MAY 3 0 2013

Final

510(k) Summary

(k123844)

Chemtrue® Human Chorionic Gonadotropin (hCG) Pregnancy Test

With the following configurations:

1. Chemtrue® hCG Pregnancy Urine Dipstick Test
2. Chemtrue® hCG Pregnancy Urine Cassette Test
3. Chemtrue® hCG Combo (Serum/Urine) Cassette Test

Prepared By:
Jane Zhang, Director of QA/RA
Sponsor: Chemtron Biotech, Inc.
8370 Juniper Creek Lane, Suite 1-2
San Diego, CA 92126
Office phone: (858) 530-2868
Mobile phone: (858) 997-7472
Fax (858) 530-2878

Date: May 30, 2013

510(k) Summary

AS REQUIRED BY 21 CFR 807.92(c)

The Assigned 510(k) number is k123844

Date of Summary: May 30, 2013

Purpose for Submission: New Device

Measurand: Human Chorionic gonadotropin (hCG) in human urine / serum

Type of Test: Qualitative

Applicant: Chemtron Biotech, Inc.

Trade/Proprietary Name:
Chemtrue® hCG Pregnancy Urine Dipstick Test
Chemtrue® hCG Pregnancy Urine Cassette Test
Chemtrue® hCG Combo (Serum/Urine) Cassette Test

Regulatory Information:

1. Regulation section: 21CFR §862.1155, human chorionic gonadotropin (hCG) test system.
2. Identification: An hCG test system is intended for the early detection of pregnancy. It is intended to measure hCG, a placental hormone, in urine or serum.
3. Classification: II
4. Product code: JHI

Panel: Clinical Chemistry (75)

Proposed Labeling or Promotional Material for the Device:

A 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 the 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.

Intended Use

See indications for use below. The Chemtrue® hCG urine or Combo test is a rapid lateral flow immunoassay for the visual qualitative detection of human chorionic gonadotropin (hCG) in human urine or serum as an aid in the early determination of pregnancy. The Dipstick/Cassette and Combo Tests are for prescription use only, including at physician's offices or other Point-Of-Care sites (POC).

Indication(s) for Use:

Chemtrue® hCG Pregnancy Urine Dipstick Test

The Chemtrue® hCG Pregnancy Urine Dipstick Test is a rapid lateral flow qualitative immunoassay for early detection of human chorionic gonadotropin (hCG) in human urine in the device format of Dipstick. The test is designed to aid early detection of pregnancy. The device is intended for Prescription Use Only.

The test kits are intended for prescription use including at physician's offices or other Point-Of-Care sites (POC).

Chemtrue® hCG Pregnancy Urine Cassette Test

The Chemtrue® hCG Pregnancy Urine Cassette Test is a rapid lateral flow qualitative immunoassays for early detection of human chorionic gonadotropin (hCG) in human urine in the device format of Cassette format. The test is designed to aid early detection of pregnancy. The device is intended for Prescription Use Only.

The test kits are intended for prescription use including at physician's offices or other Point-Of-Care sites (POC).

Chemtrue® hCG Combo (Serum/Urine) Cassette Test

The Chemtrue® hCG Combo (Serum/Urine) Cassette Test is rapid lateral flow qualitative immunoassays for early detection of human chorionic gonadotropin (hCG) in human urine or serum in Cassette format only. The test is designed to aid early detection of pregnancy. The devices are intended for Prescription Use Only.

The test kits are for prescription use including professionals at physician's office laboratories (POLs) or Point-Of-Care site (POC).

Special conditions for use statement(s):
The devices are for prescription use.

Special instrument requirements: None

Device Description:

The Chemtrue® hCG urine test is designed in Dipstick and Cassette formats. The hCG Combo (Serum/Urine) test is available in Cassette format only. Each test device consists of one (1) individual test strip and each test strip in the device consists of:

1) A conjugate pad contains colloidal gold conjugated with monoclonal anti-hCG antibody specific to the beta subunit of hCG.
2) A nitrocellulose membrane which is striped with the specific goat anti-hCG in the test line (T line) and goat anti-mouse antibody in the control line (C line). The C line serves as an internal quality control of the system and appears as a colored band during the test regardless of the hCG level in the test sample.

