-colloidal gold conjugate pad. When a sufficient amount of drug is present in the urine, 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 control band with a different antigen/antibody reaction is added to the membrane strip at the control region (**C**) to indicate that the test has performed properly. This control line is manufactured as a built-in internal control of the test device and should always appear regardless of the presence of drug or metabolite. If the control line does not appear the test cassette should be discarded. The presence of this colored band in the control region also serves 1) as verification that adequate specimen volume is added (flooding, if too much urine is added, or no flow, due to insufficient urine volume), 2) the test device is properly functioning, and 3) as reagent control.

Comparison with Predicate

The Chemtron Biotech, Inc.'s Chemtrue® Single/Multi-panel Drug Screen Cassette and Dip Card tests are similar or the same as the previously cleared predicate(s) in the following ways: test principle, indication for use, used in a professional, point-of-care setting, OTC use, read time and sample matrix. The candidate device and the predicates are both visually-read single use devices. All of these products are based on the same technological characteristics, scientific principle and similar testing procedures. The similarities and differences between these tests are summarized as follows:

SIMILARITIES			
Item		**Chemtrue® Device**	**Predicate Kit**
Indications For Use		A rapid qualitative lateral flow immunoassay for the detection of potential abuse of one or more drugs	Same
Specimen		Urine	Same
Technological Characteristics and Principle		One-Step lateral flow competitive Immunoassay	Same
Device Design/ Performance	**Positive result**	1 colored line	Same
	Negative result	2 colored lines	Same
	Detection reagent	Colloidal gold	Same
	Accuracy Assessment	Confirm with GC/MS reference method	Same
Drug Analytes and Cut-off		Benzodiazepines 300 ng/mL Barbiturates 300 ng/mL Ecstasy (MDMA) 500 ng/mL Methadone 300 ng/mL Opiates 2000 ng/mL Oxycodone 100 ng/mL	Same Same Same Same Same Same
Safety and Precaution		All urine specimens should be considered potentially hazardous and handled in the same manner as infectious agent.	Same

Read time	5 minutes	Same
Storage	2 – 30 °C (36 – 86°F)	Same

DIFFERENCES		
Item	Chemtrue® **Device**	**Predicate Kit**
Intended use	For Over-the-Counter (OTC) Use	For Prescription Use Only

DISCUSSION AND CONCLUSION:

Based on the technological characteristics/principle, features of the device design, test specimen matrix, test method and performance characterizations, as the set forth above, it can be concluded that Chemtrue® Single/ Multi-panel Drug Screen tests are substantially equivalent to the predicate kit and the other like products that are manufactured by Alere and Alfa Scientific Design Inc. presently distributed commercially.

Performance Data:

Chemtron Biotech, Inc. has reviewed the requirements of Section 514 of the Act, which states that to date no performance standards has been established for drug screen test systems by the FDA.

However, the studies listed in the notification were conducted according to "Assessing the Safety and Effectiveness of Home-Use *in vitro* Diagnostic Devices (IVDs): Draft Points to Consider Regarding Labeling and Premarket Submissions (Text Only). Center for Devices and Radiological Health. October 1988", "The Draft Guidance for Industry and FDA Staff" - " Premarket Submission and Labeling Recommendations for Drugs of Abuse Screening Tests, issued on: December 2, 2003", including the design of draft labeling and package inserts.

Chemtrue® Single / Multi-panel Drug Screen Cassette and Dip Card tests are one-step, lateral flow, colloidal gold based chromatographic immunoassays for the rapid, qualitative detection of Benzodiazepines, Barbiturates, MDMA, Methadone, Opiates (Morphine) 2000 and Oxycodone in human urine. They are intended for Over-the-Counter (OTC) Use.

This assay provides only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method for most drugs (HPLC is the preferred confirmatory method for tri-cyclic antidepressants). Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are indicated.

Concise Summary of OTC Accuracy Study:

A panel format was evaluated in separate studies at these three (3) sites. A total of 200 OTC lay-users from these three separate (3) sites were selected and participated in the study. 100 OTC lay-users tested the Dip Card format and 100 lay-users tested the Cassette format. These lay-

users were between the ages of 21 to 79 with varying education levels. Male and female were in proportion. For details, refer to "Performance Characteristics" section, page 36 of this submission.

