510(k) Summary

MAY 17 2012

AS REQUIRED BY 21 CFR 807.92(c)

The Assigned 510(k) number is K121339

Date of Summary: May 02nd, 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. Amphetamine test strip
2. Cocaine test strip
3. Marijuana (THC) test strip
4. Methamphetamine test strip
5. Opiates (Morphine) cut-off: 300ng/ml test strip
6. Phencyclidine 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 Test	K102203

The predicate kit package insert is enclosed in ATTACHMENT A, page 41 of this submission.

Proposed Labeling or Promotional Material for the Device:

Description of the device can be found in the attached proposed labeling, including an explanation of how the device functions, technical principle and concepts that form the basis for the device, as well as the physical and performance characteristics of the device, such as device design, materials used and physical properties. In accordance with FDA labeling requirements 21 CFR 809.10, enclosed are the draft copies of product labeling including copies of the technical product inserts. See ATTACHMENT B and C, page 42 and 46 of this submission.

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.

Clinical consideration and professional judgment should be applied to any drugs 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 into 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 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
Cut-off		Amphetamine 1000 ng/ml Methamphetamine 1000 ng/ml Cocaine 300 ng/ml Marijuana (THC) 50 ng/ml Phencyclidine 25 ng/ml Opiates(Morphine) 300 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 designs, 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 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 Amphetamine, Methamphetamine, Marijuana (THC), Phencyclidine, Cocaine and Opiates (Morphine) 300 in human urine. It is intended for Over-the-Counter (OTC) Use.

This assay provides a preliminary test result. A more specific alternate chemical method must be used to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory result. Clinical and professional judgment must be applied to any drug of abuse test result, particularly when preliminary positive results are obtained.

The product performance characteristics of Chemtrue® Single/Multi-panel Drug Screen cassette and Dip Card were evaluated by 200 of OTC lay-users from three (3) sites with the confirmed GC/MS

values in a blind-labeled spiked urine correlation study. The results of these studies demonstrate Chemtrue® Single/ Multi-panel Drug Screen Test to be substantially equivalent to the performance characteristics of GC/MS methodology. Correlation studies produced a 98.9% total correlation when compared to the GC/MS methodology.

Chemtrue® Single /Multi-Panel Drug Screening Tests *vs* GC/MS Value Analysis

Samples with drug concentration above the cut-off level were considered presumptive positive and concentration below the cut-off were considered negative.

Table 1. Method comparison (OTC Accuracy) study result summary between the Chemtrue® Dip Card Test and the GC/MS values

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)	
AMP	(+)	0	0	1	30	30	30	100%
	(-)	30	30	29	0	0	0	98.9%
COC	(+)	0	0	0	30	30	30	100%
	(-)	30	30	30	0	0	0	100%
MET	(+)	0	0	0	30	30	30	100%
	(-)	30	30	30	0	0	0	100%
OPI300	(+)	0	0	0	30	30	30	100%
	(-)	30	30	30	0	0	0	100%
PCP	(+)	0	0	1	30	30	30	100%
	(-)	30	30	29	0	0	0	98.9%
THC	(+)	0	0	0	30	30	30	100%
	(-)	30	30	30	0	0	0	100%

Table 2. Method comparison (Accuracy) study result summary between the Chemtrue® Cassette Test and the GC/MS values

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)	
AMP	(+)	0	0	0	30	30	30	100%
	(-)	30	30	30	0	0	0	100%
COC	(+)	0	0	0	30	30	30	100%
	(-)	30	30	30	0	0	0	100%
MET	(+)	0	0	0	30	30	30	100%

	(-)	30	30	30	0	0	0	100%
OPI300	(+)	0	0	1	30	30	30	100%
	(-)	30	30	29	0	0	0	98.9%
PCP	(+)	0	0	1	30	30	30	100%
	(-)	30	30	29	0	0	0	98.9%
THC	(+)	0	0	0	30	30	30	100%
	(-)	30	30	30	0	0	0	100%

CONCLUSION:

Compared to the GC/MS values of the spiked urine samples that were tested by 200 OTC Lay-users from separate three (3) sites, the OTC accuracy study results demonstrate that the intended lay-users can perform the testing and interpret the results correctly with equal to and greater than 98.9% agreement with the GC/MS assayed values. The results also showed the substantial equivalency between the Chemtrue® Single/ Multi-Panel Drug Screen tests of both Dip Card and Cassette formats and the GC/MS reference method. Based on the study results, it can conclude that Chemtrue® Single/ Multi-panel Drug Screen cassette and Dip card is safe and effective in detecting Amphetamine, Cocaine, Methamphetamine, Marijuana, Opiates (Morphine) 300 and Phencyclidine in human urine.

Other performance data, such as analytical sensitivity (Cutoff characteristics), precision (Reproducibility), specificity (Cross-reactivity and interference) and stability studies were established in k102203.

510(k) Summary was prepared By: Jane Zhang on May 02nd, 2012

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

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MAY 17 2012

Re: k121339
Trade/Device Name: Chemtrue Single/Multi-Panel Drug Screen Cassette and Dip Card Tests
Regulation Number: 21 CFR 862.3100
Regulation Name: Amphetamine test system
Regulatory Class: Class II
Product Code: DKZ, DIO, DJC, DNK, LCM and LDJ
Dated: May 02, 2012
Received: May 03, 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 such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. 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) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm

Sincerely yours,

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

Enclosure

Indications for Use

510(k) Number (if known): K121339

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 designed cutoff concentrations and the calibrators used for these drugs are as follows:

Analyte	Abbreviation	Calibrator	Cutoff Concentration
Amphetamine	AMP	d-Amphetamine	1000 ng/mL
Cocaine	COC	Benzoylecgonine	300 ng/mL
Marijuana	THC	11-nor-Δ^9-THC9-COOH	50 ng/mL
Methamphetamine	MET	d-Methamphetamine	1000 ng/mL
Opiates	OPI/MOR	Morphine	300 ng/mL
Phencyclidine	PCP	Phencyclidine	25 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 professional, *in vitro* diagnostic and Over-the-Counter (OTC) use. These assays 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.

Prescription Use _____
(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 Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) 121339