All the configurations have the same membrane format, reagents and gold conjugate pad, as well as the same flow characteristics, except the test line in the nitrocellulose membrane for hCG Combo test is striped with polyclonal goat anti-hCG antibodies.

Devices are packaged one device per foil pouch and 25 devices in each kit.

Human source materials was tested by FDA approved methods and found to be negative for the presence of antibodies to HIV-1, HIV-2, HbsAg and HCV.

Substantial Equivalence Information:

The Chemtrue® hCG Pregnancy Urine Dipstick/Cassette Test and hCG Combo Test are substantially equivalent to other tests currently on the market.

1. Predicate device name(s) and 510(k) number(s):

Predicate Device Name	510(k) k number
Genzyme Diagnostics OSOM® Card hCG Urine Test	K990578
Teco Diagnostics One-Step Urine/Serum Combo Pregnancy Card Test	K964461

2. Comparison with predicate:

The Chemtrue® hCG Pregnancy test device is similar to the predicate(s) with regard to the technology principle, indication for use, detection limit and sample matrix, etc. The candidate device and the predicates are both visually-read single use devices. The similarities and differences among these tests are summarized as follows:

2-a. hCG urine Tests:

Item	SIMILARITIES	
	Proposed Device Chemtrue® hCG Pregnancy Urine Tests	**Predicate Device** OSOM® Card hCG Urine Test k990578
Intended Use	A rapid qualitative immunoassay for rapid determination of	Same

	human chorionic gonadotropin (hCG) to aid in the early detection of pregnancy	
Technology principle	Lateral-flow immunoassay	Same
Indication of Use	For prescription use, including professionals at physician's office labs (POLs)	Same
Specimen matrix	Human urine	Same
Results	Qualitative	Same
Result Interpretation	Visually-read line intensity	Same
Sensitivity/Cutoff characteristics	20 mIU/mL	Same
Quality Control	Built-in Internal Control	Same

Item	**DIFFERENCES**	
	Proposed Device Chemtrue® hCG Pregnancy Urine Test	**Predicate Device** OSOM® Card hCG Urine Test k990578
Read time	Read the results at 5 minutes.	Read the results at 3 minutes.
Device format	Dipstick and Cassette	Cassette only
Storage	4°C – 30°C	15°C -30°C

2-b. hCG Combo Test:

Item	**SIMILARITIES**	
	Proposed Device Chemtrue® hCG Combo (Urine/Serum) Cassette Test	**Predicate Device** Teco Diagnostics One-Step Urine/Serum Combo Pregnancy Card Test K964461
Intended Use	A rapid qualitative immunoassay for rapid determination of human chorionic gonadotropin (hCG) to aid in the early detection of pregnancy	Same
Technology principle	Lateral-flow immunoassay	Same
Indication of Use	For prescription use, including professionals at physician's office labs (POLs)	Same
Specimen matrix	Human urine or serum	Same
Results	Qualitative	Same
Result Interpretation	Visually-read line intensity	Same
Read time	Read the results at 5 minutes	Same
Sensitivity/Cutoff characteristics	25 mIU/mL	Same
Quality Control	Built-in Internal Control	Same

Items	**DIFFERENCES**	
	Proposed Device	**Predicate Device**

	Chemtrue® hCG Combo (Urine/Serum) Test	Teco Diagnostics One-Step Urine/Serum Combo Pregnancy Card Test K964461
Storage	4°C – 30°C	18°C -30°C or refrigerated (2-8°C)

Standard/Guidance Document Referenced (if applicable):

- FDA guidance: Review Criteria for Assessment of Professional Use Human Chorionic Gonadotropin (hCG) In Vitro Diagnostic Devices – Document Issued on: November 6, 1996.
- National Committee for Clinical Laboratory Standards. Evaluation of precision performance of clinical chemistry devices; tentative guideline – Second Edition. NCCLS Document EP5-T2. Wayne, PA: NCCLS, 1992.
- CLSI EP7-A2; Interference Testing in Clinical Chemistry
- ISO 14971:2007, Medical Devices-Application of Risk Management to Medical Devices