A. OTC accuracy study results are summarized in Table 1 and 2 below:

Table 1. OTC accuracy study result summary for the Chemtrue® Dip Card Test

Chemtrue® Drug Screen Dip Card Test		(-)			(+)			% Agreement with GC/MS values
		No drug present	GC/MS Negative (-50% to -25% cutoff)	Near cutoff negative (–25% cutoff to cutoff)	Near cutoff positive (cutoff to +25% cutoff)	GC/MS Positive (+25% to +50% cutoff)	GC/MS Positive (+50% to 200% cutoff)	
BAR	(+)	0	0	0	29	30	30	98.9%
	(-)	30	30	30	1	0	0	100%
BZO	(+)	0	0	0	30	30	30	100%
	(-)	30	30	30	0	0	0	100%
MDMA	(+)	0	0	1	30	30	30	100%
	(-)	30	30	29	0	0	0	98.9%
MTD	(+)	0	0	2	30	30	30	100%
	(-)	30	30	28	0	0	0	97.8%
OPI 2000	(+)	0	0	0	30	30	30	100%
	(-)	30	30	30	0	0	0	100%
OXY	(+)	0	0	2	30	30	30	100%
	(-)	30	30	28	0	0	0	97.8%

Table 2. OTC accuracy study result summary for the Chemtrue® Cassette Test

Chemtrue® Drug Screen Cassette Test		(-)			(+)			% Agreement with GC/MS values
		No drug present	GC/MS Negative (-50% to -25% cutoff)	Near cutoff negative (–25% cutoff to cutoff)	Near cutoff positive (cutoff to +25% cutoff)	GC/MS Positive (+25% to +50% cutoff)	GC/MS Positive (+50% to 200% cutoff)	
BAR	(+)	0	0	0	30	30	30	100%
	(-)	30	30	30	0	0	0	100%
BZO	(+)	0	0	0	30	30	30	100%
	(-)	30	30	30	0	0	0	100%
MDMA	(+)	0	0	0	30	30	30	100%
	(-)	30	30	30	0	0	0	100%
MTD	(+)	0	0	2	30	30	30	100%
	(-)	30	30	28	0	0	0	97.8%
OPI 2000	(+)	0	0	0	30	30	30	100%
	(-)	30	30	30	0	0	0	100%
OXY	(+)	0	0	1	30	30	30	100%
	(-)	30	30	29	0	0	0	98.9%

The OTC accuracy study results showed that lay-users can perform the testing and interpret the results correctly with greater than 97.8% accuracy. It also demonstrated the substantial equivalency between the Chemtrue® Single/ Multi-Panel Drug Screen tests and the GC/MS reference method with ≥97.8% agreement for both Dip Card and Cassette formats.

Discordant results: Total of nine (9) discordant results were observed and listed in tables below:

Table 3. Chemtrue® 6-Panel Drug Screen Dip Card Tests

Sample Code	Cutoff Value (ng/mL)	Analyte assay (POS/NEG)	Drug/Metabolite GC/MS value (ng/mL)	
			Drug/Metabolite	GC/MS Value (ng/mL)
Aa79	300	+	Methadone	218
Aa133	300	+	Methadone	218
Ae83	500	+	MDMA	403
Ab98	300	-	Pentobarbital	390
Ab80	100	+	Oxycodone	70
Ab146	100	+	Oxycodone	70

Table 4. Chemtrue® 6-Panel Drug Screen Cassette Tests

Sample Code	Cutoff Value (ng/mL)	Analyte assay (POS/NEG)	Drug/Metabolite GC/MS value (ng/mL)	
			Drug/Metabolite	GC/MS Value (ng/mL)
Ba67	300	+	Methadone	218
Ba73	300	+	Methadone	218
Bb176	100	+	Oxycodone	70

The concentrations of these nine (9) discordant results were at ±25% of the cutoff levels [eight (8) were at -25% of the cut-off and one (1) was at +25% of the cut-off] which were close to the cut off of the drug test.