Test Principle:

The device employs lateral flow immunoassay technology for detection of human chorionic gonadotropin (hCG) in urine and or serum. Monoclonal (Polyclonal for hCG Combo) goat anti-hCG antibodies are pre-striped in the nitrocellulose membrane on the test region (T line) and goat anti-mouse antibodies on the control region (C line). During testing, the urine/serum specimen reacts with the conjugate pad (It contains colloidal gold particles conjugated with monoclonal anti-hCG antibody specific to the beta subunit of hCG) located just beneath the sample pad and above the membrane of the test strip. The specimen migrates upward on the membrane by capillary action to react with the antibodies on the membrane. If the hCG concentration in the specimen is at or above the designated detection limit, a red colored line at the test region will be present indicating a positive result, while its absence indicates a negative result. The control line (C line) serves as an internal quality control. The control line should always appear, regardless of the hCG concentration of the test specimen, and the C line is an indicator that sufficient sample volume has been added to the test device and the sample has correctly migrated up the test strip.

Performance Characteristics

Chemtron Biotech, Inc. has reviewed the FDA guidance documents "Review Criteria for Assessment of Professional Use Human Chorionic Gonadotropin (hCG) In Vitro Diagnostic Devices (IVDs) – Document Issued on: November 6, 1996" and CFR809.10 labeling regulations and conducted the studies listed in the notification were conducted, including the design of draft labeling and package inserts.

1. **Sensitivity (Cutoff Characteristics):** Three (3) lots of each device formats were used for the study with spiked hCG urine pool from non-pregnant donors. The hCG was traceable to WHO 5th IS (07/364) at the concentrations of 0, 10,15,20,40 and 80 mIU/mL. The hCG concentrations were quantitatively confirmed by Abbott i2000 instrument. The controls were blind coded. Separate sets of the blind codes were assigned for each device format, Dipstick, Cassette and hCG Combo Test. Five (5) replicates

were tested at each hCG control level by three (3) operators at 5 minutes as the read time, per package insert request. The results are summarized in tables below:

Table 1-a. Results of Chemtrue® hCG Dipstick Pregnancy Test:

hCG Conc. (mIU/mL)	# of Samples Tested	Lot 1		Lot 2		Lot 3		# of Positives
		+	-	+	-	+	-	
0	15	0	5	0	5	0	5	**0/15**
10 (-50% Cutoff)	15	0	5	0	5	0	5	**0/15**
15 (-25% Cutoff)	15	1	4	1	4	1	4	**3/15**
20 (Cutoff)	15	5	0	5	0	5	0	**15/15**
40 (+200% Cutoff)	15	5	0	5	0	5	0	**15/15**
80 (+400% Cutoff)	15	5	0	5	0	5	0	**15/15**

Table 1-b. Results of Chemtrue® hCG Cassette Pregnancy Test:

hCG Conc. (mIU/mL)	# of Samples Tested	Lot 1		Lot 2		Lot 3		# of Positives
		+	-	+	-	+	-	
0	15	0	5	0	5	0	5	**0/15**
10 (-50% Cutoff)	15	0	5	0	5	0	5	**0/15**
15 (-25% Cutoff)	15	1	4	1	4	1	4	**3/15**
20 (Cutoff)	15	5	0	5	0	5	0	**15/15**
40 (+200% Cutoff)	15	5	0	5	0	5	0	**15/15**
80 (+400% Cutoff)	15	5	0	5	0	5	0	**15/15**

Chemtrue® hCG Combo Test: Three (3) lots of test devices were used for the study. The controls were prepared using spiked hCG in twenty (20) non-pregnant human serum and urine pools, respectively. The hCG controls were traceable to WHO 5th IS (07/364). The following six (6) hCG concentrations were used for the study:

hCG Concentration (mIU/mL) in Serum	hCG Concentration (mIU/mL) in Urine
0	0
10	10
20	20
25	25
50	50
100	100

Results:

Table 2-a. Chemtrue® hCG Combo (Urine) Test:

hCG Conc. (mIU/mL)	# of Samples Tested	Lot 1		Lot 2		Lot 3		# of Positives
		+	-	+	-	+	-	
0	15	0	5	0	5	0	5	**0/15**
10 (-60% Cutoff)	15	0	5	0	5	0	5	**0/15**
20 (-20% Cutoff)	15	1	4	1	4	1	4	**3/15**
25 (Cutoff)	15	5	0	5	0	5	0	**15/15**
50 (+200% Cutoff)	15	5	0	5	0	5	0	**15/15**
100 (+400% Cutoff)	15	5	0	5	0	5	0	**15/15**

Table 2-b. Chemtrue® hCG Combo (Serum) Test:

hCG Conc. (mIU/mL)	# of Samples Tested	Lot 1		Lot 2		Lot 3		# of Positives
		+	-	+	-	+	-	
0	15	0	5	0	5	0	5	**0/15**
10 (-60% Cutoff)	15	0	5	0	5	0	5	**0/15**
20 (-20% Cutoff)	15	1	4	1	4	1	4	**3/15**
25 (Cutoff)	15	5	0	5	0	5	0	**15/15**
50 (+200% Cutoff)	15	5	0	5	0	5	0	**15/15**
100 (+400% Cutoff)	15	5	0	5	0	5	0	**15/15**

CONCLUSION: The results confirmed the claimed cutoff (sensitivity/detection limit) levels for the Chemtrue® hCG Tests in Dipstick/Cassette configurations, as well as the hCG Combo Test. Also the results demonstrated that the functional performance is consistent between lot-to-lot of all the device formats/ configurations.

Linearity/assay reportable range: Linearity is not applicable since this is a qualitative test.

Traceability, Stability, Expected values (controls, calibrators, or methods): Chemtrue® hCG Pregnancy Tests are calibrated against reference material traceable to WHO International Standard 5th edition.

A shelf-life stability test of the devices was performed in real-time and accelerated testing. The results showed that the devices were stable for 24 months when stored at 25°C±2°C in the sealed foil pouch. Protocol and acceptance criteria were reviewed and are acceptable.

The sensitivity was evaluated in conjunction with the Cut-off characteristics and precision testing. Refer to the precision data in section 2 below. The detection limit was demonstrated to be 20 mIU/mL for urine test and 25 mIU/mL for hCG Combo test.

2. Reproducibility (Precision) Study:

The study was conducted in three (3) POL sites by a total of nine (9) operators and three (3) operators for each site with three (3) lots of each proposed device formats over three (3) non-consecutive days. The blind coded controls were used with hCG spiked at the concentrations of 0, 10, 15, 20, 25, 30 and 35 mIU/mL in urine; 0, 15, 20, 25, 30 and 35 mIU/mL in serum (Used for hCG Combo Test). The controls were calibrated against WHO 5th IS (07/364) and the values were confirmed with a FDA cleared Abbott chemiluminescent quantitative immunoassay, i2000 (Abbott Park, Illinois, 60064-3500, U.S.A). Every device was tested and interpreted by the same operator at 5 minutes as the read time, per package insert request. The reproducibility between the sites is summarized in tables below:

Table 3: hCG Dipstick Test (Cut-off 20 mIU/mL)

		Sites						TOTAL	
		1		2		3			
hCG concentration (mIU/mL)	Spec.	+	-	+	-	+	-	+	-
	0	0	9	0	9	0	9	0	27
	10 (-50%cutoff)	0	9	0	9	0	9	0	27
	15 (-25%cutoff)	1	8	1	8	1	8	3	24

	20 (Cut-off)	9	0	9	0	9	0	27	0
	25 (+25%cutoff)	9	0	9	0	9	0	27	0
	30 (+50%cutoff)	9	0	9	0	9	0	27	0
	35 (+75%cutoff)	9	0	9	0	9	0	27	0

Table 4. hCG Cassette Test (Cut-off 20 mIU/mL)