B. The OTC accuracy study results within site and between the sites, in comparison to the GC/MS values: The study results for all six (6) drug tests for both Dip Card and Cassette formats from three (3) independent sites are summarized in Tables below:

Barbiturates 300:

		Site 1	Site 2	Site 3
Agreement	Within Site	100%	100%	99.2%
	Between Sites	99.7%		

Benzodiazepines 300:

		Site 1	Site 2	Site 3
Agreement	Within Site	100%	100%	100%
	Between Sites	100%		

MDMA 500:

		Site 1	Site 2	Site 3
Agreement	Within Site	100%	100%	99.2%
	Between Sites	99.7%		

Methadone 300:

		Site 1	Site 2	Site 3
Agreement	Within Site	100%	99.2%	97.7%
	Between Sites	99%		

Opiates 2000:

		Site 1	Site 2	Site 3
Agreement	Within Site	100%	100%	100%
	Between Sites	100%		

Oxycodone 100:

		Site 1	Site 2	Site 3
Agreement	Within Site	100%	98.3%	99.2%
	Between Sites	99.2%		

Conclusion: The results demonstrate that there is no significant difference of the testing results by the lay-users from the independent three (3) sites. An overall greater than 97.7% agreement was obtained within the site and between the sites. The results are comparable to the FDA cleared Instant-View Drug Screen Test device k063545 and the device performance is substantially equivalent to the predicate kit and other like products that are manufactured by Alere and Alfa Scientific Design Inc. and presently distributed commercially.

Package Insert Evaluations:

The package inserts were analyzed and received a 7th grade Flesh-Kincaid reading score and a Flesch Reading Ease score of 83. The evaluation was also conducted through a questionnaire survey of 200 lay-users with both Dip Card and Cassette formats. The results demonstrate that a minimum of 95% rating as "Easy/Very easy to understand" to follow the instruction, perform the test and interpret the results for both Chemtrue® Drug Screen Dip Card and Cassette formats. For details, refer to Section G-7, Package insert evaluation and analysis, page 40 and 41 of this submission. The raw data is enclosed in ATTACHMENT E of this submission.

Analytical sensitivity (Cut-off characteristics), precision (reproducibility), Accuracy (Method comparison study with clinical samples), specificity and stability study data were established in k111322.

510(k) Summary was prepared by: Jane Zhang on September 28th, 2012 and updated on November 26, 2012.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

November 29, 2012

Chemtron Biotech, Inc.
c/o Jane Zhang
8370 Juniper Creek Lane
Suite 1-2
San Diego, CA 92126

Re: k123080
Trade/Device Name: Chemtrue® Single/Multi-Panel Drug Screen Cassette and Dip Card Tests
Regulation Number: 21 CFR §862.3170
Regulation Name: Benzodiazepine Test System
Regulatory Class: Class II
Product Code: JXM, DIS, DJC, DJR, DNK, DJG
Dated: September 28, 2012
Received: October 25, 2012

Dear Ms. 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.

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

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); 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 regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostics and Radiological Health at (301) 796-5450. 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 Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Carol C. Benson
for

Courtney H. Lias, Ph.D
Director
Division of Chemistry and Toxicology Devices
Office of *In Vitro* Diagnostics and
Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): k123080

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

Indications for Use:

The Chemtron Biotech, Inc.'s Chemtrue® Single/Multi-Panel Drug Screen Cassette and Dip Card Tests are rapid lateral flow immunoassays for the qualitative detection of up to six of the following drugs in a variety of combinations in human urine. The designated cutoff concentrations of each drug and the calibrators used for these drugs are as follows:

Analyte	Abbreviation	Calibrator	Cutoff Concentration
Benzodiazepines	BZO	Oxazepam	300 ng/mL
Barbiturates	BAR	Secobarbital/Pentobarbital	300 ng/mL
Ecstasy	MDMA/XTC	d,l-Methylenedioxymethamphetamine	500 ng/mL
Methadone	MTD	Methadone	300 ng/mL
Opiates	OPI/MOR	Morphine	2000 ng/mL
Oxycodone	OXY	Oxycodone	100 ng/mL

The Chemtrue® Single/Multi-Panel Drug Screen Cassette and Dip Card Tests are intended for the qualitative detection of drugs of abuse for health care professionals, *in vitro* diagnostic and Over-The-Counter (OTC) use.

The BAR,BZO and OXY assay will yield preliminary positive results when BAR, BZO, and OXY is ingested at or above therapeutic doses. There are no uniformly recognized drug levels for Barbiturate, Benzodiazepine and Oxycodone in urine. The Chemtrue® Single/Multi-Panel Drug Screen Cassette and Dip Card Tests shows the drug was or was not present at the cutoff level. This assay provides only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method for most drugs (HPLC is the preferred confirmatory method for tri-cyclic antidepressants). Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are indicated.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use ___X___ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Division Sign-Off
Office of In Vitro Diagnostics and Radiological Health