		Sites						**TOTAL**	
		1		**2**		**3**			
	Spec.	**+**	**-**	**+**	**-**	**+**	**-**	**+**	**-**
hCG concentration (mIU/mL)	**0**	0	9	0	9	0	9	0	27
	10 (-50%cutoff)	0	9	0	9	0	9	0	27
	15 (-25%cutoff)	0	9	1	8	1	8	2	25
	20 (Cut-off)	9	0	9	0	9	0	27	0
	25 (+25%cutoff)	9	0	9	0	9	0	27	0
	30 (+50%cutoff)	9	0	9	0	9	0	27	0
	35 (+75%cutoff)	9	0	9	0	9	0	27	0

Table 5. hCG Combo Urine Test (Cut-off 25 mIU/mL)

		Sites						**TOTAL**	
		1		**2**		**3**			
	Spec.	**+**	**-**	**+**	**-**	**+**	**-**	**+**	**-**
hCG concentration (mIU/mL)	**0**	0	9	0	9	0	9	0	27
	15 (-40% cutoff)	0	9	0	9	0	9	0	27
	20 (-20% cutoff)	1	8	2	7	2	7	5	22
	25 (Cut-off)	9	0	9	0	9	0	27	0
	30 (+20% cutoff)	9	0	9	0	9	0	27	0
	35 (+40% cutoff)	9	0	9	0	9	0	27	0

Table 6. hCG Combo Serum Test (Cut-off 25 mIU/mL)

		Sites						**TOTAL**	
		1		**2**		**3**			
	Spec.	**+**	**-**	**+**	**-**	**+**	**-**	**+**	**-**
hCG concentration (mIU/mL)	**0**	0	9	0	9	0	9	0	27
	15 (-40% cutoff)	0	9	0	9	0	9	0	27
	20 (-20% cutoff)	2	7	1	8	2	7	5	22
	25 (Cut-off)	9	0	9	0	9	0	27	0
	30 (+20% cutoff)	9	0	9	0	9	0	27	0
	35 (+40% cutoff)	9	0	9	0	9	0	27	0

Table 7. Comparison among two device formats for Chemtrue® hCG urine Tests

		Configurations				TOTAL	
		Cassette		Dipstick			
	Spec.	+	-	+	-	+	-
hCG concentration (mIU/mL)	**0**	0	27	0	27	0	54
	10 (-50%cutoff)	0	27	0	27	0	54
	15 (-25%cutoff)	2	25	3	24	5	49
	20 (Cut-off)	27	0	27	0	54	0
	25 (+25% cutoff)	27	0	27	0	54	0
	30 (+50% cutoff)	27	0	27	0	54	0
	35 (+75% cutoff)	27	0	27	0	54	0

CONCLUSION: The results demonstrate a consistent functional performance of the Chemtrue® hCG Tests between the sites and device formats/configurations.

Reproducibility study data among the operators: The results demonstrate that the performance of each Chemtrue® hCG Test format was similar between nine (9) operators across all three (3) study sites.

3. Method Comparison Study Data Summary: Chemtrue® hCG Pregnancy Tests were compared with the Predicate kits. A total of 300 clinical urine samples were blind coded and tested with each device format by nine (9) operators from three (3) POL sites (three operators in each site) in Shanghai China. One hundred-fifty (150) hCG negative urine samples (collected from women of childbearing age, including peri-menopausal) and 150 hCG positive samples that represented women who were suspected to be pregnant within the first 30 days of pregnancy/the first trimester of pregnancy in the early pregnancy and late pregnancy. 50 hCG negative serum samples and 50 hCG positive serum samples that are representative for the populations of the intended use were used for the study. The hCG positive serum samples were quantitatively confirmed by Abbott i2000 instrument. Each specimen was evenly split into three aliquots. Each site tested 100 samples with a unique set of blind codes for each device format/configuration. The results are summarized in tables below:

Table 8. Chemtrue® hCG Pregnancy Urine Dipstick Test (Cutoff: 20 mIU/mL)

		Predicate Device OSOM® Card hCG Urine Test (k990578)		Total Agreement %
		Positive	Negative	
Chemtrue® hCG Dipstick Test N=300	**Positive**	150	0	**100%**
	Negative	0	150	
	Total	150	150	

Sensitivity = *(150 / (60+90))* x100 = 100%; Specificity = *(150 / (150+0))* x 100 = 100%

Table 9. Chemtrue® hCG Pregnancy Urine Cassette Test (Cutoff: 20 mIU/mL)

Predicate Device OSOM® Card hCG Urine Test (k990578)		Total Agreement %
Positive	Negative	

Chemtrue® hCG Cassette Test N=300	**Positive**	149	0	**99.7%**
	Negative	1	150	
	Total	150	150	

Sensitivity = *(149 / (59+90+0))* x100 = 100%; Specificity = (150 / (150+1)) x 100 = 99.3%

One discrepant result in this table was from a single sample with a hCG concentration near the cut-off of the device (20 mIU/mL).

Table 10. Chemtrue® hCG Combo Pregnancy Serum Test (Cutoff: 25 mIU/mL)

		Predicate Device One-Step Urine/Serum Combo Pregnancy Card Test (k964461)		**Total Agreement**
		Positive	**Negative**	
Chemtrue® hCG Combo Serum Test N=300	**Positive**	150	0	**100%**
	Negative	0	150	
	Total	150	150	

Sensitivity = *(150 / (12+138))* x100 = 100%; Specificity = (150 / (150+0)) x 100 = 100%

Table 11. Chemtrue® hCG Combo Pregnancy Urine Test (Cutoff: 25 mIU/mL)

		Predicate Device One-Step Urine/Serum Combo Pregnancy Card Test (k964461)		**Total Agreement**
		Positive	**Negative**	
Chemtrue® hCG Combo Urine Test N=300	**Positive**	150	0	**100%**
	Negative	0	150	
	Total	150	150	

Sensitivity = *(150 / (60+90))* x100 = 100%; Specificity = (150 / (150+0)) x 100 = 100%

Discussion and Conclusion: Based on the technological 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® hCG Pregnancy tests are substantially equivalent to the predicate kits which are currently distributed commercially.

Table 12. Accuracy assessment within site and between sites:

		Site 1	**Site 2**	**Site 3**
Agreement	Within Site	100%	99.5%	100%
	Between Sites	**99.8%**		

Conclusion: The results demonstrate an overall 99.8% agreement within the site and between the sites. The device performance is substantially equivalent to the predicate kit OSOM® Card Pregnancy Test and other products that are presently distributed commercially.

4. Clinical studies:

a. Clinical Sensitivity: Not applicable
b. Clinical specificity: Not applicable

5. Clinical cut-off: Not applicable

6. Expected values/Reference range: Not applicable

7. Analytical specificity: The cross-reactivity study was conducted with three (3) lots of each test format/configuration with spiked concentration of the structurally related or potential interfering substances in urine and serum hCG negative and 50 mIU/mL controls. The results demonstrate that the Chemtrue® hCG Tests do not cross react with hLH up to 300 mIU/mL, hFSH up to 1000 mIU/mL and hTSH up to 1000 mIU/mL. The following compounds do not interfere with Chemtrue® hCG Tests at the concentrations tested:

Table 13.

Substance	Concentration
Acetylsalicylate Acid	20 mg/dL
Albumin (Human)	2000 mg/dL
Ascorbic Acid	20 mg/dL
Atropine	20 mg/dL
Bilirubin	2 mg/dL
Caffeine	20 mg/dL
Cannabinol	10 mg/dL
Ephedrine	20 mg/dL
Gentisic Acid	20 mg/dL
Glucose	2000 mg/dL
Hemoglobin	250 mg/dL
Ibuprofen	40 mg/dL
Methadone	10 mg/dL
Morphine	6 µg/dL
Phenylpropanolamine	20 mg/dL
Salicylic acid	20 mg/dL
Uric Acid	20 mg/dL

The detailed data is summarized in Section "Performance Characteristics, Specificity", page 56 of 510(k) Submission.

An interference study with hCGßcf was also performed with three (3) lots each format at the concentrations 125,000, 250,000, 500,000 and 1,000,000 pmol/mL of hCGßcf that were added into 5 and 50 mIU/mL hCG urine and serum controls. The results are summarized in Table 14 below:

Table 14-a. Interference study results with hCGßcf – Urine Dipstick Test

	# of Positive Results with Concentrations of hCG βcf											
	125,000 pmol/mL			**250,000** pmol/mL			**500,000** pmol/mL			**1,000,000** pmol/mL		
hCG Conc. in urine	Lot #1	Lot #2	Lot #3	Lot #1	Lot #2	Lot #3	Lot #1	Lot #2	Lot #3	Lot #1	Lot #2	Lot #3
5 mIU/mL	0/10	0/10	0/10	0/10	0/10	0/10	0/10	0/10	0/10	0/10	0/10	0/10
50 mIU/mL	10/10	10/10	10/10	10/10	10/10	10/10	10/10	10/10	10/10	10/10	10/10	10/10

Table 14-b. Interference study results with hCGßcf – Urine Cassette Test

	# of Positive Results with Concentrations of hCG βcf											
	125,000 pmol/mL			**250,000** pmol/mL			**500,000** pmol/mL			**1,000,000** pmol/mL		
hCG Conc. in urine	Lot #1	Lot #2	Lot #3	Lot #1	Lot #2	Lot #3	Lot #1	Lot #2	Lot #3	Lot #1	Lot #2	Lot #3
5 mIU/mL	0/10	0/10	0/10	0/10	0/10	0/10	0/10	0/10	0/10	0/10	0/10	0/10
50 mIU/mL	10/10	10/10	10/10	10/10	10/10	10/10	10/10	10/10	10/10	10/10	10/10	10/10

Table 15-a. Interference study results with hCGßcf – hCG Combo Urine Test

	# of Positive Results with Concentrations of hCG βcf in Urine											
	125,000 pmol/mL			**250,000** pmol/mL			**500,000** pmol/mL			**1,000,000** pmol/mL		
hCG Conc. in urine	Lot #1	Lot #2	Lot #3	Lot #1	Lot #2	Lot #3	Lot #1	Lot #2	Lot #3	Lot #1	Lot #2	Lot #3
5 mIU/mL	0/10	0/10	0/10	0/10	0/10	0/10	0/10	0/10	0/10	0/10	0/10	0/10
50 mIU/mL	10/10	10/10	10/10	10/10	10/10	10/10	10/10	10/10	10/10	10/10	10/10	10/10

Table 15-b. Interference study results with hCGßcf – hCG Combo Serum Test

	# of Positive Results with Concentrations of hCG βcf in Serum											
	125,000 pmol/mL			**250,000** pmol/mL			**500,000** pmol/mL			**1,000,000** pmol/mL		
hCG Conc. in Serum	Lot #1	Lot #2	Lot #3	Lot #1	Lot #2	Lot #3	Lot #1	Lot #2	Lot #3	Lot #1	Lot #2	Lot #3
5 mIU/mL	0/10	0/10	0/10	0/10	0/10	0/10	0/10	0/10	0/10	0/10	0/10	0/10
50 mIU/mL	10/10	10/10	10/10	10/10	10/10	10/10	10/10	10/10	10/10	10/10	10/10	10/10

CONCLUSION: The results demonstrate that hCGßcf up to 1,000,000 pmol/mL does not interfere with the Chemtrue® hCG Tests.

The effect of specific gravity (SG) and pH were evaluated by testing duplicates at each sample level of hCG negative and 20 mIU/mL (25 mIU/mL for Combo Test) urine controls with pH 2.0 to 9.0, and SG of 1.003 to 1.030. No interference was observed for pH value 2.0 to 9.0 and SG values from 1.003 to 1.030. However, labeling states that low concentrations of hCG may not be detected in very dilute urine and, if pregnancy is suspected, testing should be repeated after 48 hours. The detailed data is enclosed in ATTACHMENT D, page 74 of the submission.

Flex studies were performed and include read time and sample volume verifications. The results support the claims in the package inserts. The study reports are presented in ATTACHMENT H, pages H9 to H25 of the submission.

8. High dose (hook effect): The studies for both hCG Urine and Combo Tests were performed on three (3) lots of each test format with spiked non-pregnant urine and serum pools at hCG concentrations of 50, 100, 200, 300 and 500 IU/mL. Five replicates of each lot were tested at each hCG concentration. The results are summarized in Table 14 and 15 below:

Table 14. High Dose Effect Study Results Summary with hCG Urine Tests

hCG Concentrations (IU/mL)	hCG Urine Tests			
	Dipstick		Cassette	
	+	-	+	-
50	15	0	15	0
100	15	0	15	0
200	15	0	15	0
300	15	0	15	0
500	15	0	15	0
TOTAL	**75**	**0**	**75**	**0**

Table 15. High Dose Effect Study Results Summary with hCG Combo (Urine/Serum) Test

hCG Concentrations (IU/mL)	hCG Combo Tests			
	Urine Test		Serum Test	
	+	-	+	-
50	15	0	15	0
100	15	0	15	0
200	15	0	15	0
300	15	0	15	0
500	15	0	15	0
TOTAL	**75**	**0**	**75**	**0**

Conclusion: No hook effect was observed with hCG concentrations up to 500 IU/mL in urine and serum for hCG urine and Combo tests in all the formats.

CONCLUSION:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.

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

May 30, 2013

Chemtron Biotech, Inc.
C/O Ms. Jane Zhang
8370 Juniper Creek Lane, Suite 1-2
SAN DIEGO CA 92126

Re: K123844
Trade/Device Name: Chemtrue® hCG Pregnancy Urine Dipstick
Chemtrue® hCG Pregnancy Urine Cassette Test
Chemtrue® hCG Combo (Serum/Urine) Cassette Test
Regulation Number: 21 CFR 862.1155
Regulation Name: Human chorionic gonadotropin (HCG) test system
Regulatory Class: II
Product Code: JHI
Dated: April 29, 2013
Received: May 3, 2013

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. 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 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 Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Carol C. Benson -S 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): k123844

Device Name: Chemtrue® hCG Pregnancy Urine Dipstick
Chemtrue® hCG Pregnancy Urine Cassette Test
Chemtrue® hCG Combo (Serum/Urine) Cassette Test

Indications for Use:

Chemtrue® hCG Pregnancy Urine Dipstick Test

The Chemtrue® hCG Pregnancy Urine Dipstick Test is a rapid lateral flow qualitative immunoassay for early detection of human chorionic gonadotropin (hCG) in human urine in the device format of Dipstick. The test is designed to aid early detection of pregnancy. The device is intended for Prescription Use Only.

The test kits are intended for prescription use including at physician's offices or other Point-Of-Care sites (POC).

Chemtrue® hCG Pregnancy Urine Cassette Test

The Chemtrue® hCG Pregnancy Urine Cassette Test is a rapid lateral flow qualitative immunoassays for early detection of human chorionic gonadotropin (hCG) in human urine in the device format of Cassette format. The test is designed to aid early detection of pregnancy. The device is intended for Prescription Use Only.

The test kits are intended for prescription use including at physician's offices or other Point-Of-Care sites (POC).

Prescription Use __X__ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____. (21 CFR Part 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)

Denise Johnson-Iyles -S
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Division Sign-Off
Office of In Vitro Diagnostics and Radiological Health

510(k) k123844

Indications for Use

510(k) Number (if known): k123844

Device Name: Chemtrue® hCG Pregnancy Urine Dipstick
Chemtrue® hCG Pregnancy Urine Cassette Test
Chemtrue® hCG Combo (Serum/Urine) Cassette Test

Indications for Use:

Chemtrue® hCG Combo (Serum/Urine) Cassette Test:

The Chemtrue® hCG Combo (Serum/Urine) Cassette Test is rapid lateral flow qualitative immunoassays for early detection of human chorionic gonadotropin (hCG) in human urine or serum in Cassette format only. The test is designed to aid early detection of pregnancy. The devices are intended for Prescription Use Only.

The test kits are for prescription use including professionals at physician's office laboratories (POLs) or Point-Of-Care site (POC).

Prescription Use ___X___ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____. (21 CFR Part 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)

Denise Johnson-lyles -S
2013.05.30 11:07:40 -04'00'

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

510(k) ___k123844_____